VOLUME 12 • NUMBER 1 JANUARY 2005

FOCUS

PAPANICOLAOU SOCIETY OF CYTOPATHOLOGY

Companion Society of the United States and Canadian Academy of Pathology

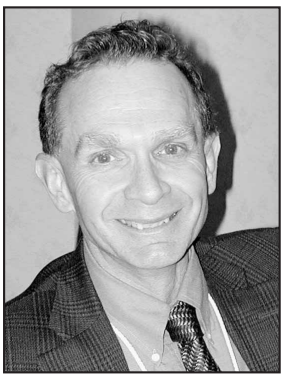
Dedicated to Clinical Practice, Clinical Education and Clinical Research

PRESIDENT'S MESSAGE

Kim Geisinger, MD • Wake Forest University School of Medicine Winston-Salem, North Carolina

"MALIGNANT LYMPHOMAS AND ASPIRATION BIOPSIES"

Damn! Just when I was certain that the excessively long-lived controversy of the utilization of fine needle aspiration biopsies (FNAB) for the diagnosis of malignant lymphomas was laid to rest, it appears to have arisen again (unnecessarily). Much of this new foray centers on a recently published article by Hehn et al in the Journal of Clinical Oncology, a very prestigious journal.1 These authors concluded that FNAB in this specific setting was "woefully inadequate." Their sweeping conclusions fly in the face of the vast majority of recently published investigations on this topic.2



Kim Geisinger, MD (President)

However, even superficial perusal of this article shows clearly that the methodology and thus the results and conclusions are terribly flawed; how did this ever get past knowing reviewers? First, it is not stated in the methodology section whether or not the FNA smears themselves were reviewed at the University of Arizona (by a cytopathologist or anyone) and if so, were all of the cases reviewed or only a proportion of them. If the latter, why were not all reviewed? However, on page 3049 in their results section, it states that a disagreement regarding FNAB interpretations were found in three of 93 specimens, which suggests that, in at least some instances, there was a morphologic re-examination of the aspiration specimens. This also suggests that there was a review of the slides with an agreement in nearly 92%. As 21% of these apparently reviewed specimens were stated to possess a diagnosis of "atypical or abnormal" without further specification, then perhaps the in-house expert should have been an individual with greater personal experience in the interpretation of malignant lymphomas by FNAB. To me, this proportion is simply way too high.

Another obvious problem is that nowhere in the manuscript does it state whether or not the lymph node sampled by FNAB was the same exact one subsequently obtained by excisional biopsy. Simply looking at two physically different nodes could be a significant reason for their discrepancies. I have personally witnessed this situation on multiple occasions.

Another fascinating and unexplainable aspect of their publication is that they compared the cytologic interpretation rendered by more than 70 pathologists (if a chart review was carefully done, why could they not provide an exact number here?) from 32 different practice groups and settings, with the subsequent histologic diagnosis made by a single group of hematopathologists at the University of Arizona. On average, each referral pathologist was responsible for less than two aspiration interpretations over the 5 year study period. This reminds me of the old adage of comparing apples and oranges.

One absolutely crucial feature, well known to any card-carrying cytologist, is the value of on-site evaluation of all FNABs. Perhaps, nowhere is this more important than with aspirates of benign and malignant lymphoproliferative disorders. Nowhere in this

Continued on page 3

IN THIS ISSUE

Focus is published by the Papanicolaou Society of Cytopathology

EDITOR
Aylin Simsir, M.D.

ASSOCIATE EDITOR
Joan F. Cangiarella, M.D.

EDITORIAL OFFICE
Aylin Simsir, M.D.
New York University Medical Center
Phone: (212) 263-5479 Fax: (212) 263-5509
email: aylin.simsir@med.nyu.edu

PUBLISHER
Carlos Bedrossian, M.D.

Stay connected with PSC
Join the Listserv
To subscribe: Send an e-mail to majordomo@www.papsociety.org with ONLY the words "subscribe PSC list" in the body of the message (do not include any signature or V-card). You should get a confirmation e-mail immediately.

PROFILES IN CYTOPATHOLOGY

KIM GEISINGER UNPLUGGED

ANDREA ABATI, MD, NATIONAL CANCER INSTITUTE, BETHESDA, MARYLAND

Before I met Kim Geisinger, he was sort of a conundrum to me.... I saw him clearly as an incredibly bright guy; a leader in his field; very intense; impeccably honest, and in many respects fearless. Yet his public persona had another side - a major athlete (runner and a first degree black belt in Tai Kwon do) and a really funny, charming guy with a tremendous passion for life. In the last four years he has become a good friend and , well, I still find him to be rather an enigma. He is a limitless source of knowledge, personal and professional experiences, ideas, and directed energy that have benefited our specialty and the practice of cytopathology in innumerable ways. He is also the guy you would probably most want to hang out with at the PSC cocktail party....

Kim spent his undergraduate years at Drexel University and went to medical school at the Medical College of Pennsylvania. His residency was at the University of Michigan , where Dr. Bernard Naylor was a tremendous influence on his career path. His fellowship in cytopathology was done in New York at Memorial Sloan Kettering Cancer Center. Since then, his career has been at Wake Forest University Medical School where he wears several hats: Professor of Pathology, and Director of both Surgical and Cytopathology. He has published over 180 articles in peer reviewed journals, authored 4 cytopathology textbooks, and given over 125 lectures and workshops in diagnostic cytopathology around the world. His 5th text will be out early next year - the AFIP fascicle (with Travis and Nicholson) on tumors of the lower respiratory tract. Kim chaired the ASCPs Council on Cytopathology for 4 years and was the recipient of the ASCP Distinguished Service Award for teaching. He has also served as the President of the Papanicolaou Society of Cytopathology since 2002. During Kim's tenure as President of the PSC, we made an important step towards continued education of the cytopathology community with the commencement of the Afternoon International Scientific Session - a look at how cytology is practiced around the globe.

Aside from Kim's robust professional life, he takes the time to be an involved dad to two children . His daughter, Kristen is 19 years old and a freshman at the University of South Carolina. A part time model, life guard and pre-med student, Kristen has been very busy beating off the guys at school, although currently has a steady (and wealthy...) boyfriend.

Kim's son, Brian, 15, is over 6 feet tall and has a size 42 chest. He is not only a straight A student , but is also a super athlete avid basketball player, who plays on school and travel teams. One of Kim's favorite past times is driving Brian to his games (which may be hundreds of miles away), and screaming on the sidelines. Brian is considering becoming a sports lawyer.

As mentioned previously, Kim is a first degree black belt in Tai Kwon do and a dedicated runner. This is not surprising since his mom, who is in her 80's, still makes the time to jog several miles every day!

It would be impossible to say anything about Kim and not mention the extremely popular textbook that he was the lead author on, "Modern Cytopathology". Thus far, he regards this labor of love to be his greatest professional achievement. Much to the delight of the publishers and authors, since its release shortly over a year ago, the book has been through several printings.

What's next for Kim? Well, you can bet it won't be early retirement.

FOCUS

PAPANICOLAOU SOCIETY OF CYTOPATHOLOGY

PRESIDENT
Kim Geisinger, M.D.
Pathology Department
Wake Forest University
School Of Medicine
Medical Center Boulevard
Winston-Salem,
North Carolina 27157
Phone: (336) 716-2608
email: kgeis@wfubmc.edu

PRESIDENT-ELECT
Andrea Abati, M.D.
Cytopathology Section
National Cancer Institute
Building 10, Room 2A19
Bethesda, MD 20892
Phone: (301) 496-6355
Fax: (301) 402-2585
email: abatia@mail.nih.gov

PAST-PRESIDENT
Mary K. Sidawy, M.D.
Department of Pathology
The George Washington University
Ross Hall #419
2300 Eye Street, NW
Washington, D.C. 20037
Phone: (202) 994-8824
Fax: (202) 994-2618
email: msidawy@mfa.gwu.edu

Visit the PSC website
www.papsociety.org

Features
About PSC
PSC Events
Awards
Newsletter
Case of the Month
Listserv
Membership
Elections
Links

 Continued from page 1

manuscript do the authors state whether or not on-site evaluations were performed in any or all of these FNABs. The lack of such information is glaring. I suspect that if such evaluation had been performed, the results of this invalid comparison would have been much better for cytology. Such evaluation permits the cytology team, in concert with the clinicians and the radiologists, to ensure adequacy of the sample, markedly reduce sampling error up to 100%, and improve drastically the ability to distinguish reactive elements from malignant lymphoid cells. Why? On-site evaluation is a major factor in obtaining additional material (usually with one or more dedicated needle passes) for immunophenotyping, whether by flow cytometry or immunocytochemistry, as well as other ancillary procedures, e.g., cytogenetics.3 This clearly would have exponentially reduced the criticism by these authors on the limitations of nodal aspirates.

Hehn et al found it interesting that none of the few T-cell lymphomas in this study were correctly interpreted by FNAB. Compared to most B-cell neoplasms, the T-cell lymphomas may prove to be more challenging. In part, this is derived from their relative rarity. In addition, although it may provide supportive evidence, immunophenotyping cannot prove monoclonality beyond a doubt. Here, additional testing, e.g., gene rearrangement studies, may prove invaluable on aspirated cellular material. The authors also claimed that the examination of smears for Hodgkin's disease was "better than expected." In my own experience, the diagnosis of Hodgkin's disease may be more challenging than that of most B-cell lymphomas, and I was not surprised by the 50% accuracy with aspiration biopsy in their investigation.2

On page 3050 of their manuscript in the discussion section, the authors stated that their reference 10 "acknowledges that many pathology training programs do not give adequate exposure of diagnostic cytology to trainees, therefore, questioning the usefulness of FNAB cytology in the general community practice." Well, it turns out that I am the senior author on that cited publication.4 I did not remember that in our writing (or anything else I have said recently) and thus re-read this paper several times. Nowhere in the manuscript by Meda et al does the text make any such statement.4 Clearly, Hehn et al took one phrase out of context completely. In the initial paragraph of the introduction of the paper by Meda and colleagues, we stated "some authorities . . . believe this approach should almost never be used . . . Reasons for this situation include inadequate exposure during pathology residence training to the benefits and limitations of FNA." We were not stating our own beliefs but those of a few "outliers" in this arena. I suggest that Dr. Hehn and colleagues, as well as, the reviewers of this manuscript, re-read the article by Meda et al.4 Talk about woefully inadequate.

As a response to the Hehn article, Al-Saleem et al composed a letter to the editor which they submitted to the Journal of Clinical Oncology. In addition to Dr. Al-Saleem, a hematopathologist, this included Dr. N. Young and Dr. H. Ehya, two highly respected cytopathologists with a strong interest in malignant lymphomas, and Dr. Mitchell Smith, an oncologist who treats many patients with lymphoma. I have had the privilege to read this letter. It points out several of the serious problems with the basic design, evaluation, and conclusions of Hehn et al. Shockingly, the editors rejected this letter for publication without offering any explanation.

Along these same lines, at the recent International Academy of Pathology meeting in Brisbane, verbal skirmishes occurred between well respected and internationally recognized pathologists on the value of FNAB in the diagnosis of malignant lymphomas. Due to limitations on space, I will not further discuss this topic as it would require a completely separate article. However, kudos to Dr. Ruth Katz.

Everyone is entitled to their own opinions concerning medical care, including the use of FNAB for the diagnosis of lymphoma. Yet, due to the numerous problems with this publication by Hehn et al, I believe that the authors, the reviewers, and the editors of the Journal of Clinical Oncology have done a disservice to patients with lymphadenopathy. I believe it would behoove Dr. Hehn and his colleagues to discuss this with medical oncologists who do believe in the use of FNAB to diagnose these lymphoid proliferations, as the advantages far outweigh the disadvantages.

On a completely different subject, I would like to take just a few lines to thank the innumerable individuals who assisted me during my tenure (which is in its waning moments) as president of the Papanicolaou Society. There are simply too many to name specifically. Still, I want to express my extreme gratitude to Dr. Andrea Abati whose continual and invaluable assistance allowed me to survive this period.

References:

1. Hehn ST, et al. Utility of fine0needle aspiration as a diagnostic technique in lymphoma. J Clin Oncol 2004;22:3046-3052

2. Geisinger KR, et al. Lymph Nodes and Spleen. In Modern Cytopathology, Churchill Livingstone, 2004. New York, 643-688.

3. Safley AM, et al. The value of fluorescence in situ hybridization and polymerase chain reaction in the diagnosis of B-cell non-Hodgkin's lymphoma by fine-needle aspiration.

THIS ISSUE OF

FOCUS

HAS BEEN MADE POSSIBLE BY AN UNRESTRICTED EDUCATIONAL GRANT FROM THE CYTYC CORPORATION.

THE MEMBERS OF THE PAPANICOLAOU SOCIETY THANK YOU FOR YOUR GENEROUS SUPPORT.

CALL FOR ELECTIONS

DEMOCRACY IN ACTION

IT IS TIME TO CAST YOUR VOTES AGAIN!

MEET THE CANDIDATES FOR THE FOLLOWING POSITIONS...

CANDIDATES FOR PRESIDENCY

Martha B. Pitman, M.D.

Dr. Pitman received her anatomic, clinical and cytopathology training at the Massachusetts General Hospital (MGH) and also trained in fine needle aspiration biopsy technique at the Karolinska Hospital in Stockholm, Sweden with Dr. Torsten Lowhagen. Dr. Pitman is board certified in anatomical, clinical and cytopathology. Dr. Pitman joined the staff of the MGH following her training in 1991 and is currently Associate Professor of Pathology at Harvard Medical School and Director of the Fine Needle Aspiration Biopsy Service of the MGH. Dr. Pitman's primary research interests are in fine needle aspiration biopsy of the liver and pancreas. She is co-author of *Fine Needle Aspiration Biopsy of the Liver* and *Fine Needle Aspiration Biopsy of the Pancreas*, and is co-authoring the 4th series AFIP fascicle on Tumors of the Pancreas with Drs. Ralph Hruban and David Klimstra. Dr. Pitman is active in most national pathology organizations and has provided continuing medical education workshops for the ASC, ASCP and USCAP. She has also served on numerous committees for these organizations, is on the Executive Board of the Papanicolaou Society and serves on the editorial board of *Cancer Cytopathology and Diagnostic Cytopathology*. Dr. Pitman is an early member of the PSC. She served on the Awards Committee in 2000. She has served the past two years as Chair of the Budget and Finance Committee, a new committee designed to work with the Treasurer to organize and oversee the financial health of the PSC. Dr. Pitman has been asked to serve a third term in this position. She is also concurrently serving on the Executive Board. Dr. Pitman's goals as President of the Society are to expand and enhance the profile of the organization and the specialty of Cytopathology through increased collaboration with the USCAP, CAP and international cytology societies for PSC sponsored cytopathology educational ventures and joint surgical-cytopathology seminars, increased membership outreach, increased commercial sponsorship, and increased resident/fellow research support.

Stephen S. Raab, M.D.

Dr. Steve Raab is the Chief of Pathology, Director of the Division of Pathology Quality and Healthcare Research and Director of Cytology at the University of Pittsburgh Medical Center Shadyside. He did his pathology training at Washington University, completed a fellowship in epidemiology at the University of Pennsylvania, and studied health services research at Stanford University. He currently practices diagnostic cytology and surgical pathology and performs funded research on improving pathology practice and patient outcomes. He was a forum director at the 2001 Bethesda Conference and writes and teaches extensively on gynecological and non-gynecologic cytology. He is a strong advocate for cytology education, the role of cytology in patient-centered care, and the advancement of cytology practice. He has contributed to humanitarian medical causes throughout the world and is the Vice President of the Viet American Cervical Cancer Prevention Project, an endeavor aimed at improving the health of women in Vietnam. Dr. Raab currently is the Principal Investigator on the first and only grant from the National Institutes of Health to study patient safety through quality assurance and improvement in cytopathology and surgical pathology. This is a multi-center study which includes, among others, the University of Pittsburgh, the University of Iowa and Henry Ford Hospital. Current areas of investigation include gynecologic cytology and histology, thyroid fnas, and urinary cytology. It has strong support from several important national organizations including the JCAHO. He is co-investigator on a smaller related grant supported nationally by the Center for Disease Prevention. Dr. Raab has over 100 peer-reviewed publications, has given numerous national and international invited lectureships and has extensive editorial review board responsibilities. He is one of the authors of the *Modern Cytopathology* text and has recently completed co-authoring another text dedicated to urinary tract cytology. Dr. Raab has been actively involved in the Papanicolaou Society since its infancy serving on the International Relations Committee and for several terms on the Executive Board. He was instrumental in the development of the new afternoon International Scientific Session, the latest educational effort of the society.

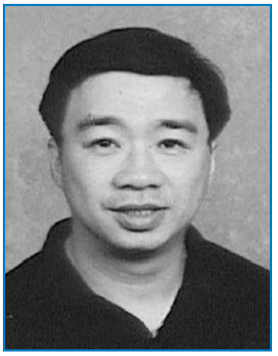
CANDIDATES FOR SECRETARY

Claire W. Michael, M.D.

Dr. Michael is Associate Professor of Pathology and Director of Cytopathology at The University of Michigan. A member of the PSC since its inception, she has served as a member of the Committee of Standards of Practice and chaired the Research committee. Having served as the Secretary for the society for the last 3 years, Dr. Michael was asked to serve in that capacity for a second term. She is the author of numerous peer-reviewed publications. Dr. Michael is a section editor for Diagnostic Cytopathology and serves as a reviewer for several Cytopathology/Pathology journals. In addition to her clinical responsibilities, Dr. Michael is an active investigator or co-investigator in studies involving ductal lavages, bile duct brushes, and pulmonary specimens including mesothelioma. She has been invited as a guest speaker both nationally and internationally and has given numerous workshops and seminars. Dr. Michael has been active in many professional pathology societies including the ASC, ASCP, USCAP, and the PSC.

CANDIDATES FOR MEMBERS-AT-LARGE

David Chhieng, M.D., M.B.A.



Dr. David Chhieng is an Associate Professor with the Department of Pathology at the University of Alabama at Birmingham (UAB). He is also the director of the Immunohistochemistry Laboratory at the University Hospital. He received his M.D. degree from the University of Hong Kong in 1987 and his M.B.A. degree from UAB in 2003. He completed his pathology residency at Albany Medical College at Albany, NY and his fellowship training in oncologic pathology and cytopathology at Memorial Sloan Kettering Cancer Center in 1997 and New York University in 1998, respectively. He has been a member of PSC since 1998 and is now serving as the Chairman of the Education and Training Task Force. He is also the State Commissioner for Alabama and Florida Panhandle for the College of American Pathologists (CAP) Laboratory Accreditation Program. He also serves in the American Society of Cytopathology as the Chairman of the Laboratory Advisory Committee. He is a member of the Editorial Board for the journal *"Diagnostic Cytopathology"*.

Aylin Simsir, M.D.

Dr. Simsir completed the first two years of her AP/CP residency at SUNY at Stony Brook, New York, and the last two years at Columbia Presbyterian Medical Center in New York City. She then did a surgical pathology fellowship at Memorial Sloan Kettering Cancer Center, followed by a cytopathology fellowship at the National Cancer Institute in Bethesda, Maryland. She served as the interim director of cytopathology at the University of Maryland from 1998 to 2000. Since July of 2000, she has been at New York University Medical Center in New York City as the associate director of cytopathology. She recently became the director of the residency training program at NYU. Dr. Simsir joined the Papanicolaou Society of Cytopathology in 1997, when she was a cytopathology fellow under the guidance of Dr. Andrea Abati. Since then, she has been an active member of the PSC in a variety of committees. She currently is the chair of the publication committee and is the editor of the Focus newsletter. Dr. Simsir authored numerous abstracts presented at a variety of scientific meetings and articles published in peer-reviewed journals. Among Dr. Simsir's passions are aspiration biopsy of breast lesions, and gynecologic cytopathology. Dr.Simsir, along with six other cytopathologists at NYU, runs an extremely busy aspiration biopsy service. She truly believes cytopathology represents the best of what medicine has to offer. She views the PSC as the primary source to disseminate valuable information about the field of cytopathology to colleagues in and outside of pathology.

ANNOUNCEMENTS
PSC ANNUAL ACTIVITIES IN SAN ANTONIO, TEXAS

SATURDAY, FEBRUARY 26, 2005

Save the date and the times!

2 - 4pm ***Scientific Session of the International Relations Committee (Room 12)***

CELLS WITHOUT BORDERS II:
Medicolegal Aspects of Cytopathology on the International Front

Moderators: Carlos Bedrossian, MD, Steve Raab, MD and Eric Suba, MD

Coming to Terms with Vietnam: The Association between War and Cervical Cancer Among Vietnamese Women
Eric J. Suba, MD, Vietnam/American Cervical Cancer Prevention Project, San Francisco, California

Medicolegal Issues and Tort Reform in Australia
Andrew Field, MD, St. Vincents Hospital, Sydney, Australia

Medicolegal Aspects of the Association between the Vietnam War and Cervical Cancer
David Richards, Esq., Attorney, Activist, Author, Mill Valley, California

Cervical Cancer Screening in Brazil: Political and Medico-Legal Implications
Prof. Carlos Alberto Ribeiro, MD, Federal University of Minas Gerais-Belo Horizonte, Brazil

Automated Cytoscreening for Cancer of the Cervix: The Dutch Experience and Its Medico-Legal Impact
Prof. Mathilde E. Boon, MD, FIAC, The Leiden Cytology and Pathology Laboratory, Leiden, The Netherlands

4 - 5 pm ***Annual Business Meeting (Room 12)***

5 - 7 pm ***Annual Cocktail Reception (Room 18)***

7 - 9 pm **Evening Companion Meeting: *Annual Scientific Session***

MEDICOLEGAL ASPECTS OF THE PAP TEST:
THE EXPERTS SPEAK "FROM BOTH SIDES NOW"

Moderators: Andrea Abati, MD and Maureen Zakowski, MD
Rivercenter Salon K

Presentation of Awards
Kim Geisinger, M.D., President, Papanicolaou Society of Cytopathology

Defending the Public Interest and the Pap Test, Medical History's Most Effective Cancer Screening Test
R. Marshall Austin, M.D., Coastal Pathology Laboratories, Charleston, South Carolina

The PAP Smear Case: The Defense Perspective
Alex J. Hagan, Esq., Ellis Winters, LLP, Raleigh, North Carolina

Pap Test Litigation: A Pathologist's Perspective from the Plaintiff's Side
Dorothy Rosenthal, M.D., Johns Hopkins Bayview Medical Center, Baltimore, Maryland

The PAP Smear Case: A Plaintiff's Perspective
Jerry I. Meyers Esq., Meyers, Kenrick & Giuffre, Pittsburgh, Pennsylvania

U.S. Federal and State News

Joan Cangiarella, M.D. • New York University, New York, NY

CMS ANNOUNCES ITS NEW GYNECOLOGIC PATHOLOGY PROFICIENCY TESTING PROGRAM REQUIREMENTS

CLIA regulations require cytology laboratories and individuals who interpret gynecologic cytology specimens to enroll in a CMS-approved cytology proficiency testing program and annually achieve a passing score. Previously this regulation was not enforced due to the lack of a national cytology proficiency testing program that was approved by the Centers for Medicare and Medicaid Services (CMS). However, the full implementation of a CMS-approved proficiency testing program is now complete. Currently there are two available testing programs. The State of Maryland Cytology Proficiency Testing Program enrolls only physicians and cytotechnologists who examine Pap tests from residents of Maryland. The other recently approved program, the Midwest Institute for Medical Education is national, accepting enrollments in 2005 from all states. The CMS will be implementing these program requirements in phases over the next two years. Laboratories will be required to enroll all individuals involved in gynecologic cytology testing in a CMS-approved cytology program by June 30, 2005. By April 2, 2006, all pathologists and cytotechnologists must be tested at least once by a CMS approved gynecologic cytology proficiency testing program. For individuals who fail the first testing, re-testing with successful results must occur by December 31, 2006. CMS is planning a national conference call for all laboratories to discuss these requirements in early 2005.

2005 CPT CODE CHANGES

Changes in the CPT coding for flow cytometry includes the elimination of the 88180 code and the addition of new codes. The increase in flow cytometric analysis and the use of multiple markers has led some payers to reevaluate the reimbursement for these services. The development of these new codes (88184, 88185, 88187, 88188, 88189) addresses these concerns. Code 88184 is the code for the technical component of the first marker (flow cytometry, cell surface, cytoplasmic or nuclear marker) tested. Code 88185 is an add-on code for the technical component of each additional marker. Thus, code 88185 is always used in conjunction with 88184. New codes for professional interpretation include 88187 for two to eight markers, 88188 for nine to 15 markers and 88189 for 16 or more markers. Only one of these codes should be used per specimen. For example, flow cytometric analysis on a lymph node using a panel of 10 antibodies would be coded as 88184 for the first marker (technical), 88185 x 9 for the additional 9 markers (technical), and 88188 for ten markers (professional).

CMS INSTITUTES NEW ICD-9 CODES FOR CERVICOVAGINAL CYTOLOGY

On October 1, 2004 CMS instituted new ICD-9 codes to align with the nomenclature of the Bethesda system. The new ICD-9 changes define abnormalities according to the Bethesda terminology. Code 795.01 indicates a Papanicolaou test of the cervix with atypical squamous cells of undetermined significance (ASC-US) and 795.02 indicates a Papanicolaou test of the cervix with atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H). An additional coding edit deletes HSIL from the 622.1 cervical dysplasia code definition and creates a new code for HSIL, 795.04, Papanicolaou test of the cervix with high grade squamous intraepithelial lesion. CMS also instituted a new code to report an inadequate or unsatisfactory Papanicolaou test, 795.08. This may indicate a need for a repeat smear but whether payers will acknowledge this code remains to be determined.

NEW MOLECULAR TEST TO PREDICT RISK OF RECURRENCE AND BENEFIT FROM CHEMOTHERAPY IN BREAST CANCER PATIENTS

Research supported by the National Cancer Institute in collaboration with the National Surgical Adjuvant Breast and Bowel Project and Genomic Health Inc. have developed a test that will predict the risk of recurrence and the benefit of chemotherapy in estrogen-positive, node-negative breast cancer patients. The test is based on the expression of a panel of breast cancer related genes through the measurement of RNA and is capable of being performed on paraffin-embedded tissue. The researchers created a formula based on the expression patterns of the genes in the tissue sample to generate a recurrence score that will measure the risk that the cancer will recur. This technology is called Oncotype DX tm . The results of this research may allow low risk patients to avoid the potentially harmful side effects of chemotherapy. *(Paik S, Shak S, Wolmark N et al. A Multigene assay to predict recurrence of node-negative, estrogen receptor positive breast cancer in tamoxifen-treated patients. New England Journal of Medicine 351(27), December 30, 2004).*

Stay connected with PSC
Join the Listserv

To subscribe: Send an e-mail to majordomo@www.papsociety.org with ONLY the words "subscribe PSC list" in the body of the message (do not include any signature or V-card). You should get a confirmation e-mail immediately.

This Issue of Focus was supported through an unrestricted educational grant from Cytyc Corporation.

The members of the Papanicolaou Society of Cytopathology thank you for your generous support.

TIMELY TOPICS

CREATING A "HIPAA FRIENDLY" CYTOLOGY LABORATORY: PART II

Janie Roberson, SCT (ASCP), Gary W Gill, CT (ASCP)*, CFIAC, David C. Chhieng, MD. University of Alabama at Birmingham, Birmingham, AL and DCL Medical Laboratories, Indianapolis IN*

In the first half of this article, published in the last issue of Focus, the origin of HIPAA-privacy act and some of the terminology was discussed. This section continues our discussion on how to incorporate HIPAA-privacy act into existing laboratory practice and workflow and examine the implications of the rule on research practices.

INCORPORATE THE LANGUAGE INTO EXISTING LABORATORY PRACTICE AND WORKFLOW

To streamline and incorporate HIPAA requirements into laboratory workflow, look for existing policies that can be expanded to include HIPAA language. Staff will more readily accept and understand the requirements if they can be related to already familiar policies. Responses to several requirements on the CAP Cytopathology and General Checklists can be expanded with inclusion of the HIPAA. 1

CYP.0660

Are Cytopathology records retained for an appropriate period?

CYP.06900

Are all glass slides retained for an appropriate period?

In addition to retention requirements, a disposal process should be detailed. The disposal process of material containing PHI must result in the inability to identify the patient (Table 2). If outdated/expired materials are retained for educational or research purposes, patient identifiers should be removed.

Table 2 Retention Requirements for Cytopathology Files and Records

Material (PHI)	Minimum Retention-CAP/CLIA	Recommended Method for Discard	Comments
Requests/requisitions	2 years	Shred	Business associate agreement
QC/QA records	2 years	Shred	Business associate agreement
Final reports	10 years	Shred	Business associate agreement
Microfilm	Depends on content	Hazardous materials	Business associate agreement
Glass slides—gyn and Non-gyn	5 years	Sharps container	No need to decapitate if handled as a sharp. Disposal by licensed waste hauler.
Cell blocks/ FNA glass slides	5 or 10 years	Sharps container (including cell blocks?)	No need to decapitate if handled as a sharp. Disposal by licensed waste hauler.
Labeled specimen containers	Until case is finalized	Biohazardous waste Red bag and incinerate	—

Continued on page 9

Continued from page 8

CYP.02100

Are documented records of extradepartmental consultations maintained?

Develop a step by step procedure manual for receiving and/or mailing slides and other consultation materials. Request for extra-departmental consultations should be submitted in writing. There should be clear documentation of who reviews and at whose request material is reviewed.

CYP.07100

Is there a documented policy for protecting and preserving the integrity and retrieval of original slides in Cytopathology?

CYP.07200

Is there a policy to ensure defined handling and documentation of the use, circulation, referral, transfer and receipt of original slides to ensure availability of materials for consultation and legal proceedings?

The procedure manual should contain policy for slide checkout that is followed by all staff. Files should be located in a secure area with limited access to authorized personnel only.

CYP.07300

Is there documentation, including acknowledgment of receipt, when material is loaned to special programs such as the CAP Interlaboratory Comparison Program in Cervicovaginal Cytology (PAP)?

The CAP provides a Business Associates Agreement to cover slides loaned to the college.

GEN.46500

If data in other computer systems can be accessed through the LIS (e.g., pharmacy or medical records), are there documented policies to prevent unauthorized access to that data through the LIS?

GEN.48000

If the facility uses a public network (such as the Internet) as a data exchange medium, are there adequate network security measures in place to ensure confidentiality of patient data?

Institutions should have clear policies of confidentiality and provide audit trails in information systems.

At first glance, the HIPAA Privacy Rule requirement regarding an individual's access to his/her PHI appears to be in conflict with the CLIA'88 requirement that clinical laboratories provide test records and reports only to "authorized persons" as defined by state law. However, the HIPAA Privacy Rule includes an exception to individual's general right to access his/her PHI if granting an individual such access would be in conflict with CLIA and/or state laws.

DEVELOP TOOLS AND RESOURCES

Laboratory standards must be developed locally that address basic considerations such as:

- Employees and trainees who have access to PHI should sign a Confidentially Agreement, which is provided during orientation.
- All requests for transfer of PHI must be submitted in writing. Developing a standard Request Form or letter helps to get consistent information and provides support personnel with a working checklist. This request should be maintained in the laboratory records and at a minimum include; patient demographics, requestor information, who made the request, purpose of the request, and materials requested (slides, recuts, and reports). Policy must be communicated to personnel for handling Medico-Legal related requests and requests for research or investigational purposes.
- FAX machines receiving PHI should be located in areas not accessible to non-laboratory personnel. Outgoing FAX reports/data should be sent only to sources considered valid and secure. Cover sheets should state intended recipient and proper use guidelines.
- PHI entered and retrieved from the Laboratory Information System (LIS) must be limited to authorized individuals. User IDs and passwords to the LIS must not be shared.

EXAMINE RESEARCH PRACTICES

Before HIPAA, the privacy of subjects and confidentiality of information were protected under the so called "Common Rule" of the Food and Drug Administration's (FDA) human subject protection regulations. HIPAA adds a dimension to the protection; further specifying under what conditions PHI can be used or disclosed by covered entities for research purposes. 2 The lawmakers insist that HIPAA should not hinder the researchers' access to medical information that is necessary for conducting vital research. Unlike some other regulations, HIPAA applies regardless of whether the research is funded by the government.

Prior authorization from the research participants is required for the use and disclosure of PHI for research that includes treatment such as clinical trials. The authorization is limited to the research protocol for which it is designed. Few exceptions exist that allow the use or disclosure of PHI without first obtaining the

Continued on page 10

Continued from page 9

authorization of the research participants. These include:

- When research does not involve treatment.
- When the research participants are dead.
- When the information has been de-identified under one or two standards set forth: (1) removal of all 18 identifying characteristics and (2) proven statistically that there is minimal chance that the data can be used to identify an individual. However, researchers may assign a code or other means of record identification to allow de-identified information to be re-identified by the researchers provided that the re-identifying code is not derived from or related to information about the individual and is not used or disclosed for any purpose other than re-identification.
- When a "limited data set" is used. This is similar to de-identified sets except certain direct identifiers must be removed. The limited data set can include identifiers such as DOB, dates of hospital admissions and discharges, and individuals' residence by city, count, state, and zip code. The researchers are required to enter a Data Use Agreement with the covered entities to assure how the limited data set be used and protected.
- When a research protocol is deemed by an Institutional Review Board (IRB) that the use/disclosure of PHI poses minimal risk to the individuals, that the research cannot be conducted without the waiver, and that the research could not be conducted without access to PHI.
- When PHI is used solely for the preparation of a research protocol and no PHI is removed from the covered institute.

Irrespective of whether prior authorization by research participants is waived or not, review and approval of the research protocol by the IRB may be still be required at the local institutional level. The authorization should include details regarding who may see PHI, where and when it may be used. If prior authorization is waived, there should be an adequate plan to protect identifiers from improper use and disclosure, to destroy identifiers at the earliest possible time, and to assure against reuse or re-disclosure of PHI.

Although HIPAA offers individuals the right to review their PHI, access to information collected pursuant to a treatment-oriented research study may be denied as long as the study is active, provided the research participants understand and consent to this. The use of PHI for research is also exempted from the HIPAA's Accounting of Disclosure of requirement of patients' PHI for the previous six years.

CONCLUSION

HIPAA regulations tend to affect pre-analytic and post-analytic portions of laboratory testing more so than the analytic phase. For this reason, it is essential that personnel throughout the testing process (clerical, cytopreparationists, cytotechnologists, pathologists and researchers), are familiar with the policy and have resources for resolving questions. An environment must be created that recognizes and values individual privacy. Training should be appropriate for each workforce member and should be reviewed periodically to stay current. A documented annual review of the policy and procedure manual is an efficient way to incorporate this into routine competency and training. The laboratories should maintain written and/or electronic records of their communications and actions to show that the laboratories have acted in compliance with the rules. These records must be maintained for 6 years from the date of it creation or the date it was last in effect. In conclusion, HIPAA can reasonably be incorporated into good laboratory practice. Policies must be clearly defined and be communicated to all personnel who have access to PHI. With a common sense approach, HIPAA provides an opportunity to take a critical look at the often-overlooked non-technical phases of testing that have potential for medical error.

REFERENCES:

1. College of American Pathologists Laboratory Accreditation Checklists Available at http://www.cap.org/apps/docs/laboratory_accreditation/checklists/checklistftp.html Accessed Apr 10th 2004

2. Department of Health and Human Services Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule Available at http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf Accessed Apr 10th 2004

Bulletin Board
Papanicolaou Society Committees and Task Forces

New Technology: The committee has been working to update the PSC webpage including the application of several new features that may be beneficial to PSC members. Andrew J. Creager, MD (Chair), Duke University Medical Center, Department of Pathology, DUMC 3712, Durham, NC 27710. Tel (919)668-3353, e-mail:creag001@mc.duke.edu Members: I Jovanovic, R Dash.

Awards Committee: The committee's charge is to select the best candidate for the Papanicolaou Society of Cytopathology Educator of the Year Award. William J. Frable (Chair), VCUMC Box 980115,Richmond, VA 23298-0115. Tel (804)828-4918, Fax (804)828-8733, email: wfrable@mail2.vcu.edu. Members: LG Koss, T Bonfiglio, Y Erozan

Budget and Finance: The committee prepares a budget for the ensuing year in concert with the treasurer, to recommend a change in membership dues if and when necessary, and to recommend ways to increase the financial stability of the PSC. Martha Bishop Pitman(Chair) ,Director, Fine Needle Aspiration Biopsy Service Department of Pathology, Massachusetts General Hospital, 14 Fruit Street, Boston, MA 02114, Tel 617-726-3185, Fax: 617-724-6564, email: mpitman@partners.org Members: M Zarka, R Tambouret, M Cohen, W Faquin, U Bedrossian (ex officio)

Program Development: The committee's goals are to raise funds to support the various programs and activities of the PSC. Joel S. Bentz (Chair), Department of Pathology, University of Utah School of Medicine, 50 No. Medical Dr.,Salt Lake City, UT 84132. Tel (801)583-2787 ext. 2060 Fax (801) 584-5031, e-mail: bentzj@aruplab.com Members: J Linder, BM Ljung, R Luff.

Publication Committee: The Publication Committee prepares and publishes the biannual PSC newsletter "Focus". Focus is published online, and also, is mailed to all PSC members through a generous donation from Cytyc Corporation. The newsletter aims to disseminate information related to the past and upcoming PSC events, society related news, new developments and timely topics associated with the practice of cytopathology. Aylin Simsir (Chair), NYU Medical Center, 530 First Avenue, West Tower, Suite 10U, New York, NY 10016. Tel 212-263-5479, e-mail:aylin.simsir@med.nyu.edu Members: J Cangiarella, O Lin, M Stanley, B Winkler

Scientific Program: The Scientific Program Committee has selected and developed what we hope will be an exciting and timely program for the 2005 San Antonio meeting of the Society. Along with the International Relations Committee, we have rekindled the afternoon scientific session, aptly named "Cells without Borders". Distinguished cytopathologists from around the globe will discuss advances and issues affecting their practices. The evening session entitled "Medicolegal Aspects of the Pap Test: The Experts Speak "From Both Sides Now""will feature 4 prominent speakers. Andrea Abati (Chair), Cytopathology Section, NIH/NCI. Tel 301-496-6355, fax 301-402-2585, e-mail:abatia@mail.nih.gov Members: S Raab, D Rosenthal, M Stanley, C Bedrossian, K Geisinger

Education & Training: Last year the committee focused on two main areas. Cytology Training: During the year, the committee worked on a draft of learning objectives that Larry Fowler of the ASCP shared with us, and also, on documents pertaining to the Cytopathology Competency Task Force for the ASC, which Doug Clark shared with us. Our comments on these documents are now with Doug Clark. We hope that the three committees will be able to consolidate the findings, and publish these guidelines. The second focus is to continue publishing interesting cases on the PSC website. David Chhieng (Chair), University of Alabama at Birmingham, KB 627, 619 19St S Birmingham AL 35249-6823. Tel (205) 934-6160, Fax (205) 975-7284, e-mail: dchhieng@path.uab.edu Members: A Afify, J Cangairella, I Eltoum, O Lin.

Government Relations: The Government Relations Task Force monitors legislative and regulatory issues and proposes areas for advocacy efforts by the membership. The Task Force communicates and partners with other medical and cytopathology organizations including the CAP, ASC, and AMA, on topics important to cytopathology. Diane Davey (Chair), Univ of KY Medical Center, 800 Rose Street, Lexington, KY 40536-0298, Tel (859) 257-9547, Fax (859) 323-2094, e-mail: ddavey@uky.edu Members: A Berry, E Volk, T Miller, M Austin.

Research Task Force: The purpose of the task force is to encourage quality research and exchange of ideas relevant to Cytopathology among pathologists-in-training. Every year, members of the research committee review Cytopathology abstracts submitted to the USCAP in order to select the recipients of the Papanicolaou Society Research Awards. Applications for the awards are accepted automatically via the Stowell-Orbison award or by submitting the application form distributed via the society listserv. The winners this year will be announced during the evening session of the PSC annual meeting in San Antonio. Sana O. Tabbara (Chair), The George Washington University, Department of Pathology, 2300 eye Street, NW, Ross Hall Room 502, Washington DC 20037. Tel (202) 994-0313, Fax (202) 994-2618. Members: B Atkinson, A Creager, H Ehya, M Henry, J Silverman

Quality Assurance: The major activity of the committee is to propose quality assurance guidelines and standards of practice in various avenues of GYN and Non-GYN cytology. This is accomplished by a thorough review of recent literature and personal institutional experiences. Zubair Baloch, MD, Ph.D, UPENN Medical Center.3400 Spruce Street. Philadelphia, PA. 19104. Tel: (215) 662-3209, Fax: (215) 349-8994, e-mail: baloch@mail.med.upenn.edu. Members: E Bourtsos, C McGrath , K Khurana, Y Dai

International Relations: The function of this committee is the interchange of ideas and information between members and committees of various cytology organizations at the international level. The committee facilitates joint sessions among these organizations and assists PSC in the recruitment of prospective members. Carlos Bedrossian (Chair), Department of Cytopathology, Northwestern Memorial Hospital 303 East Superior, Chicago IL 60611. Tel (312) 908-1191, Fax (312) 908-8950. email: c-bedrossian@nwu.edu Members: F Schmitt, L Palombini, F Bleggi-Torres, B Knight, T Kobayayashi

Continued on page 12

Continued from page 11

Constitution & Bylaws: The Constitution and ByLaws Committee has completed an updated version of the Constitution and ByLaws which was approved at the March 2003 business meeting in Washington DC. R. Marshall Austin (Chair), Coastal Pathology Laboratories ,1128 Lango Avenue, Charleston, South Carolina 29407 .Phone 843-769-6345 ext 14, Fax: 843-769-7614 austindr@aol.com Members: A Abati, K Geisinger, D Kurtycz, A Moriarity, R DeMay, S Raab, E Cibas

Nominating Committee: It is the charge of the nominating committee to produce a slate of nominees for all elections for the PSC. Most recently, the committee sought nominations from the membership and submitted to the Board a slate of nominees for the President, Secretary and members-at-large (1 position) for the 2005 elections. Mary Sidawy (Chair), The George Washington University, 2300 Eye St. NW, Washington, DC 20037. Tel (202) 994-8824 email msidawy@mfa.gwu.edu Members: C Bedrossian, M Stanley.

Practice Guidelines: The Practice Guidelines Task Force is working on the recommendations regarding educational notes and disclaimers on reports of negative cervical cytologic examination. In addition, the task force is also working on the recommendations for procedures and reporting of urinary cytology. Lester Layfield (Chair), Department of Pathology, University of Utah, 50 N. Medical Dr., Salt Lake City, UT. Tel (801)585-2541, Fax (801) 585-3831, email:layfield@aruplab.com Members: H Cramer, T Elsheik , V Shidham

Membership Committee: The charge of the Membership Committee is to increase membership with a particular focus on recruiting junior members. To attract other young pathologists, the Membership Committee plans to contact recent graduates of cytopathology and surgical pathology fellowship programs who are not yet members of the Papanicolaou Society and invite them to become full members. Also, Dr. Ursula Bedrossian has provided a list of former members who have not renewed their membership to the chair of the Membership Committee. The committee will attempt to contact these individuals to learn why they have not renewed their membership and if appropriate, invite them to reconsider membership in the PSC. The data gleaned from this may prove helpful to other committees looking at the development and future directions of the PSC. Lisa A.Teot (Chair), Department of Pathology,Children's Hospital of Pittsburgh, 3705 Fifth Avenue, Pittsburgh, PA 15213. Tel 692-5650, e-mail: Lisa.Teot@chp.edu Members: D Hamela-Bena, S Bergman, K Clary, B Centeno