

Papanicolaou Society of Cytopathology Guidelines for Educational Notes, Disclaimers, and Similar Comments on Reports of Cervical Cytology Specimens

Papanicolaou Society of Cytopathology Practice Guidelines Task Force¹

Controversy exists regarding the need for and appropriate form of notes addended to cervical cytology reports. The Guidelines Task Force of the Papanicolaou Society of Cytopathology reviewed the pertinent literature and formulated a list of suggested guidelines to aid practicing cytopathologists in conforming to the National Cancer Institute Bethesda Workshop's consensus recommendations and to fill the requirements of the College of American Pathologists inspections. Diagn. Cytopathol. 2003;28:282–285.

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The Papanicolaou (Pap) test represents a screening examination for cervical cancer. Although highly effective with regular screening, the Pap test has important limitations, including an inherent false-negative rate. The degree to which clinicians and the general public recognize the inherent limitations of the Pap test is less clear. Although the Bethesda System and the College of American Pathologists (CAP) have recognized this problem, currently there is no

consensus regarding the optimal methods, including educational notes and recommendations, to address it.

The Practice Guidelines Task Force of the Papanicolaou Society of Cytopathology (PSC) therefore decided to examine this issue and report its recommendations. A review of the recommendations of the Bethesda forum groups and CAP, as well as comparison with educational notes and disclaimers issued by radiologists for negative mammograms, however, is prudent before PSC recommendations are formulated.

Discussion

A somewhat comparable situation to the cervical cytology examination exists in radiology practice. Screening mammography is also associated with an inherent false-negative rate for the detection of breast cancer, and radiologists have had to address how best to convey this limitation to their patients and clinical colleagues. To date, radiology societies have not issued formal guidelines or recommendations as to the necessity or desirability of educational notes or disclaimers addended to negative screening mammography reports. Although many radiologists appear to include an educational note/disclaimer stating that mammography is a screening test with a low, but not negligible, false-negative rate, the use of such notes is far from universal and remains controversial among radiologists. Other radiologists have preferred to use educational programs, including conferences, grand rounds, and educational brochures. Hence, review of radiology practice does not appear to give definitive guidance on the best use of educational notes/disclaimers in our practice.

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In 1988, the first National Cancer Institute Bethesda Workshop was convened and unanimously established the cytology report as a medical consultation.¹ At that time, the issue of recommendations and educational notes or disclaimers in cytology reports was discussed; recommendations were issued that “the report should include a recommendation for further patient evaluation when appropriate.” This recommendation was subsequently modified in the 1991 Bethesda workshop² and replaced by the statement “recommendations are not required, but are included at the discretion of the cytopathologist.” Since then, various concerns have been raised regarding the nature of the cytology report and the medical and legal responsibility of the cyto-technologists/cytopathologists and health care providers requesting the Pap test. Other developments complicating the issue include federal mandates increasing the availability of the medical record to patients, the rapid move to utilization of electronic medical records, and, finally, a rise in the number of health care providers not primarily trained in gynecology who are ordering and interpreting Pap test results. Secondary to these concerns, many laboratories began including a disclaimer-like educational note describing the limitations of cervical/vaginal cytology screening in their reports. This was done in the hope that it might reduce the legal liability engendered by the limitations of an imperfect screening test. Additionally, many cytologists expressed fears that as our understanding of the pathophysiology of lower genital tract preinvasive and invasive disease continues to evolve, knowledge gaps might develop among various clinical health care providers, which could vary dramatically, depending on their knowledge base and expertise.

In 2001, the Bethesda Workshop (TBS 2001) Forum Groups³ addressed the potential use of recommendations and educational notes, including disclaimer-like notes in cervical cytology reports. The following conclusions were drawn by consensus opinion: “Since the cervical cytology report is in part a medical consultation, any written comments regarding the validity and significance of a cytology report should be directed by the laboratory to the provider requesting the test. Any written or oral comments are to be the responsibility of the pathologist. Contact with the patient, either directly or indirectly by the laboratory should be avoided, as this establishes a new laboratory/patient association that may unnecessarily interfere with the original provider/patient relationship. Direct contact between the patient and the laboratory may be acceptable if specifically requested by the provider.”³

There was a consensus among the participants at the 2001 Bethesda Workshop that disclaimer-like notes have little or no value in relieving a laboratory of liability related to interpretation of a cervical cytology slide. Disclaimer notes could have value in educating the health care provider regarding the limited accuracy of any screening test, such as

the Pap test. The committee (TBS 2001) recommended that suggestions/recommendations and educational notes be optional. When used, they should be carefully worded, concise, clear, and evidence based. As an example, brief notes explaining how the smear quality can be improved or why a patient may require further workup would be considered appropriate. Recommendations on abnormal cervical cytology reports may be helpful in providing the clinician with useful information regarding the significance of a particular result or the reason for a specific recommendation in selected patients. A statement addressing the limitations of cervical cytology may be included in the cytology report, if the laboratory so desires, as long as the laboratory understands that the intent of such a statement is solely educational. Because the field of cervical pathology, including cervical carcinogenesis and management of patients with cervical cancer precursors, is undergoing change, alerting health care providers to pertinent resources such as consensus conferences and clinical management guidelines published by professional organizations⁴ may also be helpful.

Clinicians, particularly gynecologists, have traditionally objected to the inclusion of recommendations and educational notes in the Pap test cytology report. Their chief concerns were that the laboratory lacked detailed clinical history and that pathologists sometimes had limited clinical experience, resulting in inappropriate recommendations. Also, clinical practice varies by locale due to differences in patient populations, unique community practices, patient concerns, and different management care guidelines, such that standardized recommendations were not always suitable. Consequently, inappropriate recommendations could be made that pressured clinicians to perform unnecessary procedures or to go to great lengths documenting why they were not done.

Over the last decade, there has been a dramatic increase in nonspecialty health care providers performing Pap test screening. Some of these providers have little experience or training in the management of lower female genital tract disease, and may not necessarily be informed of recent advances in cytology terminology or management of these patients. These nonspecialty providers and their patients might benefit from recommendations and educational notes included in the cervical/vaginal cytology reports.

CAP has also made recommendations concerning the “educational note” attached to negative Pap smear reports. In the most recent CAP checklist for site evaluation under CAP.06466, the inspectors are asked to determine “is there a policy to educate providers of cervical/vaginal specimens that the Pap test is a screening test for cervical cancer with an inherent false-negative rate?” Failure to have such a policy is a phase 1 deficiency. While it has been assumed by some inspectors and laboratory directors that an educational note on all negative Pap test reports is the preferred mech-

anism, it appears that other mechanisms, including periodically sending educational information to providers, grand rounds, conference presentations, and continuing medical education courses for appropriate providers ordering cervical/vaginal specimens, also fulfill this requirement. It is apparent that CAP is not mandating that educational notes appear on all negative cervical/vaginal smear reports, since they have outlined other mechanisms within their explanatory note appended to the checklist item.

More recently, medical practice, including the availability of the medical records to patients has changed, potentially influencing how and to whom educational notes should be directed. Recent federal mandates have had the effect of increasing patient access to their medical records and of increasing the likelihood that reports generated by the laboratory may in fact be viewed by the patient. Such an eventuality may require reassessment as to the need for and nature of educational notes and recommendations included in cytology reports. In this milieu, educational notes may, in the future, be as much directed to the patient as to the health care provider.

Summation

From the above discussion and the preponderance of current opinion among cytopathology laboratory directors, the following conclusions may be drawn:

1. Standardized educational notes/disclaimers and recommendations/suggestions have been used for some years by radiologists in their reports, documenting the inherent false-negative rate associated with screening mammography. The arguments pro and con for such notes are similar to those associated with the Pap test. The use of such disclaimers with screening mammography reports remains controversial and definitive recommendations from radiology societies do not currently exist.
2. Standardized educational notes/disclaimers do not appear to protect the cytology laboratory from legal liability associated with false-negative Pap tests, regardless of whether the erroneous report is due to interpretive error or screening error. The routine usage of such notes in cytology reports may detract from the perceived significance of specific comments added to reports in special circumstances.
3. From examination of the recommendations by the CAP and the 2001 Bethesda Workshop Recommendations, it appears that educational notes, recommendations/suggestions and disclaimers in cervical cytology reports are optional. While an educational note may be considered the preferred method for informing the provider, such notes are not the only medium acceptable, and other avenues, including interdepart-

mental conferences, technical or educational bulletins, and lectures given on a regular basis, suffice for this CAP checklist requirement. Educational notes may also be placed on the cytopathology requisition form. Because the training and familiarity with current diagnostic and therapeutic protocols can differ substantially among health care providers, the use of specific educational notes directed toward current management and follow up recommendations may be tailored to the population of health care providers using the laboratory services.

4. Because our knowledge of female lower genital tract disease and associated diagnostic and therapeutic approaches is evolving, and federal government mandates regarding the availability of medical records to patients are being developed, reevaluation of the appropriateness and nature of educational notes, comments and disclaimers is an ongoing process.

Recommendations

The following recommendations are proffered by the PSC Practice Guidelines Task Force:

1. Educational notes, recommendations/suggestions and disclaimers in cervical cytology reports are optional and are at the discretion of the cytopathology laboratory. If used, they should be concise and evidence based. Educational notes/comments is the preferred terminology over "disclaimer."
2. Educational notes appended to cervical cytology reports should be directed to the requesting health care provider.
3. The use of educational notes/comments/recommendations should be reevaluated as clinical practices and the availability of the medical record to patients change with future developments.
4. A suggested educational note for a negative cervical cytology report is as follows: cervical cytology is a screening test with limited sensitivity⁵⁻⁷; regular screening is critical for cancer prevention⁸; and Pap tests are primarily effective for the diagnosis/prevention of squamous cell carcinoma, not adenocarcinomas or other cancers.^{9,10}

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