California Society of Pathologists
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ADOPTION OF GUIDELINES FOR REVIEW OF PAP SMEARS IN THE CONTEXT OF POTENTIAL LITIGATION

1. The pap smear is the most effective cancer screening test in medical history, and it is the only screening test which has been associated with a 70-80% decrease in the death rate due to a prevalent cancer.

2. The pap smear is an imperfect screening test such that nowhere has pap smear screening been able to completely eradicate cervical cancer even among screened women. The test is based on subjective interpretation by screening cytologists of the 50,000 to 100,000 or more cells which are present in a typical pap smear.

3. Quality assurance studies indicate that skilled screening cytologists have an irreducible false negative fraction (FNF) of at least 5% which means that at least 5 out of 100 abnormal smears may be read as within normal limits. There is an unreasonable expectation of zero error performance which is impossible even with the use of automated rescreening devices.

4. Since all laboratories have an error rate, the finding of a false negative smear by itself is not necessarily evidence of practice below the standard of care. Accordingly, errors must be judged not only as individual cases but in the context of overall laboratory performance.

5. Atypical cells of undetermined significance is a poorly defined entity with poor inter- and intra-observer reproducibility. Therefore, disputed cases of atypical cells of undetermined significance (ASCUS/AGUS) are not likely to represent reasonable grounds for allegations of practice below the standard of care.

6. Pap smear slides reviewed for possible litigation should not be reviewed with biasing history of litigation or development of carcinoma. Published studies indicate that this type of biased review is not reflective of screening in the normal working situation.

7. Pap smear slides being assessed in the context of litigation as to their degree of difficulty should be reviewed blindly by "reasonable cytologists" without knowledge of clinical outcome or litigation in a fashion which as closely as possible simulates the normal screening situation.

8. Individuals should not hold themselves out as experts in diagnostic gynecologic cytopathology unless they have had significant training and practical experience in the field. Given recent changes in this field, experts should ideally be active pathology practitioners.