

WG4 Molecular Markers for Histopathology - Public Comments February 13, 2012 – February 17, 2012

Practice Type		
Clinician	7	41%
Pathologist	6	35%
Other, please specify	4	24%

Years of Experience		
More than 20 years	4	31%
11-20 years	5	39%
10 years or less	2	15%
Currently a resident/student	2	15%

Practice Setting		
Academic	11	64%
Community/Private Practice	2	12%
Government	2	12%
Industry	1	6%
Insurance/Payers	0	0%
*Other, please specify	1	6%
*No responses received		

Clinician Public Comments

Question 1: Were any published articles omitted from consideration (please refer to Work Group scope/key questions and inclusion/exclusion criteria links above)? How would these articles impact the Work Group's conclusions?

Yes. Hopefully prevent recommendations being skewed by small sample size

yes. to decrease the skew of smaller sample size

no

Question 2: Do you think there are any significant misrepresentations or biases in the draft recommendations?

no

see survey wg 2

Question 3: Do you have any disagreements with the main conclusions and/or evaluations of the literature?

no

yes; see wg 2 survey

Question 4: What topics/gaps for future research/guidelines should be priorities?

cost/benefit analysis

Question 5: Other comments (including, if applicable, support for the recommendations):

Many patho labs hav started genotyping cervical biopsies in order (they say) to aid in diagnosis. Could you comment on the use of genotyping for this indication? Give any guidelines?

none

Pathologist Public Comments

Question 1: Were any published articles omitted from consideration (please refer to Work Group scope/key questions and inclusion/exclusion criteria links above)? How would these articles impact the Work Group's conclusions?

no

NO

no

none that I can think of

No

None that would have fundamentally changed the conclusions.

Question 2: Do you think there are any significant misrepresentations or biases in the draft recommendations?

no

no

no

No

Not a bias exactly, but assuming that the performance of p16 immunohistochemistry will be the same in routine clinical settings as in research studies, the assumption at the start of the statement, is not fully supported. There are more variables in IHC than HPV DNA testing.

No

Question 3: Do you have any disagreements with the main conclusions and/or evaluations of the literature?

no

no

no

No

Yes, the draft places too much reliance on p16 for differentiation of "CIN2" into "high grade" and "low grade" lesions. The marker is important, but requires further validation in routine settings along with follow-up of CIN2 p16 positive versus CIN2 p16 negative patients to determine if the division is clinically relevant.

No

Question 4: What topics/gaps for future research/guidelines should be priorities?

future molecular markers and combinations

Will p16 alone be a sufficient marker to specify clinical action?

Did not identify gaps

Correlation of HPV typing data with p16 IHC in CIN2 lesions in routine clinical setting, interlaboratory comparison of p16 testing and interpretation on equivocal cases.

Prognostic significance of p16 block pattern staining in CIN1. Use of p16 testing to determine if block positive immunohistochemical staining identifies HPV DNA positive CIN1 versus lesions that are classified as CIN1 but are HPV negative (i.e., can p16 block staining identify "true CIN1" versus "psuedo CIN1"?)

Question 5: Other comments (including, if applicable, support for the recommendations):

No responses received

Other

Practice Type
American College of Obstetricians and Gynecologists, Subcommittee on Gynecologic Oncology Public Health Scientist

Question 1: Were any published articles omitted from consideration (please refer to Work Group scope/key questions and inclusion/exclusion criteria links above)? How would these articles impact the Work Group's conclusions?

no

Question 2: Do you think there are any significant misrepresentations or biases in the draft recommendations?

No responses received

Question 3: Do you have any disagreements with the main conclusions and/or evaluations of the literature?

No responses received

Question 4: What topics/gaps for future research/guidelines should be priorities?

More data on p16 is needed before mandating its use.

Question 5: Other comments (including, if applicable, support for the recommendations):

The use of p16 may be acceptable as an adjunct for situations where further clarification is needed, but should not be mandatory.

The common terminology for p16 staining in the literature is negative, focal, diffuse. Why was a new terminology (block staining) introduced in these recommendations?