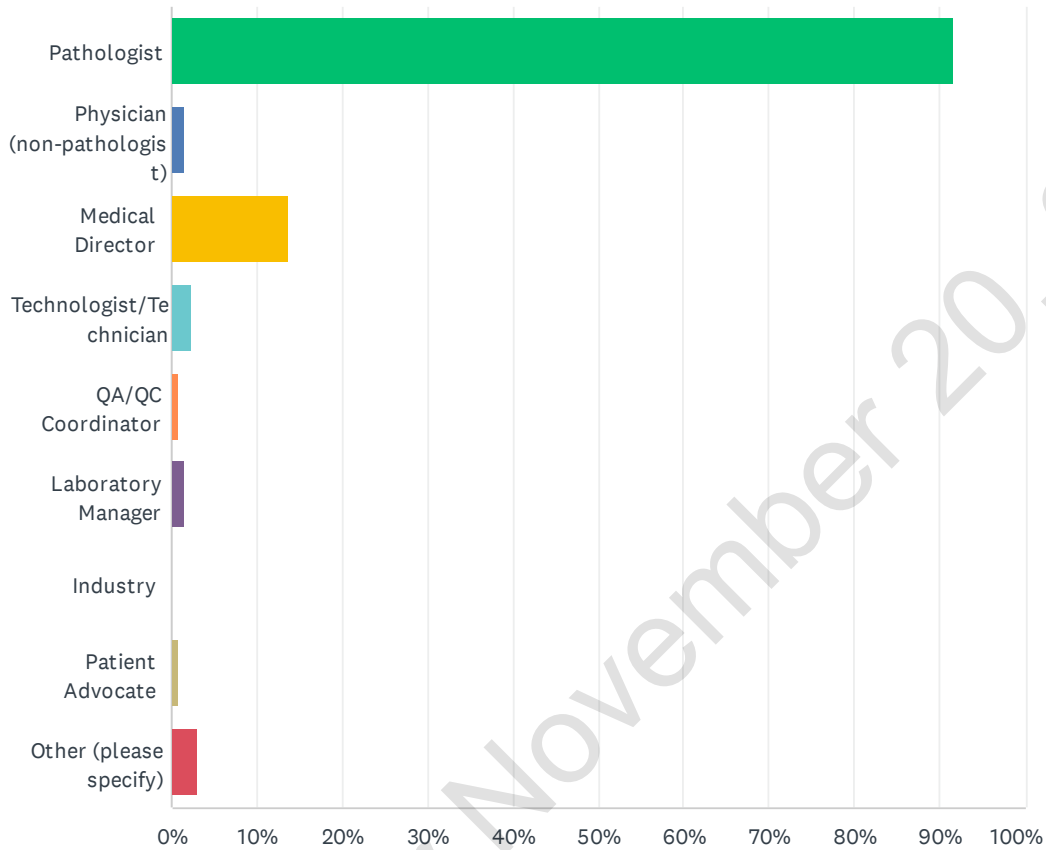


## Q1 What is your occupation/role? (select all that apply)

Answered: 131 Skipped: 0



| ANSWER CHOICES              | RESPONSES |     |
|-----------------------------|-----------|-----|
| Pathologist                 | 91.60%    | 120 |
| Physician (non-pathologist) | 1.53%     | 2   |
| Medical Director            | 13.74%    | 18  |
| Technologist/Technician     | 2.29%     | 3   |
| QA/QC Coordinator           | 0.76%     | 1   |
| Laboratory Manager          | 1.53%     | 2   |
| Industry                    | 0.00%     | 0   |
| Patient Advocate            | 0.76%     | 1   |
| Other (please specify)      | 3.05%     | 4   |
| Total Respondents: 131      |           |     |

| # | OTHER (PLEASE SPECIFY) | DATE               |
|---|------------------------|--------------------|
| 1 | Nurse                  | 10/25/2024 5:33 PM |

Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

|   |                     |                    |
|---|---------------------|--------------------|
| 2 | consultant          | 10/23/2024 3:44 PM |
| 3 | Retired pathologist | 10/23/2024 2:16 PM |
| 4 | Pathology resident  | 10/23/2024 2:07 PM |

Not Valid After November 20, 2024

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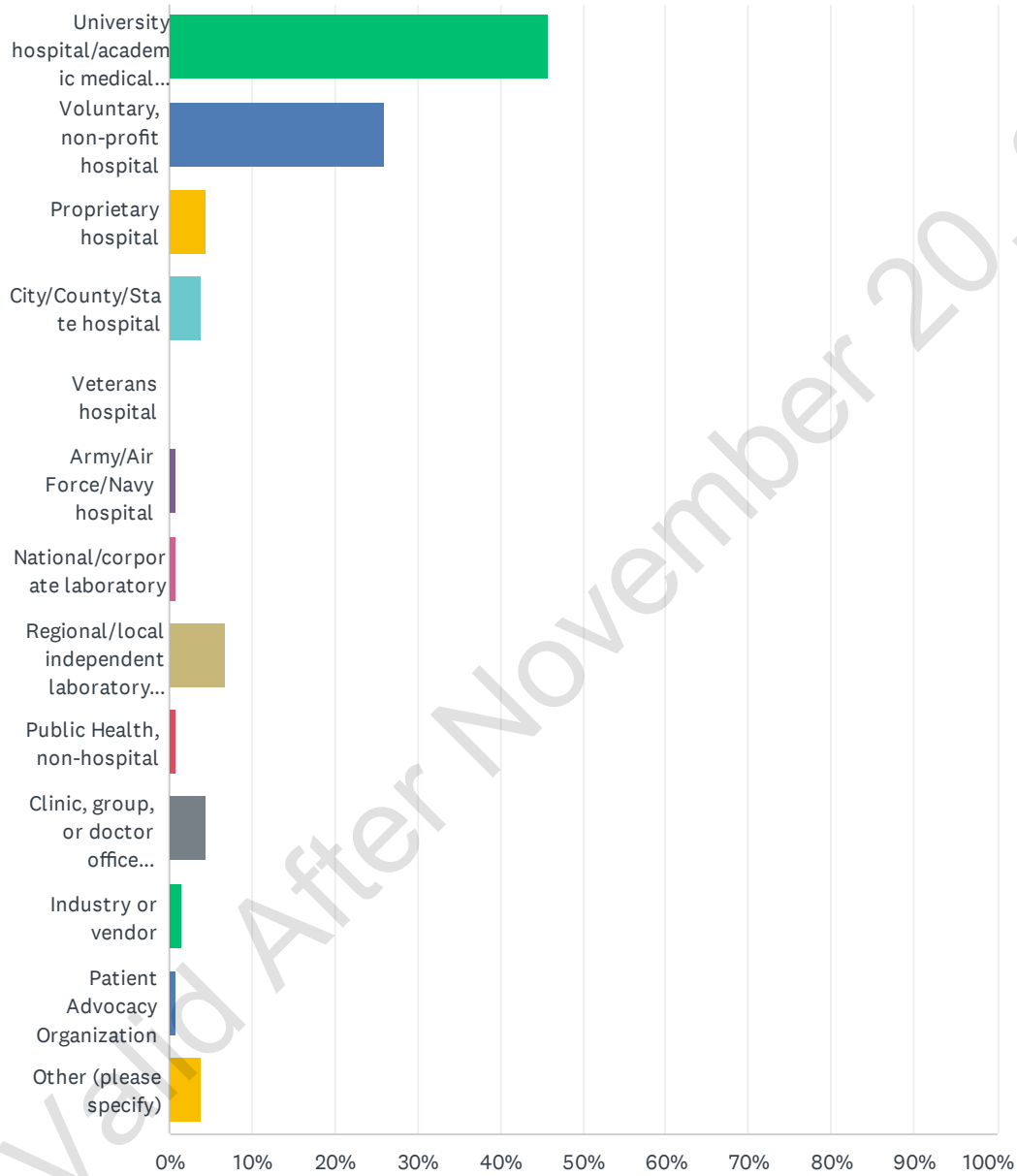
The draft recommendations along with the public comments received and completed evidence review will be reassessed by the expert panel in order to formulate the final recommendations.

These draft materials should not be stored, adapted, or redistributed in any manner.

Please note: comments are not posted automatically. All comments will be posted on a weekly basis beginning October 30, 2024.

## Q2 Which of the following best describes your practice setting? (select one)

Answered: 131 Skipped: 0



Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

| ANSWER CHOICES   | RESPONSES  |
|--|------------|
| University hospital/academic medical center  | 45.80% 60  |
| Voluntary, non-profit hospital   | 25.95% 34  |
| Proprietary hospital   | 4.58% 6    |
| City/County/State hospital   | 3.82% 5    |
| Veterans hospital  | 0.00% 0    |
| Army/Air Force/Navy hospital   | 0.76% 1    |
| National/corporate laboratory  | 0.76% 1    |
| Regional/local independent laboratory (except clinic or group practice and not owned by a national corporation(s)) | 6.87% 9    |
| Public Health, non-hospital  | 0.76% 1    |
| Clinic, group, or doctor office laboratory   | 4.58% 6    |
| Industry or vendor   | 1.53% 2    |
| Patient Advocacy Organization  | 0.76% 1    |
| Other (please specify)   | 3.82% 5    |
| <b>TOTAL</b>   | <b>131</b> |

| # | OTHER (PLEASE SPECIFY)         | DATE               |
|---|--------------------------------|--------------------|
| 1 | retired                        | 11/13/2024 2:52 PM |
| 2 | NIH                            | 11/4/2024 9:33 AM  |
| 3 | Retired from hospital practice | 10/24/2024 8:33 AM |
| 4 | unknown                        | 10/23/2024 7:19 PM |
| 5 | Retired                        | 10/23/2024 2:16 PM |

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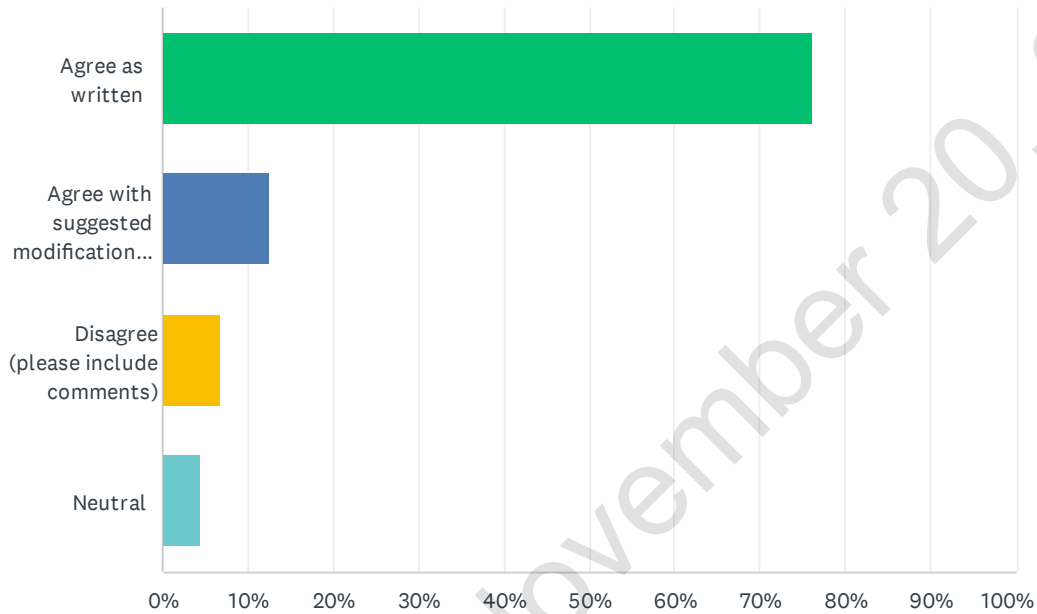
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### Q3 Draft Statement 1 – Anatomic pathologists should develop procedures for review of pathology cases in order to detect disagreements and potential interpretive errors, and to improve patient care.(Strong Recommendation)

Answered: 88 Skipped: 43



| ANSWER CHOICES   | RESPONSES |           |
|--|-----------|-----------|
| Agree as written   | 76.14%    | 67        |
| Agree with suggested modifications (please include comments) | 12.50%    | 11        |
| Disagree (please include comments)                           | 6.82%     | 6         |
| Neutral  | 4.55%     | 4         |
| <b>TOTAL</b>   |           | <b>88</b> |

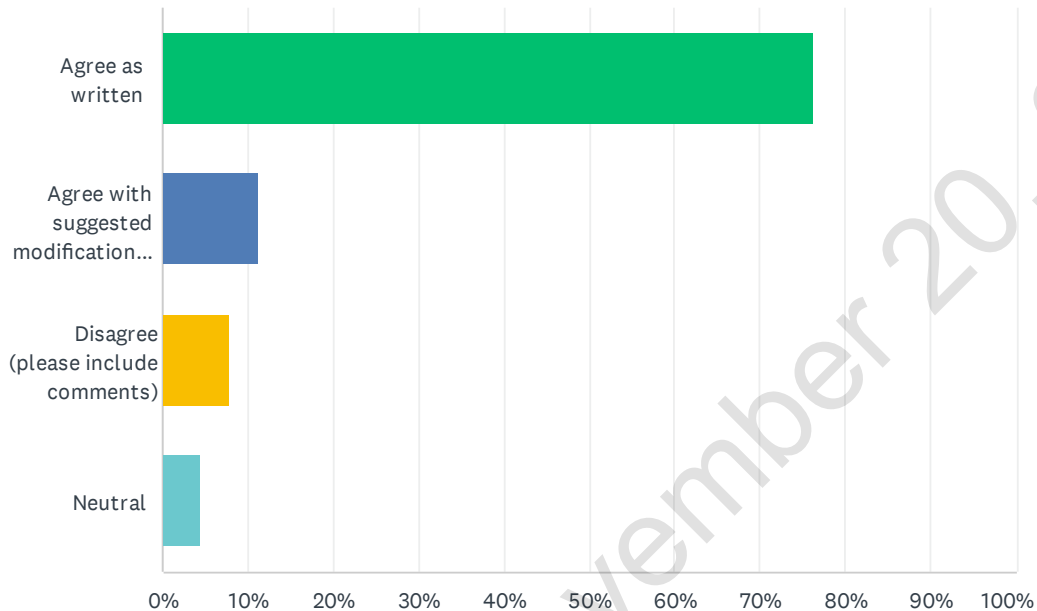
| # | COMMENTS   | DATE               |
|---|--|--------------------|
| 1 | Too prescriptive and presumptuous. Is there data to support this approach over the long standing best practice (ie the lab director ensures quality and assumes responsibility)? Also the language is vague, why would a disagreement be an issue, if there was no potential interpretive error, sounds like an attempt to enforce a specific style on everyone. | 11/13/2024 1:39 PM |
| 2 | Maybe add cytopathology for clarification as all encompassing? ...for review of pathology/cytopathology cases...   | 11/7/2024 11:47 AM |
| 3 | "... procedures for targeted review ..."   | 10/30/2024 6:06 PM |
| 4 | As written with the addition of a percentage of random peer review. The facility I currently work at does not mandate any type of peer review "because it's not required".   | 10/30/2024 5:50 PM |
| 5 | Should develop WAYS or procedures (procedures are too formal in my opinion; ways could be written or oral guidelines which are less formal)  | 10/26/2024 9:17 PM |

Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

|    |  |                     |
|----|--|---------------------|
| 6  | This statement is so general that it is impossible to disagree with it. But the devil is in the details.   | 10/25/2024 3:44 PM  |
| 7  | Should be up to each practice or medical director to have or not have specific procedures.   | 10/25/2024 12:45 PM |
| 8  | Evidence for improved patient outcomes is non-existent so that no Guideline is warranted.  | 10/24/2024 5:57 PM  |
| 9  | Total disagreement to the statement. It puts the burden to do so only on the anatomic pathologist and completely neglects the duty for other stakeholders to provide the respective conditions (financing of the additional work) How should that work under low resources conditions - The priority has to be on the primary report not its reviewing if there are not enough pathologists I have to concentrate them on the report and not reviewing. These are prerequisites that are necessary and by this statement it relieves all other stakeholders (healthcare insurances, hospital administrations, politics) from doing anything as it is stated as an integral obligation of each pathologist not requiring any support. Therefore, not the anatomic pathologist is the addressee, but the health care system and thus all statements have to be changed in order to avoid trouble to Pathologists. QA and QM costs a lot of time and money and it is seldom refinanced. Statements like that are cited in legal cases and turn against Pathologists   | 10/24/2024 12:03 PM |
| 10 | This seems a little underspecified. In particular, the meaning of "review" is underspecified. Maybe it will be clarified by the framing of this manuscript. My initial microscopic exam of a case could be considered a review and indeed my goal is to prevent errors. Suggest: "Anatomic pathology workflows should include procedures to detect disagreements and errors in order to improve patient care." I am also struggling with whether you need to say this will improve patient care. Some disagreements have no impact on patient care and I don't know if we need to catch them. There is also a category of errors that is not a disagreement or an interpretive error, but rather a typo or reporting error. For example, a wrong word can be left in a report, or contradictory information can be present (say, between diagnosis and synoptic). Isn't it important to catch those? They can have a major effect on patient care. My colleague leaves incorrect information in her reports all the time (e.g., "One lymph node with evidence of malignancy" which is "obviously" meant to be "no" evidence of malignancy, but was misinterpreted by clinician and was very difficult to counsel the patient about, because she became convinced there was an actual disagreement about the status of the node). | 10/24/2024 10:15 AM |
| 11 | Intraprofessional bureaucratic overreach   | 10/24/2024 6:10 AM  |
| 12 | I would suggest that interpretative errors should be reviewed from the perspective of existing guidelines (such as CAP's), as sometimes difficult interpretation by clinicians relies on too "descriptive" diagnoses instead of synoptic ones.   | 10/24/2024 4:54 AM  |
| 13 | ... in order to detect potential clinically relevant interpretive disagreements and diagnostic errors, so as to improve patient care.  | 10/23/2024 9:28 PM  |
| 14 | One size does not fit all. Small community practices have limited resources. Procedures for review need to take that into account.   | 10/23/2024 5:25 PM  |
| 15 | more specific procedures or "suggested best practice" would be really useful, even just "minimum" numbers  | 10/23/2024 3:40 PM  |
| 16 | The review process can be based on stringent Pre-selected criteria. Alternatively, a climate can be encouraged in which cases of interest or doubt are shared amongst colleagues, voluntarily, and amicably. In such an environment, a target percent of the cases to be reviewed or shared could be set.  | 10/23/2024 2:40 PM  |
| 17 | "... should develop risk-based procedures" I suggest you weave that in since it's where both LAP and CAP15189 are going.   | 10/23/2024 2:39 PM  |
| 18 | I'm curious about the recommendation's scope of "satisfying" the task. For example, does tumor board review count? Does this have to be a systematic re-review (which can be extraordinarily time consuming with limited resources)? Does external consult review reconciliation and documentation count? It's hard to "agree" without more details on the intended implementation.  | 10/23/2024 2:14 PM  |

## Q4 Draft Statement 2 – Anatomic pathologists should perform case reviews in a timely manner to have a positive impact on patient care. (Strong Recommendation)

Answered: 89 Skipped: 42



| ANSWER CHOICES   | RESPONSES |           |
|--|-----------|-----------|
| Agree as written   | 76.40%    | 68        |
| Agree with suggested modifications (please include comments) | 11.24%    | 10        |
| Disagree (please include comments)                           | 7.87%     | 7         |
| Neutral  | 4.49%     | 4         |
| <b>TOTAL</b>   |           | <b>89</b> |

| # | COMMENTS  | DATE               |
|---|---|--------------------|
| 1 | Anatomic pathologists should perform case reviews in a timely manner to have a positive impact on patient care, balancing the needs of timeliness with needs to wait for ancillary studies to improve accuracy.   | 11/13/2024 2:43 PM |
| 2 | Need to provide more detail on "case reviews".  | 11/13/2024 2:13 PM |
| 3 | If you think that there is a risk of error and want to protect patients, then you should do so before the report is signed out. A reasonable approach is for the lab director to use their experience and published data and recommendations in specific subspecialty areas in which a second review is recommended to guide individual policies that make sense for their patients. Reviewing a percent of routine cases represents a huge uncompensated workload with no proven benefits for my highly sub-specialized department | 11/13/2024 1:39 PM |
| 4 | "... should perform case reviews in a timely manner (preferably before final signout) to have..."   | 10/30/2024 6:06 PM |
| 5 | I agree, except that a review that is not timely (for example, a month after the case is signed out) may be better than no review at all.   | 10/25/2024 3:44 PM |

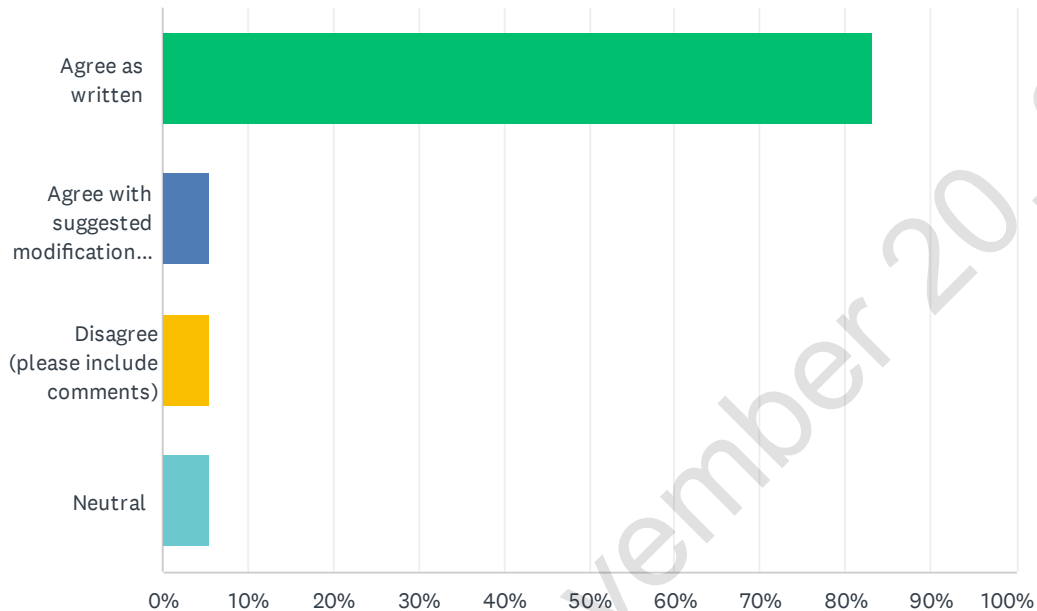
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Survey—Draft Recommendations and Good Practice Statements

|    |   |                     |
|----|---|---------------------|
| 6  | Timely is variable and could have medico legal implications.  | 10/25/2024 12:45 PM |
| 7  | I believe this is best practice, but with timely NOT defined this could be difficult to do and hence, be considered substandard and risk for lawsuit. | 10/24/2024 6:34 PM  |
| 8  | Again, there is no evidence of improved patient outcomes.   | 10/24/2024 5:57 PM  |
| 9  | Aggravates my statement above as adding time pressure to it   | 10/24/2024 12:03 PM |
| 10 | In a timely manner but in concordance with the complexity of the case   | 10/24/2024 10:58 AM |
| 11 | Suggest: "Procedures designed to detect disagreements and errors and to act on them should be sufficiently timely to improve patient care."           | 10/24/2024 10:15 AM |
| 12 | Intraprofessional bureaucratic overreach  | 10/24/2024 6:10 AM  |
| 13 | ... perform cases reviews within a clinically actionable timeframe, so as to positively influence patient care.                                       | 10/23/2024 9:28 PM  |
| 14 | Isn't "timely manner" the reason the case got signed out wrong in the first place?  | 10/23/2024 7:25 PM  |
| 15 | One size does not fit all. Small community hospital practices have limited resources. Recommended procedures need to take that into account.          | 10/23/2024 5:25 PM  |
| 16 | more specific   | 10/23/2024 3:40 PM  |
| 17 | Yes, but again this should be risk based. Screening Pap smears one can review in a week or two, biopsies prompting procedures need to be seen sooner. | 10/23/2024 2:39 PM  |
| 18 | See above comments  | 10/23/2024 2:14 PM  |



## Q5 Draft Statement 3 – Anatomic pathologists should have documented case review procedures that are relevant to their practice setting.(Good Practice Statement)

Answered: 89 Skipped: 42



| ANSWER CHOICES   | RESPONSES |           |
|--|-----------|-----------|
| Agree as written   | 83.15%    | 74        |
| Agree with suggested modifications (please include comments) | 5.62%     | 5         |
| Disagree (please include comments)                           | 5.62%     | 5         |
| Neutral  | 5.62%     | 5         |
| <b>TOTAL</b>   |           | <b>89</b> |

| # | COMMENTS   | DATE                |
|---|--|---------------------|
| 1 | Statements 2 and 3 can be combined.  | 11/13/2024 2:13 PM  |
| 2 | Well this contradicts the previous statements and is still an overreach; we should document procedures to ensure quality; case review is not always the answer | 11/13/2024 1:39 PM  |
| 3 | Language could be more precise; or list an example.  | 10/30/2024 11:50 AM |
| 4 | Again, I don't see any way to disagree with this statement.  | 10/25/2024 3:44 PM  |
| 5 | Up to each practice if they want to do this.   | 10/25/2024 12:45 PM |
| 6 | Strength of evidence is insufficient to warrant best practice recommendation in the context of a guideline.  | 10/24/2024 5:57 PM  |
| 7 | Makes it even worse as it  | 10/24/2024 12:03 PM |
| 8 | Ideally documented within an electronic, searchable database   | 10/24/2024 10:58 AM |

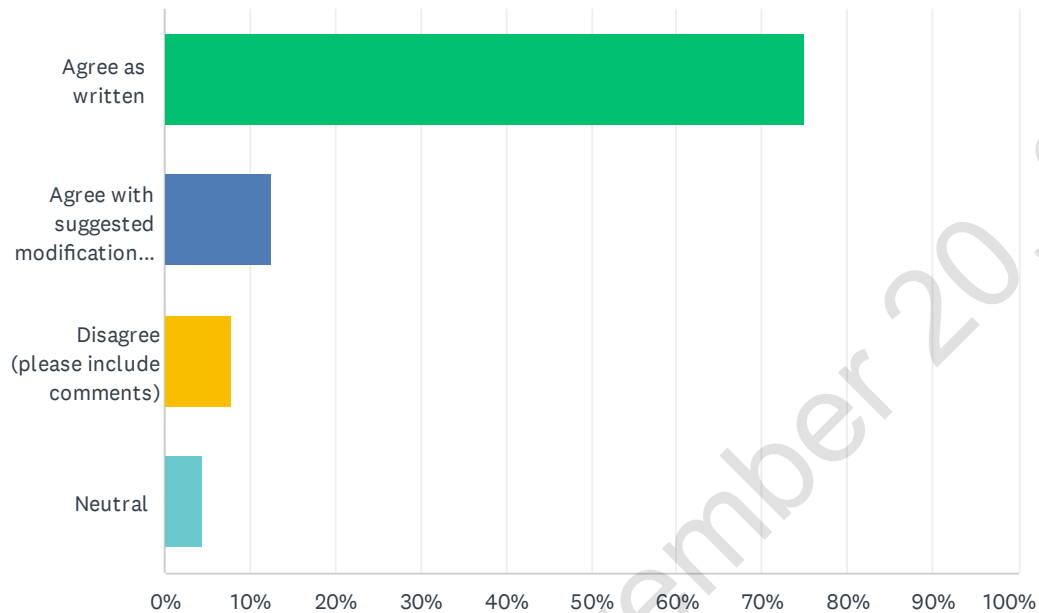
Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

|    |   |                     |
|----|---|---------------------|
| 9  | While I agree any policy or procedure should be appropriate to the setting, it seems somewhat obvious. I am not sure there will be data to support this. It is more of a general good practice and could be ancillary to statement 1. | 10/24/2024 10:15 AM |
| 10 | Intraprofessional bureaucratic overreach  | 10/24/2024 6:10 AM  |
| 11 | Documented case review procedures "that are relevant to practice setting." The Devil is in the details.   | 10/23/2024 5:25 PM  |
| 12 | Anatomic pathologists should have documented case review procedures that are relevant to their practice setting and quality management plan.  | 10/23/2024 4:12 PM  |

Not Valid After November 20, 2024

## Q6 Draft Statement 4 – Anatomic pathologists should continuously monitor and document the results of case review.(Good Practice Statement)

Answered: 88 Skipped: 43



| ANSWER CHOICES   | RESPONSES |
|--|-----------|
| Agree as written   | 75.00% 66 |
| Agree with suggested modifications (please include comments) | 12.50% 11 |
| Disagree (please include comments)                           | 7.95% 7   |
| Neutral  | 4.55% 4   |
| <b>TOTAL</b>   | <b>88</b> |

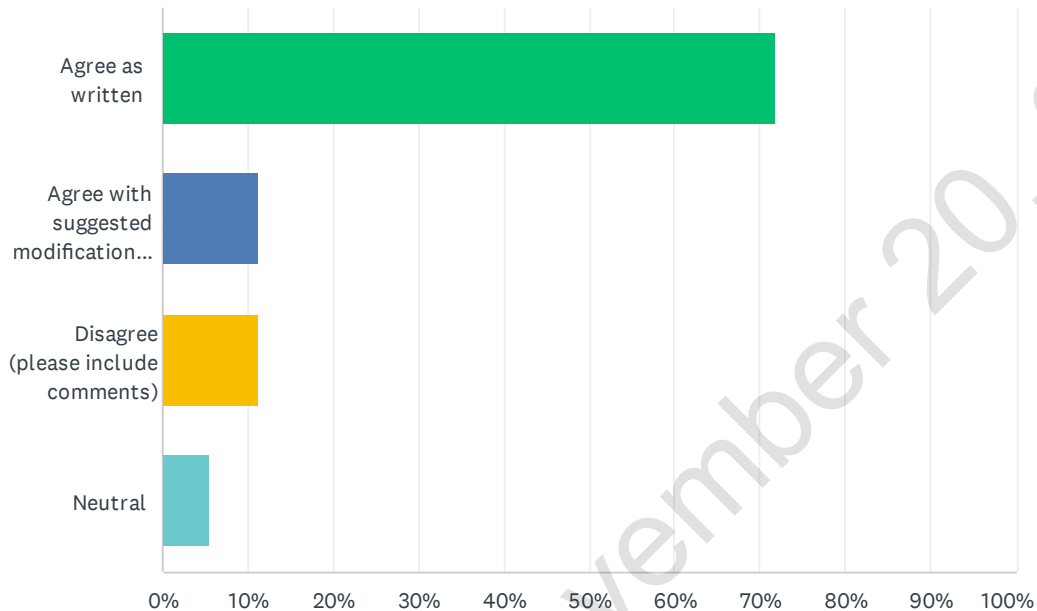
| # | COMMENTS  | DATE                |
|---|---|---------------------|
| 1 | Continuously may be a vague term, particularly if lawyers and litigation are involved. Please give this a bit more thought.   | 11/13/2024 1:15 PM  |
| 2 | Would replace "continuously" with "in a timely manner" to match language in DS2.  | 10/30/2024 11:50 AM |
| 3 | Other staff may actually be reviewing the results of QA as at our institution.  | 10/28/2024 1:52 PM  |
| 4 | Impossible to continuously monitor anything. Set up for failure and medico legal exposure.  | 10/25/2024 12:45 PM |
| 5 | Would drop the word ".....continuously....."  | 10/24/2024 6:34 PM  |
| 6 | As above, insufficient evidence.  | 10/24/2024 5:57 PM  |
| 7 | Even more worse!!!  | 10/24/2024 12:03 PM |
| 8 | prospective or retrospective?   | 10/24/2024 11:26 AM |
| 9 | What is "continuously"? Every five minutes? I think the point is that the results should be seen and not simply buried or ignored. We already said the procedures should be timely. I think this can be baked into statement 2. | 10/24/2024 10:15 AM |

Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

|    |  |                    |
|----|--|--------------------|
| 10 | Intraprofessional bureaucratic overreach   | 10/24/2024 6:10 AM |
| 11 | ... should regularly monitor and document the results...   | 10/23/2024 9:28 PM |
| 12 | Such requirements may be onerous for small community hospital settings. Requirements must be tailored to the setting.  | 10/23/2024 5:25 PM |
| 13 | Delete continuously and replace with periodically  | 10/23/2024 3:16 PM |
| 14 | It appears more important to have the process of case review and case sharing running rather than to document it meticulously. Documentation would probably be different in a small group practice of three or five pathologists compared to a larger academic center or reference laboratory. I have difficulties to visualize the benefit of meticulously documenting and possibly even categorizing in the outcome of Informal in-house review. Simple documentation could state for example "this case has been seen by a doctor XY and she/he concurs with the diagnosis" | 10/23/2024 2:40 PM |
| 15 | Not only monitor the results but also periodically review the process to see if the risks have changed and whether it is still relevant for practice setting.  | 10/23/2024 2:39 PM |

## Q7 Draft Statement 5 – If pathology case reviews show poor agreement within a defined area, anatomic pathologists should take steps to improve agreement.(Good Practice Statement)

Answered: 89 Skipped: 42



| ANSWER CHOICES   | RESPONSES |           |
|--|-----------|-----------|
| Agree as written   | 71.91%    | 64        |
| Agree with suggested modifications (please include comments) | 11.24%    | 10        |
| Disagree (please include comments)                           | 11.24%    | 10        |
| Neutral  | 5.62%     | 5         |
| <b>TOTAL</b>   |           | <b>89</b> |

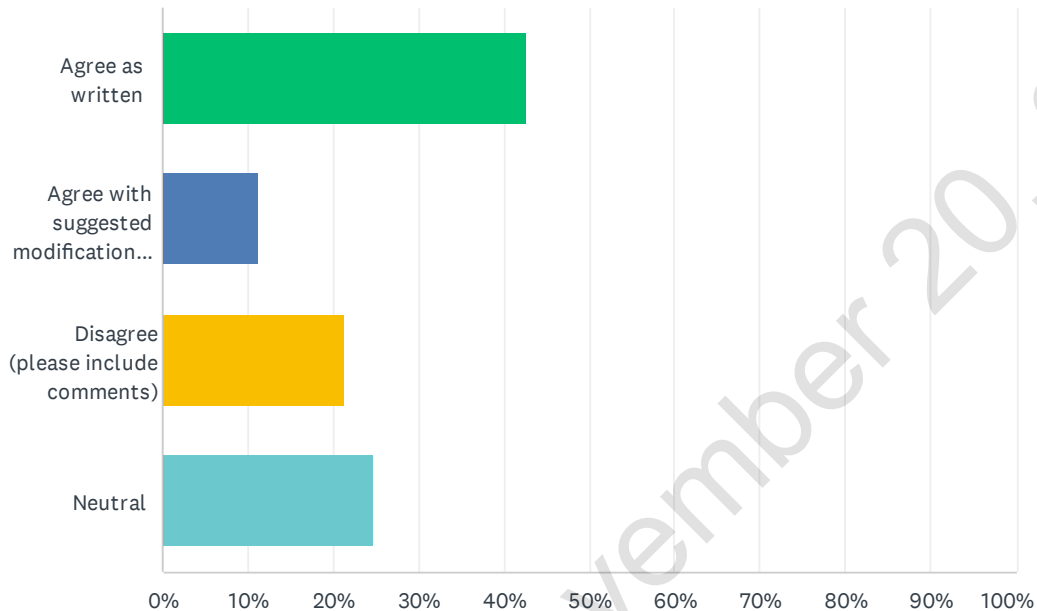
| # | COMMENTS   | DATE               |
|---|--|--------------------|
| 1 | These statements should be based in evidence to the degree possible. In most areas of anatomic pathology, there is little evidence to suggest that "improving agreement" improves "patient care". And anatomic pathologists should take steps to improve patient care, not agreement.  | 11/13/2024 8:41 PM |
| 2 | Self-evident, and unnecessarily self-incriminating   | 11/13/2024 7:38 PM |
| 3 | Procedures for improving agreement include, intra and extradepartmental consultation   | 11/13/2024 2:02 PM |
| 4 | Lets not focus on agreement, accuracy is more important than precision   | 11/13/2024 1:39 PM |
| 5 | Again, there may be a need to define what poor agreement is.   | 11/13/2024 1:15 PM |
| 6 | Agree but the steps might differ widely, depending on the circumstances. For instance, they might entail obtaining consultations (as a routine) for certain types of cases, further continuing education, or limitation of sign-out certain types of cases to particular pathologists with subspecialty expertise. Or, in the new world of AI, using AI to review certain cases. | 10/25/2024 3:44 PM |

Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

|    |   |                     |
|----|---|---------------------|
| 7  | Interfering with practices and practice of medicine.  | 10/25/2024 12:45 PM |
| 8  | Don't know what "defined area" means? Pathologists? Organ system? Poor histology?   | 10/24/2024 6:34 PM  |
| 9  | As above, insufficient evidence.  | 10/24/2024 5:57 PM  |
| 10 | Since the problem is not the agreement but rather the possibility of a misdiagnosis, I suggest a modification along the lines of: "If pathology case reviews show poor agreement within a defined area, anatomic pathologists should take steps to determine the reason of those disagreements and improve the diagnosis" | 10/24/2024 12:41 PM |
| 11 | This is immanent to any functioning QA, somewhat self understanding and justiciable anyhow, but correct if statements 1-4 are in a correct context  | 10/24/2024 12:03 PM |
| 12 | It is extremely important that each practice first defines agreement and disagreement as suitable to their practice and case types  | 10/24/2024 11:26 AM |
| 13 | Should take steps to investigate source of poor agreement and steps to improve it.  | 10/24/2024 10:58 AM |
| 14 | Intraprofessional bureaucratic overreach  | 10/24/2024 6:10 AM  |
| 15 | ... show poor agreement within a clinically relevant element of interpretation ...  | 10/23/2024 9:28 PM  |
| 16 | Will there be examples to explain this statement; just reading it here out of context I am not certain what it refers to. Interobserver variation around things like ADH/DCIS? HSIL vs LSIL, grades of dysplasia in GI bxs?   | 10/23/2024 5:34 PM  |
| 17 | I have no idea what that statement means.   | 10/23/2024 5:25 PM  |
| 18 | I agree with this statement for areas in which a gold standard exists. There are a lot of gray areas in anatomic pathology where consensus will be not be possible so it would not be clear what steps to take in these instances.  | 10/23/2024 3:59 PM  |
| 19 | poor agreement needs to be defined better, esp when it comes to cytology (e.g. one or two level differences in cyto reporting systems). Suggestions for methods of improvement would be helpful   | 10/23/2024 3:40 PM  |
| 20 | Very nebulous   | 10/23/2024 3:16 PM  |
| 21 | Phrased funny since the goal is not pathologists agreeing, the goal is getting it right. Rewrite to align with the guideline: if diagnostic errors occur within a define area, steps should be take to improve diagnostic accuracy (and probably not only in a "defined area").   | 10/23/2024 2:39 PM  |

**Q8 Draft Statement 6 – Anatomic pathologists should use fewer tiers (eg, two tiers versus three or more tiers) if possible and with clinical relevance, when there is poor agreement in grading.(Good Practice Statement)**

Answered: 89 Skipped: 42



| ANSWER CHOICES   | RESPONSES |
|--|-----------|
| Agree as written   | 42.70% 38 |
| Agree with suggested modifications (please include comments) | 11.24% 10 |
| Disagree (please include comments)                           | 21.35% 19 |
| Neutral  | 24.72% 22 |
| <b>TOTAL</b>   | <b>89</b> |

| # | COMMENTS   | DATE               |
|---|--|--------------------|
| 1 | In specific areas - such as the Bethesda System for Reporting Cervical Cytology - where there is extensive evidence for clinical relevance *despite* poor agreement in grading, more tiers are acceptable.                   | 11/13/2024 8:41 PM |
| 2 | Is the tier based on minor and major disagreements?  | 11/13/2024 7:52 PM |
| 3 | Too prescriptive   | 11/13/2024 7:38 PM |
| 4 | Too broad, Number of tiers should be disease and location-specific and defined by subspecialty experts.  | 11/13/2024 4:19 PM |
| 5 | I appreciate the loss of specificity that occurs with excessive tiering but I can see this recommendation being very confusing in application. Efforts to clarify "clinical relevance" and "poor agreement" might be needed. | 11/13/2024 4:10 PM |
| 6 | Again, a stunning overreach, no pathologist has the expertise across all specialties to make this type of broad statement. Show me the data. Best for subspecialty societies to address                                      | 11/13/2024 1:39 PM |

Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

|    |  |                     |
|----|--|---------------------|
|    | this issue.  |                     |
| 7  | If ASCO or ACOG is using 3 or 4 tiers, can we do with less??   | 11/13/2024 1:15 PM  |
| 8  | The first five are for anatomic pathologists but the last one is for practice standards/guideline committees (e.g. LAST, WHO etc.) that set the diagnostic labels for entities. One can't use fewer tiers if the 'standard of practice' is more, can one? This should be rewritten or deleted.   | 11/10/2024 7:04 PM  |
| 9  | Question - is this more applicable as an IF/THEN?? If there is poor agreement in grading, ap should use fewer tiers...   | 11/7/2024 11:47 AM  |
| 10 | I feel that 1) this statement is kinda' subsumed in statement 5, 2) does not seem to fit with the other statements, where 'anatomic pathologists' can be interpreted to mean 'anatomic pathologists practicing in a laboratory'. The 'who' here seems different and is the body that is making the 'standardized rules' for the profession rather than the laboratory, 3) I am not sure that agreement is the right goal. Everyone can agree on atypical 4) I am not sure I understand this correctly. How do you define the 'what should be divided'. Although we say that SIL is two tiered, the pap test is not really two tiered. Are you suggesting that we collapse the 5 tiered-Benign, ASCUS, LSIL, HSIL, Malignant to Tier one (LSIL and less), and tier 2 (HSIL or more)? 5) I feel that this would be different depending on screening test (where broad categories are preferable to ensure sensitivity) vs diagnostic test (where specificity is preferable). Aren't three tiers the minimum? the Good, the bad and the not sure? I am not sure that 'not sure' should be done away with for the sake of improving agreement-- the med school now has courses for students on communicating uncertainty... so this seems contrary to where medicine is going. This seems to be promoting pseudoagreement. | 10/31/2024 4:58 PM  |
| 11 | 2 tiers is not sufficient. Following the non-gyn cytology model, probably need at least 5 tiers: non-diagnostic, normal, non-malignant abnormality, indefinite for malignancy, and malignant.  | 10/30/2024 6:06 PM  |
| 12 | I think this statement should be entirely deleted.   | 10/28/2024 1:52 PM  |
| 13 | These seems less relevant to the questions at hand   | 10/27/2024 6:46 PM  |
| 14 | This is probably true in general, but "poor agreement" needs to be defined. It may vary across different cases.  | 10/25/2024 3:44 PM  |
| 15 | Case and site specific with literature for each site. A general statement is unnecessary.  | 10/25/2024 12:45 PM |
| 16 | See above. This constitutes gratuitous advice from self-designated experts.  | 10/24/2024 5:57 PM  |
| 17 | I think that this statement should be more clearly explained. Are the tiers related to agreement or not agreement? minor or major disagreement? Please further expand the text to include clarifications.  | 10/24/2024 12:41 PM |
| 18 | A somewhat isolated statement as thematically related, while the others are procedural. But how is it meant? The Pathologist is first obliged to follow state of knowledge for the different entities and related guidelines, recommendations. Thus primarily, the obligation is to adjust performance and knowledge to state of art and not change the rules. Therefore, the statement is not congruent with other obligations  | 10/24/2024 12:03 PM |
| 19 | every disagreement is not clinically relevant; they should be interpreted in the correct context otherwise it is a slippery slope  | 10/24/2024 11:26 AM |
| 20 | Anatomic pathologists should strive to adhere to current published grading guidelines.   | 10/24/2024 10:58 AM |
| 21 | This is a very specific issue that seems out of place here after the other statements that are much more general. Suggest: "Anatomic pathologists should favor classification systems that minimize diagnostic disagreement."  | 10/24/2024 10:15 AM |
| 22 | Do not understand the draft.   | 10/24/2024 8:36 AM  |
| 23 | Intraprofessional bureaucratic overreach   | 10/24/2024 6:10 AM  |
| 24 | ... if feasible and with clinical relevance...   | 10/23/2024 9:28 PM  |
| 25 | If guidelines around a particular entity have not moved in that direction, some may be reluctant to follow. Allowance to follow recognized guidelines?   | 10/23/2024 5:34 PM  |
| 26 | Not sure what that means.  | 10/23/2024 5:25 PM  |
| 27 | I disagree with this statement. The number of tiers should be context specific. Less tiers is not  | 10/23/2024 3:59 PM  |



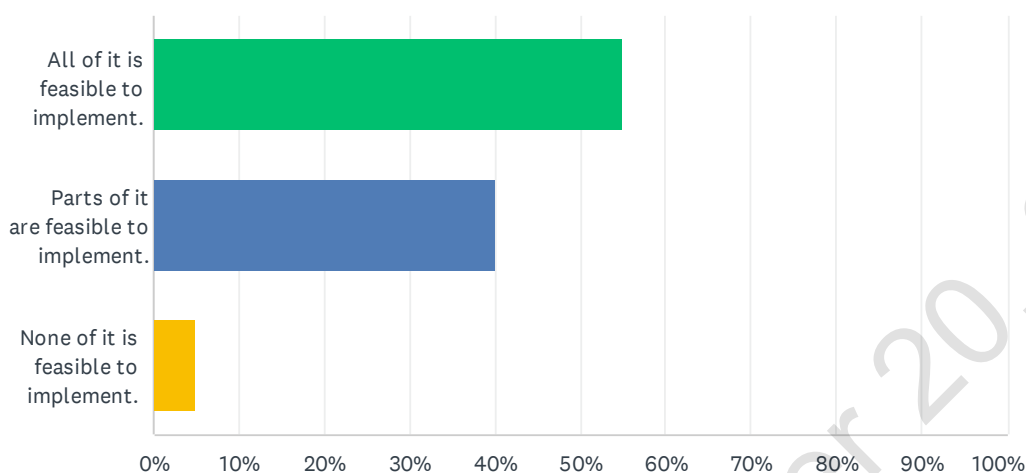
Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

always better. By the logic of this statement, 1 tier would be ideal and would help to achieve 100% agreement. But I do not think this will help our patients or clinicians. In my opinion, repeatedly changing the number of tiers up and down from year to year is unlikely to help our patients and clinicians have a better understanding of their diagnosis.

|    |  |                    |
|----|--|--------------------|
| 28 | The data does not support 2 tier in all organ systems or situations, recommend going with subspecialty guidelines/consensus (maybe something that CAP can compile as a general best practice)                                      | 10/23/2024 3:40 PM |
| 29 | For some areas of pathology, there needs to be a 3 tier system   | 10/23/2024 3:16 PM |
| 30 | This is ok but needs guidance on how to define clinical relevance. It is all too often never clinically relevant.  | 10/23/2024 2:39 PM |
| 31 | This is very general and could be interpreted subjectively across specialties. More specific guidelines by subspecialty to use case scenarios may be helpful, which is inherently difficult to formulate for many AP report types. | 10/23/2024 2:14 PM |

## Q9 How feasible is it to implement this guideline?

Answered: 80 Skipped: 51



| ANSWER CHOICES                         | RESPONSES |
|--|-----------|
| All of it is feasible to implement.    | 55.00% 44 |
| Parts of it are feasible to implement. | 40.00% 32 |
| None of it is feasible to implement.   | 5.00% 4   |
| <b>TOTAL</b>                           | <b>80</b> |

| #  | COMMENTS ABOUT THE FEASIBILITY OF IMPLEMENTING THE GUIDELINE:   | DATE                |
|----|---|---------------------|
| 1  | see comment on proposed guideline #6  | 11/13/2024 4:12 PM  |
| 2  | This is not the appropriate group to address these issues, should be at a subspecialty level.   | 11/13/2024 1:47 PM  |
| 3  | Not sure. Nothing specific to implement, is there?  | 11/10/2024 7:14 PM  |
| 4  | There is nothing specifically suggested for implementation; this guideline does not recommend change/implementation of anything. This is philosophical.   | 10/31/2024 5:00 PM  |
| 5  | Depends on the additional elements in the guideline report. The draft statements are open-ended (which is good), so depend on additional details provided   | 10/27/2024 6:47 PM  |
| 6  | Senior pathologists in my practice see error reduction as extra, non-reimbursed work. They seem to think such review are superfluous.   | 10/26/2024 3:19 PM  |
| 7  | It is feasible but it is so general that I'm not sure how useful it will be in the field.   | 10/25/2024 3:52 PM  |
| 8  | But not recommended.  | 10/25/2024 12:46 PM |
| 9  | Implementation is 'feasible', but at high cost with skimpy to no evidence of outcome benefit.   | 10/24/2024 6:04 PM  |
| 10 | see comments, would be extremely negative for our profession  | 10/24/2024 12:14 PM |
| 11 | EMR restrictions may lead to challenges in terms of monitoring these reviews and documentation of that monitoring   | 10/24/2024 11:00 AM |
| 12 | Some areas of pathology are simply controversial. The guideline so far assumes there is a right answer and a wrong answer (errors) and that reviews can detect them. Sometimes there will be a disagreement that is not an error and can't or doesn't have to be corrected. You run | 10/24/2024 10:37 AM |

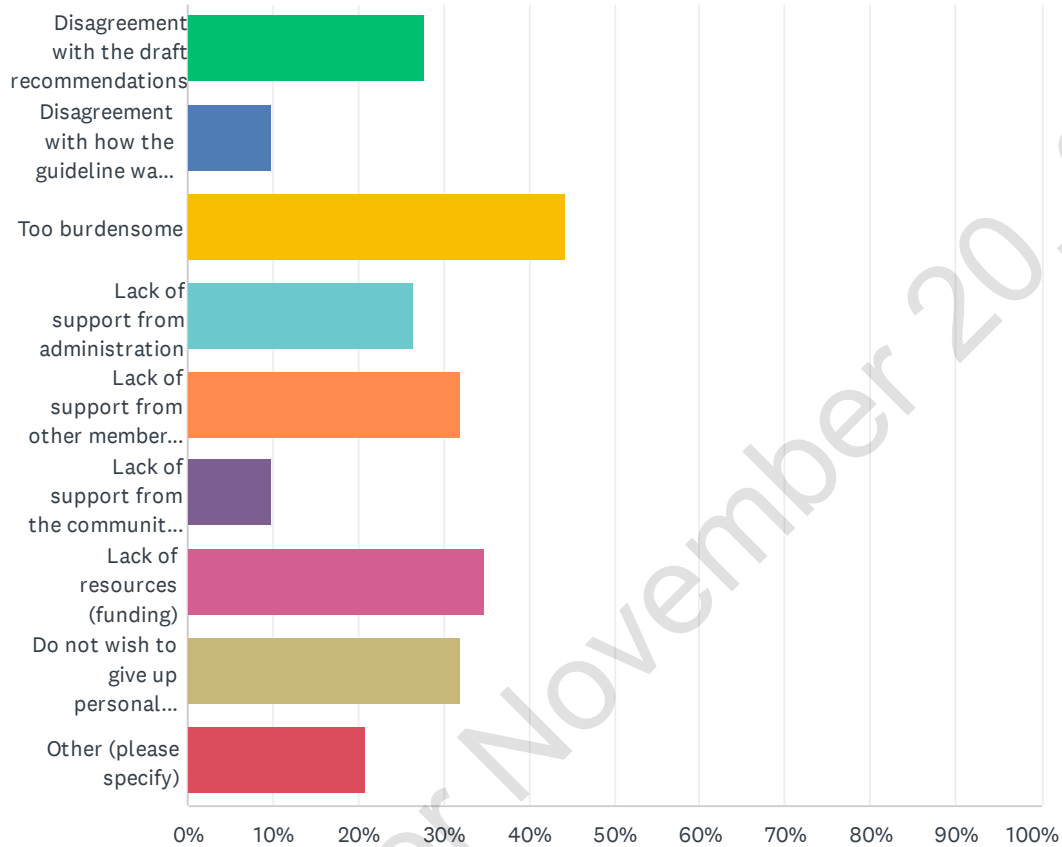
Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

the risk of creating a situation where my senior partner is right by definition because they do the reviews and their opinion holds. By the way, my section head is a bully and loves finding mistakes that I made. She is going to love these guidelines.

|    |   |                     |
|----|---|---------------------|
| 13 | vague intraprofessional bureaucratic overreach  | 10/24/2024 6:12 AM  |
| 14 | Implementing guidelines that directly impact daily routines is difficult. Still, in a clinical setting, it is mandatory to approach diagnostic issues from a more objective perspective, especially recommending the use of known and published guidelines. | 10/24/2024 5:17 AM  |
| 15 | It would be good to have sub points giving examples of how to implement the guidelines in different practice situations   | 10/23/2024 10:52 PM |
| 16 | Most practices should be doing many of these things already.  | 10/23/2024 5:35 PM  |
| 17 | It's too vague to be really useful  | 10/23/2024 3:41 PM  |
| 18 | The burden will depend on the extent of documentation and categorization of the outcome of in-house review.   | 10/23/2024 2:44 PM  |
| 19 | How would we know without having seen it? I say part because there'll be barriers in practices.   | 10/23/2024 2:42 PM  |
| 20 | The specificity of the guidelines is lacking. A published set of high quality example programs would be appreciated.  | 10/23/2024 2:15 PM  |

## Q10 What barriers might impede adoption of the final guideline? (Choose all that apply.)

Answered: 72 Skipped: 59



| ANSWER CHOICES  | RESPONSES |    |
|---|-----------|----|
| Disagreement with the draft recommendations   | 27.78%    | 20 |
| Disagreement with how the guideline was developed   | 9.72%     | 7  |
| Too burdensome  | 44.44%    | 32 |
| Lack of support from administration   | 26.39%    | 19 |
| Lack of support from other members of the medical team  | 31.94%    | 23 |
| Lack of support from the community (others outside your institution e.g., patients, industry) | 9.72%     | 7  |
| Lack of resources (funding)   | 34.72%    | 25 |
| Do not wish to give up personal autonomy to follow the guideline                              | 31.94%    | 23 |
| Other (please specify)  | 20.83%    | 15 |
| Total Respondents: 72   |           |    |

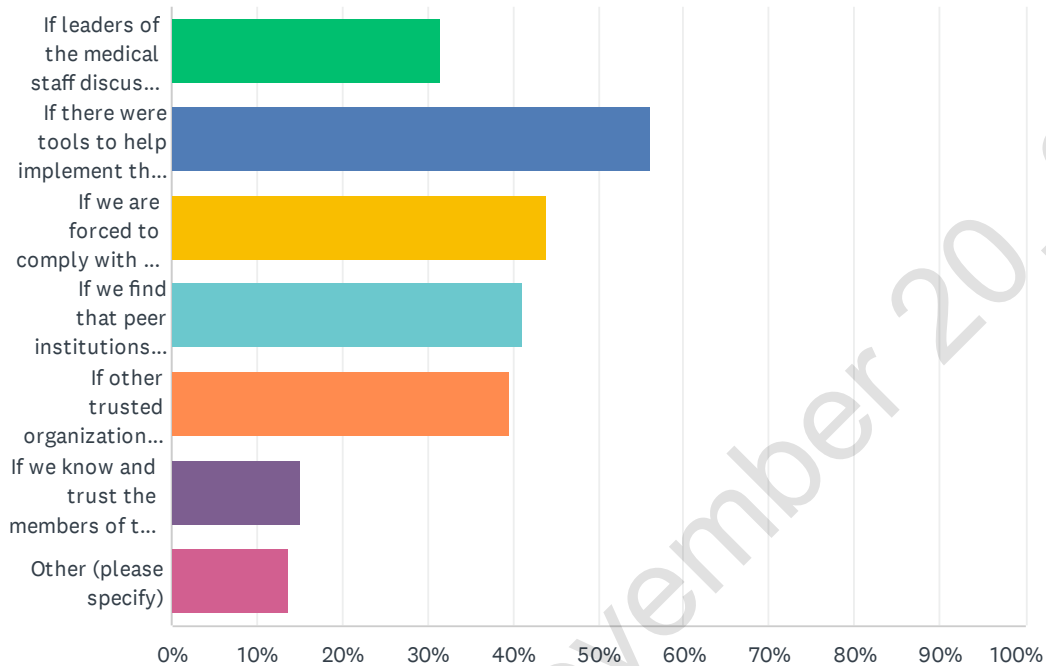
| # | OTHER (PLEASE SPECIFY) | DATE |
|---|------------------------|------|
|---|------------------------|------|

Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

|    |   |                     |
|----|---|---------------------|
| 1  | I think it just need yo be clear  | 11/13/2024 7:57 PM  |
| 2  | lack of clarity about how to implement  | 11/13/2024 4:12 PM  |
| 3  | Lack of data to support applying such broad recommendations across all AP   | 11/13/2024 1:47 PM  |
| 4  | Not sure. There is no particular 'thing' to do that can evaluated for the above.  | 11/10/2024 7:14 PM  |
| 5  | None. There is nothing to change, adopt or implemnet. No \$\$ commitment required.  | 10/31/2024 5:00 PM  |
| 6  | I think that items such as tumor board review, re-review of cases by other faculty for send-out testing, etc, should count as final review. Many of these cases do have second review by another faculty at our institution, but an easy and quick way to document and prove that these are reviewed are not necessarily in place. I think blanket review of XX% of cases is not the best way to do this, as the cases that need the most review are those that are in gray areas of pathology rather than simply wasting time on things that have low stakes or low probability of significant disagreement. | 10/25/2024 8:52 AM  |
| 7  | Concerned that guideline will be recognized in the community as a standard of care putting pathologists at risk of lawsuit unless this is implemented in their facility.  | 10/24/2024 6:38 PM  |
| 8  | Because of potential for adoption by CoA, this Guideline could become an unfunded (and unfundable) mandate, constituting financial burden on the pathologist community. Need stronger evidence that there is positive effect on patient outcomes.   | 10/24/2024 6:04 PM  |
| 9  | each institute or practice should be given flexibility in drafting it and implimenting it   | 10/24/2024 11:29 AM |
| 10 | Access to AI to facilitate reviews is limited in rural areas. It will be an added burden for rural laboratories since it is usually manned by 1 or 2 pathologist without PA or resident/fellow help. This will be on top of the burdensome CAP protocol that was adopted several years ago. These are all good initiatives to adopt, but resources in rural hospitals are very limited.   | 10/24/2024 9:37 AM  |
| 11 | No barriers   | 10/24/2024 8:40 AM  |
| 12 | Intraprofessional bureaucratic overreach  | 10/24/2024 6:12 AM  |
| 13 | Experience, habit, and personal perspectives are too often valued over standardization.   | 10/24/2024 5:17 AM  |
| 14 | It's too vague to be really useful  | 10/23/2024 3:41 PM  |
| 15 | Some of our clinicians regard the necessity of in-house review and documentation of the fact, that a case was reviewed in house as a weakness or a deficit of the pathologist signing a specific report   | 10/23/2024 2:44 PM  |

## Q11 What facilitators might assist in your adoption of the final guideline? (Please select your top 3 facilitators.)

Answered: 73 Skipped: 58



| ANSWER CHOICES   | RESPONSES |
|--|-----------|
| If leaders of the medical staff discussed adoption/adaption of the guideline for our practice setting  | 31.51% 23 |
| If there were tools to help implement the guideline  | 56.16% 41 |
| If we are forced to comply with the guideline by administration or an accreditation body               | 43.84% 32 |
| If we find that peer institutions/practices adopt the guideline  | 41.10% 30 |
| If other trusted organizations endorse the guideline   | 39.73% 29 |
| If we know and trust the members of the panel members and/or organizations who developed the guideline | 15.07% 11 |
| Other (please specify)   | 13.70% 10 |
| Total Respondents: 73  |           |

| # | OTHER (PLEASE SPECIFY)   | DATE                |
|---|--|---------------------|
| 1 | Money and increased staffing   | 11/13/2024 8:43 PM  |
| 2 | I would not adopt  | 11/13/2024 1:47 PM  |
| 3 | Nothing. Nonspecific.  | 11/10/2024 7:14 PM  |
| 4 | I see no barrier to adopting or supporting this 'philosophical' guidelines (just like the previous iteration). There is nothing that is being asked of anyone. I am 100% sure that every lab is doing something to reduce error. | 10/31/2024 5:00 PM  |
| 5 | If the guideline text does not make the Pathologist the addressee If the guideline clearly   | 10/24/2024 12:14 PM |

Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

delineates the prerequisites (e.g. resources) in further statements which are mandatory before thinking about the other statements. Such an isolated view putting only the Pathologist in the spotlight is counterproductive, dangerous and draining critical resources from Pathologies. If it poses it as an obligation to the healthcare system including mandatory resources. If the (adapted) statements are accompanied by text that outline the obstacles that prevent implementation, including those that are a fact that is not influenced by Pathologists - how can you ask this from a poorer country fighting to get resources for simple HE and having dramatic lack of Pathologists, leaving to countries that pay them better? We in Europe - having many countries that struggle with extreme personnel shortage and lack of resource - would certainly not adopt and counteract these statements

|    |   |                     |
|----|---|---------------------|
| 6  | If the implementation chosen for our site has good feasibility.   | 10/24/2024 10:37 AM |
| 7  | When one realizes that it protects the patient by improving diagnostic accuracy.  | 10/24/2024 8:40 AM  |
| 8  | Nothing since this and all CAP guidelines have been and continue to be nothing more than intraprofessional bureaucratic overreach | 10/24/2024 6:12 AM  |
| 9  | If it were locally part of an ongoing professional peer evaluation.   | 10/23/2024 4:34 PM  |
| 10 | If following the guideline is coupled to reimbursement.   | 10/23/2024 2:42 PM  |

## Q12 Please provide any general comments or concerns:

Answered: 15 Skipped: 116

| #  | RESPONSES   | DATE                |
|----|---|---------------------|
| 1  | First four are fine   | 11/13/2024 7:39 PM  |
| 2  | Clearly this is an attempt to set the stage for AI review; if this ever comes about, it should be in the form of decision support, not retrospective review and only after the literature provide evidence that there is a benefit to patient care (ie RVT level)   | 11/13/2024 1:47 PM  |
| 3  | The problem with any guideline is that it immediately becomes the standard of care, and failing to follow, for whatever reason, may lead to an unforeseen legal exposure. These need to be implemented judiciously. Good that you're asking for input and I hope CAP fellows understand the importance of such.   | 11/13/2024 1:20 PM  |
| 4  | Mission creep has taken over the CAP committees over the years. CAP should get out of the guideline business or at least not base accreditation on bureaucratic diktat. Bloated bureaucracies only get in the way of professionals that prefer to adopt best practices in the manner they see fit.  | 11/13/2024 1:12 PM  |
| 5  | Most of us didn't even know that the previous recommendations existed and we seem to have done fine. IDK why we need these.   | 11/10/2024 7:14 PM  |
| 6  | Not really sure of the real value of this. But guess we gotta start somewhere.  | 10/31/2024 5:00 PM  |
| 7  | These guidelines lack any steps for how the diagnostic modification should be communicated to the ordering physician or the patient. Building metrics for that step and tracking them would be essential to the implementation of this guideline.   | 10/26/2024 5:15 PM  |
| 8  | Please do not even think about publishing this before reflecting the context (see comments)   | 10/24/2024 12:14 PM |
| 9  | I strongly think that guidelines should stay what they are i.e. "guidelines". They cannot be mandated. Every Insitute should be allowed to have the flexibility to draft their policy using the guidelines.   | 10/24/2024 11:29 AM |
| 10 | Adding review steps has a cost. Do you have any statements about how reimbursements to pathology, lab director contracts, or turnaround time expectations should be changed to accommodate the important addition of reviews? I would maintain an emphasis on clinical relevance. Going to great lengths to discover it is secretory endometrium when someone called it proliferative is a waste of time, unless you are reading for an REI clinic, I suppose. I feel that reviews done for patient care should primarily be focused on the timeframe BEFORE the case is signed out. I do not like a world where we sign the cases out and THEN go hunting in them for errors. That is going to turn our life into a constant cycle of worry. It also sends the wrong message to patients and clinicians by implying that the signed-out reports are not reliable until some other euphemistically named and opaque process has occurred. The guidelines should recognize this issue and recommend that the majority of case reviews should occur before report verification. | 10/24/2024 10:37 AM |
| 11 | All pathology reports with slides should be reviewed by a second pathologist before being released to the patient's chart.  | 10/24/2024 8:40 AM  |
| 12 | CAP guidelines are unprofessional and fascist   | 10/24/2024 6:12 AM  |
| 13 | There is strong resistance to adopting a standardized approach to diagnosis. Synoptic reports provide clear and, somehow, unique responses, while descriptive diagnosis is open to interpretation (and, to some degree, to a defensive position). Descriptive diagnoses may lead to an incorrect TNM stage or a misunderstanding of the nature of the lesion described. Pathologists should adopt an objective and reproducible style, with the possibility of eventually adding any valuable and personal comments where needed.   | 10/24/2024 5:17 AM  |
| 14 | Physicians have become unwilling transcriptionists forced to use sketchy voice recognition transcription software to generate reports. Clinically significant errors naturally end up in reports. Has anyone looked at this problem?  | 10/23/2024 5:28 PM  |



Interpretive Diagnostic Error Reduction (IDER) Guideline Update: Open Comment Period (OCP)  
Survey—Draft Recommendations and Good Practice Statements

|    |   |                    |
|----|---|--------------------|
| 15 | It would be nice to see the guideline for public comment. | 10/23/2024 2:42 PM |
|----|---|--------------------|

Not Valid After November 20, 2024

**Disclaimer**

The information, data, and draft recommendations provided by the College of American Pathologists are presented for informational and public feedback purposes only.

The draft recommendations and supporting documents will be removed on November 27, 2024.

The draft recommendations along with the public comments received and completed evidence review will be reassessed by the expert panel in order to formulate the final recommendations.

These draft materials should not be stored, adapted, or redistributed in any manner.

Please note: comments are not posted automatically. All comments will be posted on a weekly basis beginning October 30, 2024.