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Quality Assurance/Quality Control – Cervical Cytology and Histopathology

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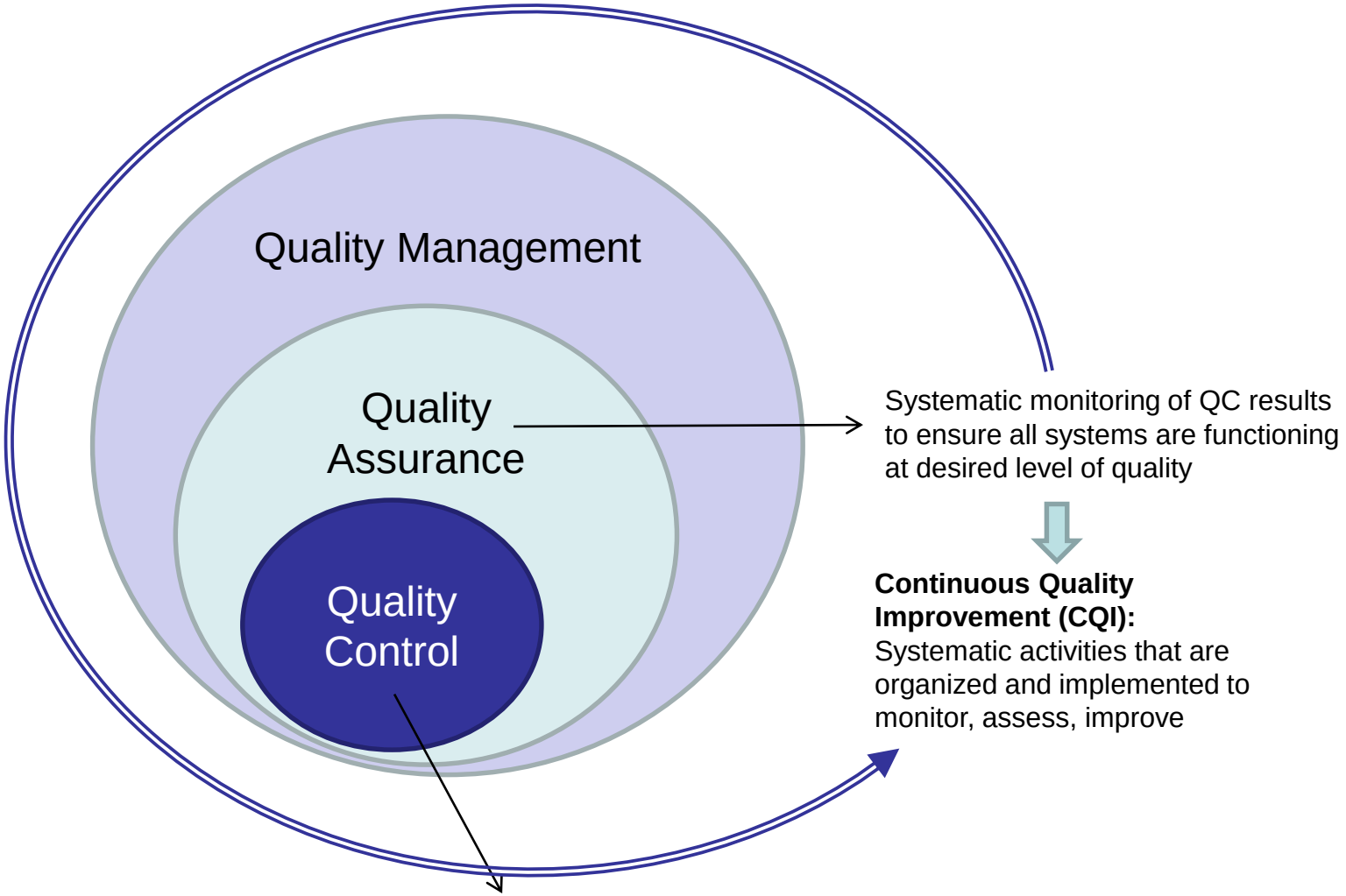

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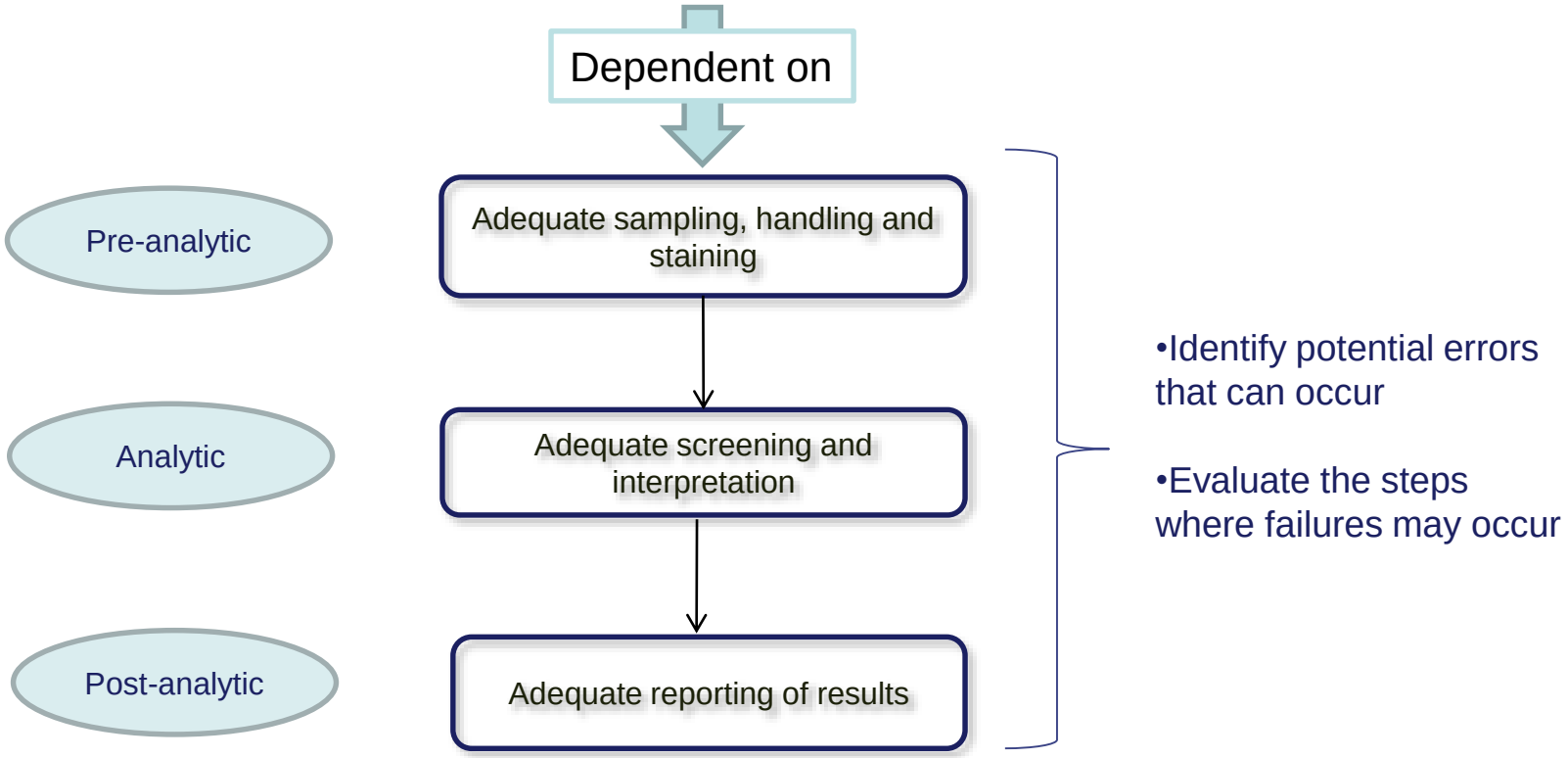
Quality Control in Cervical Cytology

Objective: to improve the performance of the Pap test to minimize False Positive + False Negative results



Pre-analytic QC

- Smear taking
  - Adequate training for all smear takers, including access to written, illustrated guidelines

Monitor:

❑ **Collect data on rates of adequacy and transformation zone sampling**

- Feedback improves the performance of Pap smear providers

- Receipt of sample in lab
  - Written criteria for rejection of specimens
    - i.e. unlabeled slides, broken slides, mislabeled specimen (slide)

Monitor:

❑ **Log of rejected specimens (include submitting clinician, reason for rejection)**

– Monitor for increases in incidence

Pre-analytic QC cont'd

- Data entry
  - Cross-check multiple patient identifiers to ensure slide and requisition match
  - Regular monitoring of possible data entry errors
    - i.e. unlikely date of birth, sample date is later than received date

  Monitor:

  - ❑ **Log of discrepancies in data entry**
  - ❑ **Number of cases requiring troubleshooting** (i.e. clarification, verification, confirmation of patient demographics or clinical history)

- Specimen staining
  - Daily monitoring of stain quality

  Monitor:

  - ❑ **Log of QC stain procedures (include date, # of times stain is filtered/changed, record of stain evaluation, any problems)**

Analytic QC

- Workload records of individual cytotechnologists

  Monitor:

  - ❑ **Productivity Report = data on individual screening and re-screening workload**
    - Use QC re-screens and other correlation data to determine workload limit

- Specimen acceptance and adequacy

  Monitor:

  - ❑ **Volume of unsatisfactory specimens**
  - ❑ **Submitting clinicians/clinics (track for need of education if in excess)**
  - ❑ **Individual rates of unsatisfactory specimens**

Analytic QC cont'd

- Screening and interpretation
  - Practices such as second screenings in women with atypical histories, ASC-US+ smears, or AGC+
  - Standard method of reporting used

Monitor:

- ❑ **Report percentages of main categories of cytologic findings (i.e. unsatisfactory, ASC-US, LSIL, ASC-H, HSIL, AGC+) for individual screeners and cytopathologists**
  - Compare with lab as a whole, also against national standard (if exists)

- ❑ **Performance evaluations**
  - Identify those under-performing or patterns of poor performance

Analytic QC cont'd

- Review of abnormal cases
  - 2nd opinion or peer review
    - i.e. significant discrepancy between screener and pathologist, difficult diagnostic cases

Monitor:

- ❑ **Documentation of peer review**
- ❑ **ASC:SIL ratio**
  - monitor to identify any potential problems with diagnostic criteria for ASC

Analytic QC cont'd

- Re-screening of negative cases

Random 10% re-screening

- full re-screen of entire slide
- cannot identify all FN smears
- statistically unlikely to detect a poor performance (low rate of abnormal smears)
- has however been proven to be effective for improving performance
- suitable for higher volume labs

Rapid re-screen

- 100% of slides get a low power stepwise review/scan (~30-60secs)
- potential to detect more false negative smears in same amount of time
- dependent on skill and experience of the reviewer
- good for lower volume labs

Monitor:

- ❑ **Plot findings of screener vs.final call**
- ❑ **Regular evaluations**

Analytic QC cont'd

Rapid pre-screen

- partial inspection of a slide (max 120 secs) before full routine screen
- all slides, not just NILM
- rapidly identifies most abnormal cases
- sensitivity gain comparable to rapid re-screen

Targeted re-screen

- smears from patients with a higher risk of having cytological atypia
- previous abnormal smears, abnormal appearance of cervix, abnormal bleeding, recurrent infections, etc
- no data on comparison with other methods, but could help to reduce screening errors
- can also be used to monitor screeners with screening issues (ie increase QC quota)

Monitor:

- ❑ **Plot findings of screener vs.final call**
- ❑ **Regular evaluations**

Sample re-screen tracking form

Screener vs Final Call Comparison Form

CAGC_q11_003F

Screener _____ Type _____ Reviewer _____

SCREENER READING

FINAL READING		UNS	NILM	Squamous: ASCUS	Squamous: LSIL	Squamous: ASC-H	Squamous: HSIL (mod)	Squamous: HSIL (cx)	Squamous: Sq ca	Gland: AGC, cyto	Gland: AGC, hstp	Gland: AIS	Gland: Adeno ca
UNSAT.													
NILM													
Squamous	ASCUS												
	LSIL												
	ASC-H												
	HSIL (mod)												
	HSIL (cx)												
	Sq ca												
Gland	AGC, cyto												
	AGC, hstp												
	AIS												
	Adeno ca												

Screener vs Final	Agree	Disagree	Missed	
No Endo/ Metaplastic Cells				Incorrect recommendations
Interpretation difficult				Inattention to details
Abnormal Bleeding				
Herpes Simplex				
Monilia				
Trichomonads				
Anucleated squames				
Endometrials ≥ 40				

Comments:

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Sample screening evaluation form

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QUARTERLY QUALITY CONTROL EVALUATION FORM

CAGC_004_2452F

Cytotechnologist ID # _____ Signature: _____ Date: _____

Quarter _____	# of Hold-outs _____	# of QC's _____

	Meets Expectation	Needs Improvement
Screening		
Smear quality		
Number of incorrect recommendations_____ (expectation of 10 or less per 3 months)		
Number of inattention to details_____ (expectation of 10 or less per 3 months)		

Comments on performance:

Suggestions for improvement:

Evaluated by Monitor/Senior: _____ **Date:** _____

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Post-analytic QC

- Report generation
  - Follow a consistent language in reporting
  - Accurate reporting keeping

Monitor:

- ❑ **Daily audit of reports (if automatic, or electronic distribution)**

- Response time (Turnaround time [TAT])
  - Establish a mutually agreed upon turnaround time from the date the smear is received in the laboratory to the date of the finalized report

Monitor:

- ❑ **Weekly tracking of specimen sign-out dates compared to date of receipt**

Post-analytic QC cont'd

- Cytology-histology correlation
  - If Pap NILM or LSIL, and biopsy is high grade → review cytology
  - If Pap HSIL, and biopsy is normal → review cytology

NOTE

- Inherent errors:
  - Colposcopic technique
  - Colposcopic sampling
  - Biopsy interpretation

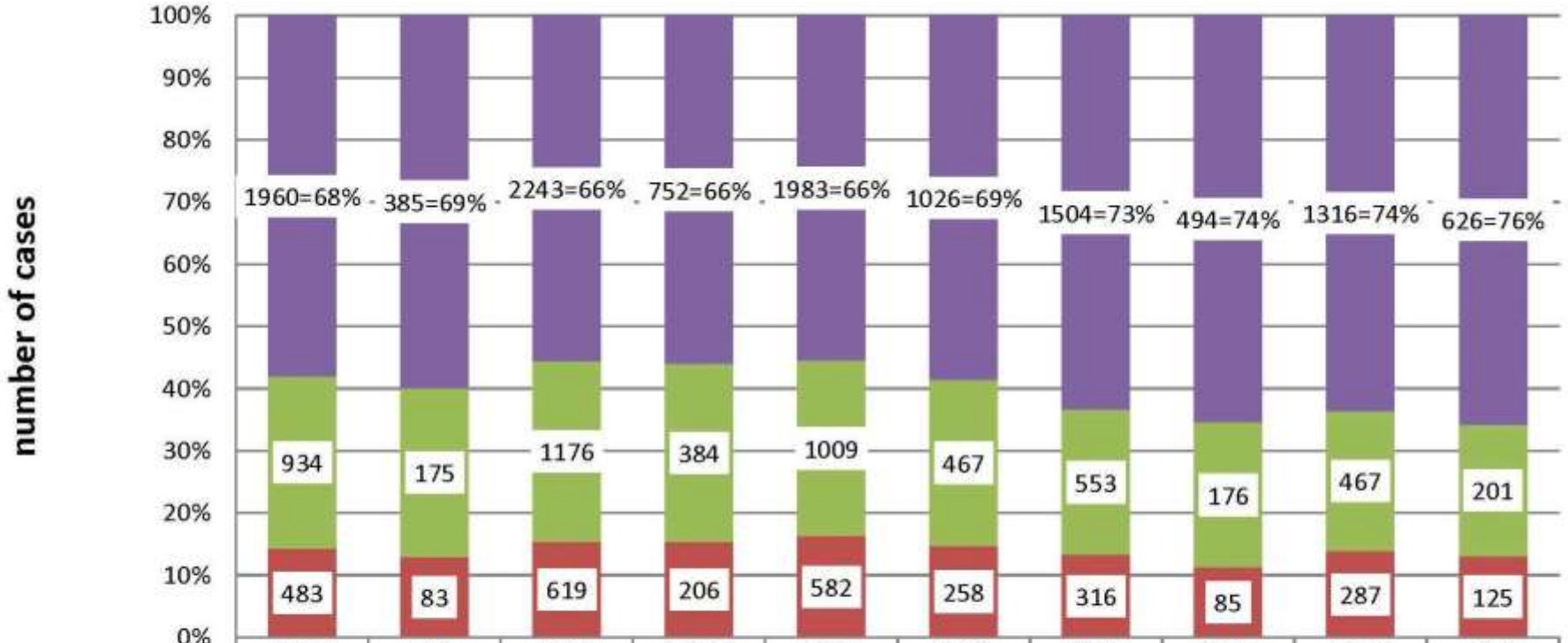
Pap test may at times better represent cervical pathology than the biopsy

Monitor:

❑ **Positive Predictive Value (PPV) reports** = % of positive Pap tests that have a histological confirmation of significant cervical dysplasia

- monitor rates of lab and individual pathologists

AGC neoplastic+ and HSIL+ Positive Predictive Value 2011-2015



	3377 2011 lab	643 2011 X	4038 2012 lab	1342 2012 X	3574 2013 lab	1751 2013 X	2373 2014 lab	755 2014 X	2070 2015 lab	952 2015 X
CIN 2 or higher	1960	385	2243	752	1983	1026	1504	494	1316	626
CIN 1 or lower	934	175	1176	384	1009	467	553	176	467	201
no pathology	483	83	619	206	582	258	316	85	287	125

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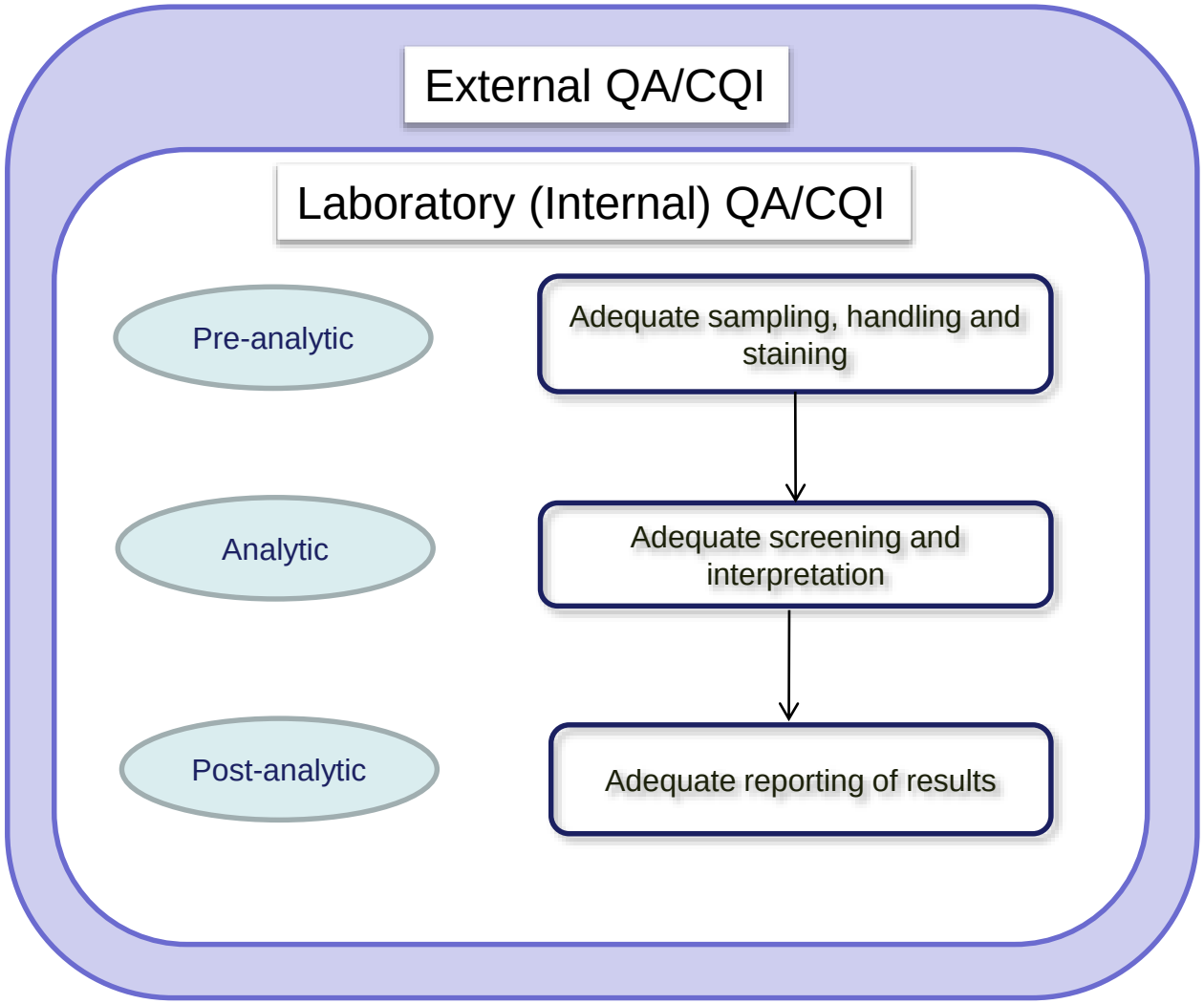
Post-analytic QA

- Targeted retrospective review = NILM Pap smears within last 5 years are retrieved for re-screening when current Pap is HSIL+
  - Biases due to knowledge of current result should be kept in mind

Monitor:

- ❑ **Internal documentation of result of re-screen**
- ❑ **Discrepancy report** = statistical data on minor and major discrepancies in retrospective reviews and re-screened cases


External QA/CQI
Laboratory (Internal) QA/CQI
Pre-analytic
Adequate sampling, handling and staining
Analytic
Adequate screening and interpretation
Post-analytic
Adequate reporting of results

External QA

- Accreditation by a certified regulatory body to determine if pre-determined standards are met

  - BCCA Cervical Cancer Screening Lab is accredited by:
    - The College of Physicians and Surgeons of British Columbia Diagnostic Accreditation Program (DAP)

    - The College of American Pathologists (CAP)
      - an internationally recognized leader in laboratory quality assurance and accreditation programs
      - Incorporates ISO:15189

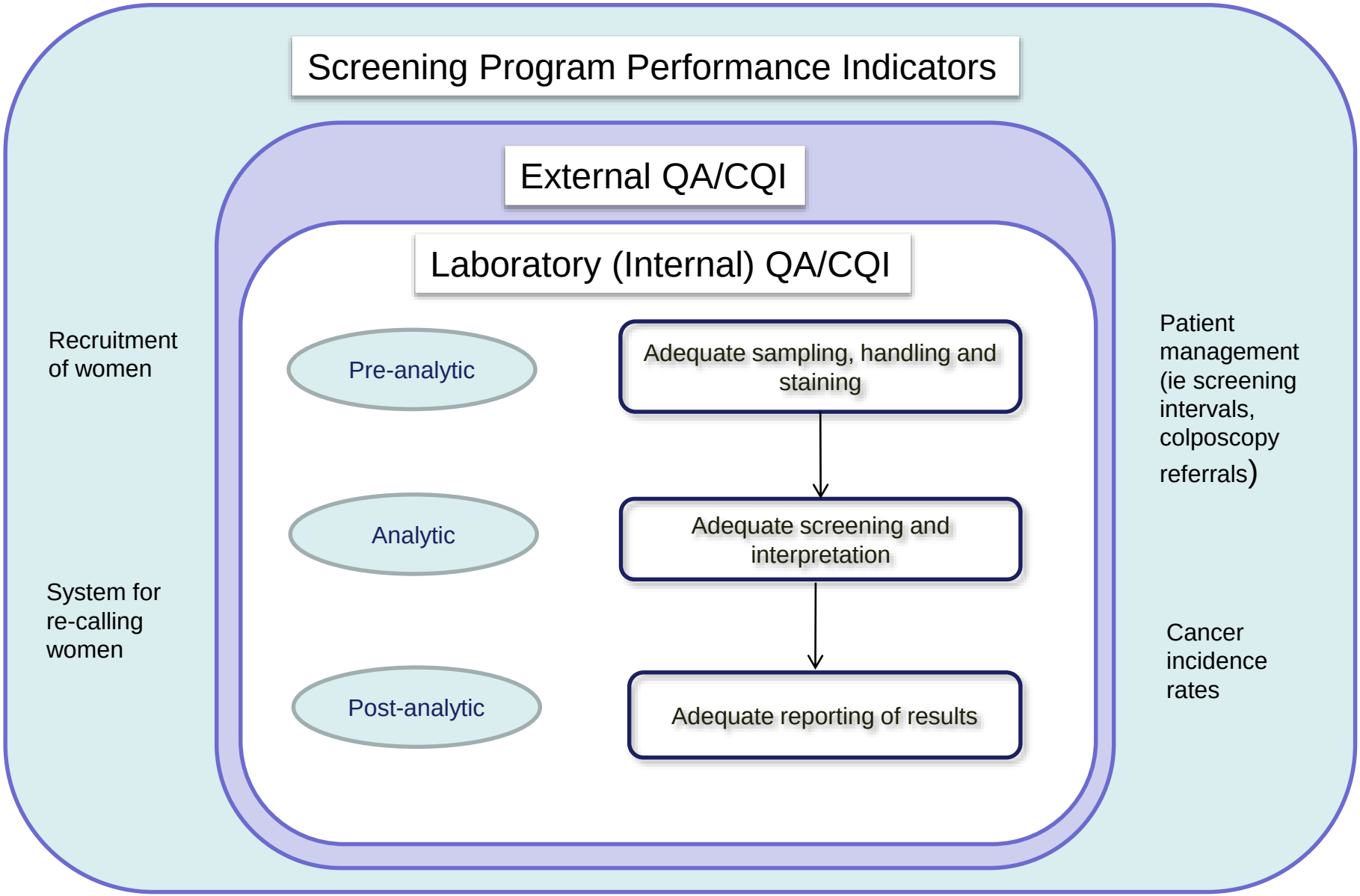
External QA cont'd

- Proficiency Testing
  - Circulation of Pap smears (good examples) from an outside facility; results submitted and inter-laboratory comparisons made
  - BCCA CCSL currently subscribes with:
    - College of American Pathologists (CAP) – 2x/year
    - American Society for Clinical Pathology (ASCP) – 2x/year

Maintenance of Competence

- On-going education is a requirement for proficiency in cytology

- Fulfilled by:
  - Cyto-morphological group discussions
  - Internal education forums
  - Attending webinars, teleconferences
  - Access to journals
  - Online education activities
  - Proficiency testing participation
  - Attending workshops and symposia



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Screening Program Performance Indicators - Canada

Coverage
1) Participation rate
2) Retention rate

Cytology Performance Indicator
3) Specimen adequacy
4) Screening test results

System Capacity Indicators
5) Cytology TAT
6) Time to colposcopy

Follow-up
7) Histological investigation
8) Cyto-Histo agreement

Outcome Indicators
9) Pre-cancer incidence rate
10) Cancer incidence rate
11) Cancers diagnosed at Stage 1
12) Screening history in cases of invasive cancer

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See Appendix for definitions & targets

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QA Topics in Histopathology

- Establish a nomenclature that is uniformly accepted

- Constant/consistent use of terminology
  - enable data to be extracted and analyzed

- Correlate histology findings with cytology
  - Patient history is viewable
  - Cytology slides are present when signing out biopsies

QA Topics in Histopathology QA cont'd

- If pathology has diagnosis of normal/benign, and cytology was HSIL/AGC+ → review cytology

- If requested, document a review in cases of ASC-H when no high grade lesion is found on biopsy

Appendix: Cervical Cancer Screening Indicators - Canada

Indicator	Definition	Target
1) Participation rate	% of eligible women in the target population who had at least one Pap test in a 3-year period.	≥ 80 percent for women aged 21 to 69 should be screened within the recommended screening interval plus six months (i.e. 3 years plus 6 months)
2) Retention rate	% of eligible women who were re-screened within 3 years after a negative Pap test. Retention reflects the ability to screen women repeatedly over time as well as the acceptability of the test	
3) Specimen adequacy	% of test results reported as unsatisfactory in a 12 month period	0.5 to ≤ 2.0% of tests should be reported as unsatisfactory
4) Screening test results	Categorize women by their most severe cytology result in a 12-month period	
5) Cytology turnaround time	Median number of days from the date of specimen collection to the date the laboratory issues the Pap test report	90 percent of Pap tests should be reported within 14 calendar days (or 10 working days)

Appendix:
Screening Indicators (Canada) cont'd

Indicator	Definition	Target
6) Time to colposcopy	% of women with a high-grade abnormal Pap test result (AGC, ASC-H or HSIL+) who had a colposcopy within three, six, nine and 12 months	90 percent of women with a high-grade Pap test result should have a colposcopy examination within six weeks from the Pap test report date or four weeks from the colposcopy referral date
7) Histological investigation	% of women with a high-grade abnormal Pap test result (ASC-H or HSIL+) who had a colposcopy, histological investigation, or both	
8) Cytology histology agreement	% of high-grade abnormal Pap test results (ASC-H or HSIL+) that had histological confirmation of CIN 2+	Target: ≥ 65 percent of high-grade Pap tests (HSIL+ cytology result) should have a pre-cancerous or an invasive cancer histological outcome
9) Pre-cancer incidence rate	The number of pre-cancerous lesions detected per 1,000 women screened in a 12-month period	

Appendix:
Screening Indicators (Canada) cont'd

Indicator	Definition	Target
10) Cancer incidence rate	The number of new cases of invasive cervical cancer per 100,000 women	
11) Cancers diagnosed at Stage 1	% of invasive cervical cancer cases detected at Stage 1 according to the International Federation of Gynaecology and Obstetrics (FIGO) classification system.	
12) Screening history in cases of invasive cancer	Screening history in cases of invasive cancer is a retrospective summary of screening prior to diagnosis and is measured as the percentage of women diagnosed with invasive cervical cancer since their last Pap test	

Reference: http://www.cancerview.ca/idc/groups/public/documents/webcontent/cervical_cancer_report.pdf

References

American Society of Cytopathology Quality Control and Quality Assurance Practices
http://www.cytopathology.org/quality-control-and-quality-assurance-practices/

Cervical Cancer Screening in Canda – Program Performance Results Report
http://www.cancerview.ca/idc/groups/public/documents/webcontent/cervical_cancer_report.pdf

Branca M, Longatta-Filho A. Recommendations on Quality Control and Quality Assurance in Cervical Cytology. Acta Cyto. 2015;58;361-369. DOI: 10.1159/000441515

European guidelines for quality assurance in cervical cancer screening
http://screening.iarc.fr/doc/ND7007117ENC_002.pdf