Colposcopy Standards: *The What and Why?*

Warner K. Huh, MD
Colposcopy in the US

• Thousands of procedures performed every year
• Performed by Ob/Gyn, Family Practice, Internists, NPs, PAs
• Training is obtained from residency, courses (like ASCCP courses), mentorship type training, and self-education

• Unclear exactly how many are being done/year? Trends?
• Unclear exactly who is doing them
• Unclear how often clinicians are doing colposcopy
• Training is uneven and inconsistent and difficult to measure
Why Now?

• Previous teaching and education was largely based on expert opinion and experience

• Accumulation of peer-reviewed data that are central to the practice and performance of colposcopy
  • More biopsies, increased detection of disease (Gage et al, Pretorius et al)
  • Disease detection with random biopsies (Huh et al, Pretorius et al, Song et al)
  • Evaluation of colposcopic scoring and grading systems (Massad et al, Hong et al, Bowring et al)
  • Adjuncts to colposcopy (Alvarez et al, Twiggs et al, Tidy et al, Richards-Kortum et al)
  • Training and Quality (Murphy et al, Sideri M et al, Leeson et al)
General Issues to Consider

• Colposcopy volume has decreased since our last treatment guidelines (Landers et al)

• Anticipate smaller, less clinically obvious lesions with increasing HPV vaccination

• Teaching and Training
Working Groups

Working Group 1: Role of colposcopy, Benefits and Harms and Terminology (Khan/Schiffman)

Working Group 2: Risk-Based Colposcopy and Biopsy (Wentzensen/Massad)

Working Group 3: Colposcopy procedures and Adjuncts (Waxman/Tedeschi)

Working Group 4: Quality Control (Einstein/Mayeaux)
Tiered approach to releasing the results

• Working Groups 1-4
  • Review/Committee Opinion
    • Description of charges
    • Literature Review
    • Findings
    • Recommendations

• White paper/Consensus document: colposcopy standards overview and summary of recommendations

• Session at the ASCCP Annual/IFCPC World Congress 2017
Timeline

• Literature review, description of key findings and draft recommendations currently ongoing

• Late 2016/Early 2017: Preparation and submission of individual working group manuscripts

• April 2017: Draft White paper/Consensus Statement for ASCCP Annual Meeting/IFCPC World Congress
Colposcopy Standards Project

Developing evidence-based colposcopy standards

Nicolas Wentzensen
# Current options for cervical cancer screening

<table>
<thead>
<tr>
<th></th>
<th>Cytology</th>
<th>HPV</th>
<th>Cotesting (Cytology and HPV)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity for precancer</strong></td>
<td>Lowest</td>
<td>Higher</td>
<td>Highest</td>
</tr>
<tr>
<td><strong>Repeat interval for negative screen</strong></td>
<td>Shortest (lowest NPV)</td>
<td>Longer (greater NPV)</td>
<td>Longest (greatest NPV)</td>
</tr>
<tr>
<td><strong>Triage test required</strong></td>
<td>For equivocal cytology results</td>
<td>For all positive results</td>
<td>For HPV-positive, cytology-negative results</td>
</tr>
<tr>
<td><strong>Diagnostic test</strong></td>
<td></td>
<td></td>
<td>Colposcopic biopsy</td>
</tr>
</tbody>
</table>

*Source: ASCCP 2016*
Some important topics that will be covered

• Colposcopy terminology
• Colposcopic biopsies: When, where, how many?
• Role of endocervical sampling
• Impact of HPV screening on colposcopy
• The role of colposcopy adjuncts
• Quality assurance measures, quality control indicators
Important controversies

• Number of biopsies: A single targeted biopsy vs. routine 4-quadrant biopsies?

• What is a truly normal colposcopy impression? Are minor acetowhite changes considered normal?

• What are random biopsies?
Evidence-based approach

• Literature search terms have been provided centrally for all working groups
• Each working group is organizing review and data abstraction for their charges

• Some areas have very limited data, we will need to rely on expert opinion
• For some charges, systematic reviews and meta-analyses are being conducted (e.g. risk-based colposcopy-biopsy)
Data sources

• Examples for primary studies on colposcopy
  • NCI-Oklahoma Biopsy Study
  • Prospective studies from the UK

• Studies with secondary evaluation of colposcopy
  • ASCUS-LSIL triage study
  • Vaccine trials
  • ATHENA trial
  • Costa-Rica Natural History Study
  • Many others
Detection of HSIL with increasing number of biopsies (Biopsy Study)

Wentzensen et al. JCO 2015
High negative predictive value of a normal colposcopy in women with low grade cytology (UK)

Table 2. Rate of disease at 1, 2, 3 and >3 years after negative colposcopy in 956 women with long-term follow up

<table>
<thead>
<tr>
<th>Time since negative colposcopy (years)</th>
<th>Negative n (%)</th>
<th>Abnormal cytology n (%)</th>
<th>CIN1 n (%)</th>
<th>CIN2 n (%)</th>
<th>CIN3 n (%)</th>
<th>Total no. of women n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>912 (95.4)</td>
<td>10 (1.0)</td>
<td>18 (1.9)</td>
<td>6 (0.6)</td>
<td>10 (1.0)</td>
<td>956 (100.0)</td>
</tr>
<tr>
<td>2</td>
<td>869 (90.9)</td>
<td>19 (2.0)</td>
<td>33 (3.5)</td>
<td>16 (1.7)</td>
<td>19 (2.0)</td>
<td>956 (100.0)</td>
</tr>
<tr>
<td>3</td>
<td>851 (89.0)</td>
<td>25 (2.6)</td>
<td>38 (4.0)</td>
<td>19 (2.0)</td>
<td>23 (2.4)</td>
<td>956 (100.0)</td>
</tr>
<tr>
<td>&gt;3</td>
<td>826 (86.4)</td>
<td>30 (3.1)</td>
<td>49 (5.1)</td>
<td>23 (2.4)</td>
<td>28 (2.9)</td>
<td>956 (100.0)</td>
</tr>
</tbody>
</table>
High sensitivity of acetowhite testing for detection of CIN3 (ALTS)

<table>
<thead>
<tr>
<th></th>
<th>Two-year follow up histology</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;CIN2/HPV-</td>
</tr>
<tr>
<td>Acetowhite lesion at baseline</td>
<td>298 (67%)</td>
</tr>
</tbody>
</table>

Massad et al. JLGTD 2009
Risk-based approach to colposcopy (ALTS)

Two-Year Risk of CIN2+

High-grade + HSIL | High-grade + HPV16+
---|---
High-grade | High-grade + HPV16+
High-grade + <HSIL | Low-grade + HPV16+
Low-grade + <HSIL | Low-grade + HPVL16+
Low-grade + <HSIL/HSIL | Low-grade + HPV16-
Normal + <HSIL/HSIL | Normal + HPV16-

Colposcopy | Colposcopy + Cytology | Colposcopy + HPV typing | Colposcopy + Cytology + HPV typing

ASCCP 2016
Focus on implementation

- Need to balance precision and complexity
- Approaches need to be robust and reproducible
- As much as possible, try to harmonize with other programs

Dynamic process:
- Some recommendations may need to be updated when screening practice, vaccination coverage change
- Additional topics will be addressed in the future
Interaction with other societies

• National and international
• We do not want to reinvent the wheel
• But there is no ‘one-size-fits-all’ international standard for colposcopy

• US situation
  • No organized screening
  • No national integrated health system
  • Wide range of providers performing colposcopy
  • Wide range of number of annual colposcopies performed
  • No colposcopy certification
Colposcopy standards working groups

- Role of colposcopy, Benefits and Harms, Terminology
- Quality Control
- Risk-based colposcopy and biopsy
- Colposcopy procedures and adjuncts
Colposcopy Standards Project

Working Group 1: Role of colposcopy, benefits and potential harms, terminology
Saturday, April 16, 2016

Co-Chairs: Michelle Khan, Mark Schiffman
Members: Teresa Darragh, Dick Guido, Cara Matthews, Martha Mitchell, Anna-Barbara Moscicki, Claudia Werner
Charge #1: to define colposcopy and its role in evaluation of cervical disease

• Use of a specific instrument, a colposcope, for the real time visualization and assessment of the uterine cervix, specifically the transformation zone, for the detection of cervical precancer and invasive cancer.

• Magnification, usually in the form of a lens or digital imaging system, and illumination are fundamental to colposcopy.

• The application of acetic acid (3% to 5%) and Lugol’s iodine is used to identify potential lesions.
• Subjective grading systems help assess observed areas of abnormality; these rely upon lesion characteristics including the qualities of lesion borders and surface contours, vascular patterns, and response to acetic acid (acetowhitening) or iodine (degree of uptake).

• In most cases, colposcopically-directed biopsies of one or more areas are taken in order to confirm a lack of precancer/cancer, or to establish a histopathologic diagnosis of the most severe disease present.
Charges #2 - 4

• To define the benefits of colposcopy.
  • Colposcopy can be used to help identify as well as to exclude cervical precancer and cancer. It permits visual and histologic confirmation of disease especially as the field moves toward biomarker screening.

• To define the potential harms of colposcopy.
  • Colposcopy harms include pain, cost, psychological impact, and possible impact of subsequent cervical procedures on obstetrical outcomes.

• To define ASCCP colposcopic terminology.
  • To determine minimally acceptable criteria and optimal terminology.
  • Will evaluate the role and possible adoption or adaptation of the 2011 IFCPC terminology.
2011 IFCPC Colposcopic Terminology

• Established by the Nomenclature Committee of the IFCPC
• Previous terminologies: 1975, 1990, 2002
• The committee critically analyzed each colposcopic sign, aiming to create an evidence-based terminology
• 5 sections:
  • General assessment
  • Normal colposcopic findings
  • Abnormal colposcopic findings
  • Suspicious for invasion
  • Miscellaneous findings

General assessment

- Adequate or inadequate (and give the reason)
  - **Satisfactory/Unsatisfactory NO LONGER USED**
  - Cervix obscured by, e.g., inflammation, bleeding, scar
- Squamocolumnar junction visibility
  - Completely visible
  - Partially visible
  - Not visible
- Transformation zone types 1, 2, 3

Normal and Abnormal Colposcopic Findings

- **Original squamous epithelium:** mature, atrophic
- **Columnar epithelium**
- **Ectopy/ectropion**
- **Metaplastic squamous epithelium**
- **Nabothian cysts**
- **Crypt (gland) openings**
- **Deciduosis in pregnancy**

- **Location of the lesion:** Inside or outside the TZ; clock position
- **Size of the lesion:** number of cervical quadrants the lesion involves
- **Size of the lesion as percentage of cervix**
- **Grade 1 (minor):** fine mosaic, fine punctation, thin AWE, irregular/geographic border
- **Grade 2 (major):** sharp border, inner border sign, ridge sign, dense AWE, coarse mosaic, coarse punctation, rapid appearance of AWE, cuffed crypt (gland) openings
- **Nonspecific:** leukoplakia (keratosis, hyperkeratosis), erosion
- **Lugol’s staining (Schiller’s test):** stained or nonstained
Suspicious for invasion

- Atypical vessels

- Additional signs: fragile vessels, irregular surface, exophytic lesion, necrosis, ulceration (necrotic), tumor or gross neoplasm

Miscellaneous findings

- Congenital TZ
- Condyloma
- Polyp (ectocervical or endocervical)
- Inflammation
- Stenosis
- Congenital anomaly
- Post-treatment consequence
- Endometriosis
• **Excision treatment types** – Excision type 1, 2, 3

• **Excision specimen dimensions** –
  • Length – the distance from the distal or external margin to the proximal or internal margin
  • Thickness – the distance from the stromal margin to the surface of the excised specimen
  • Circumference (optional) – the perimeter of the excised specimen
<table>
<thead>
<tr>
<th>Current range of practices in the U.S.</th>
<th>Change with adoption of IFCPC Terminology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of general assessment/visibility: no standard</td>
<td>Adequate/inadequate</td>
</tr>
<tr>
<td>Description of SCJ: satisfactory/unsatisfactory, adequate/inadequate</td>
<td>SCJ visualized: yes, no, partial</td>
</tr>
<tr>
<td>Description of location: no standard, usually clock description</td>
<td>Inside/outside TZ, size</td>
</tr>
<tr>
<td>Colposcopic impression: LSIL/CIN1, HSIL/CIN/2/3</td>
<td>Grade 1 Minor, Grade 2 Major</td>
</tr>
<tr>
<td>Excisional Treatment: LEEP, cold knife conization, etc.</td>
<td>Excision Type I/II/III</td>
</tr>
</tbody>
</table>
Questions for the audience
What do you consider the most important potential harm of colposcopy?

A. Pain/discomfort of the procedure.

A. Psychological impact of the procedure.

B. Personal financial cost of the procedure.

C. Downstream impact of subsequent procedures (e.g., excisional procedures) on future pregnancies.
Should a term be incorporated to indicate a global assessment of the cervix, separate from SCJ visibility? This term would indicate whether the colposcopic exam is feasible based on visibility, bleeding, patient comfort, etc.

A. Yes

B. No
If the election was today, who would you vote for?

A. Hillary Clinton
B. Ted Cruz
C. Bernie Sanders
D. Donald Trump
E. None of the above
F. None of your business
Should location of each lesion (inside or outside the TZ; clock position on the cervix) be a part of the terminology?

A. Yes, both inside/outside the TZ and clock position.

B. Only inside/outside the TZ.

C. Only clock position.

D. Location should not need to be specified.
Should **size** of the lesion(s) be specified?

A. Yes, as number of quadrants of involvement.

A. Yes, as a percentage of involvement of the cervix.

C. Yes, as a measurement in mm or cm.

D. A and B.

E. No, size does not need to be specified.
<table>
<thead>
<tr>
<th>Minimum Acceptable Criteria</th>
<th>IFCPC Terminology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix visibility Yes/No/Partial</td>
<td>General assessment: adequate/inadequate</td>
</tr>
<tr>
<td>SCJ visibility Yes/No/Partial</td>
<td>SCJ visibility: Yes/No/Partial</td>
</tr>
<tr>
<td></td>
<td>TZ type I/II/III</td>
</tr>
<tr>
<td>Lesion Yes/No (any degree of AWE)</td>
<td>Normal colposcopic findings</td>
</tr>
<tr>
<td></td>
<td>Abnormal colposcopic findings</td>
</tr>
<tr>
<td>Impression LSIL/HSIL</td>
<td>Grade 1 Minor/Grade 2 Major</td>
</tr>
<tr>
<td></td>
<td>Suspicious for invasion/Miscellaneous findings</td>
</tr>
<tr>
<td></td>
<td>Excision type and dimensions</td>
</tr>
</tbody>
</table>
Colposcopy Standards Project

Working Group 2: Risk-based colposcopy
April 16, 2016

Stewart Massad, Nicolas Wentzensen
Michelle Khan, Rebecca Perkins, Mark Schiffman,
Katie Smith, Julia Gage, Michael Gold
Goals and charges 1

Define risk-based colposcopy

- Modification of colpo encounter by risk of CIN2+ or CIN3+ based on markers identified prior to/during exam
  - Biopsy placement
  - Biopsy number
  - ECC
  - Immediate treatment without biopsy
  - No biopsy—move to follow-up
Goals and charges 1

Define risk levels

• Potential risk markers to consider include
  • Pap grade
  • Prior history
  • HPV status (primary screening and cotesting)
    • HRHPV positive vs neg
    • HPV 16/18 positive vs other positive vs neg
  • Other biomarkers
  • Colpo impression
  • Age
Goals and charges 2

• Identify clinically meaningful and reproducible risk strata that are based on easily available measures and that are portable between populations

• Examples:
  • In 2012 guidelines, when CIN3+ risk was 1-5%, return in 1y
  • In 2012 guidelines, immediate treatment was an option when CIN3+ risk >40%

➢ Can risk-based colpo identify women at similar risk for 1y FU or LEEP?
Goals and charges 2

• Define thresholds for different colposcopy interventions based on accepted standards for a benchmark to be identified. Consider alternate measures of utility and risk, such as an acceptable upper limit to number needed to biopsy
  • Can subjective thresholds (e.g., colpo impression) apply across different levels of expertise?
  • Balance precision vs simplicity
Currently used risk thresholds in screening and management

- Immediate treatment
- Colposcopy referral
- 1-year return

- How to apply in the colposcopy setting?
  - Vary number of biopsies
  - Immediate treatment
Example of risk-based colposcopy
Literature review


• 325 manuscripts identified

• Systematic review and abstraction is ongoing
### Current data collection (example)

<table>
<thead>
<tr>
<th>Colposcopic Impression</th>
<th>HPV16 Status</th>
<th>Cytology</th>
<th>ALTS</th>
<th>Biopsy Study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Normal</td>
<td></td>
<td></td>
<td>466</td>
<td>49</td>
</tr>
<tr>
<td>Acetowhiteness/Low-grade</td>
<td></td>
<td></td>
<td>1720</td>
<td>404</td>
</tr>
<tr>
<td>High-grade</td>
<td></td>
<td></td>
<td>256</td>
<td>215</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td></td>
<td>1912</td>
<td>494</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td></td>
<td>541</td>
<td>192</td>
</tr>
<tr>
<td></td>
<td>&lt; HSIL</td>
<td></td>
<td>2139</td>
<td>446</td>
</tr>
<tr>
<td></td>
<td>HSIL</td>
<td></td>
<td>314</td>
<td>214</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>446</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>398</td>
</tr>
<tr>
<td>Normal</td>
<td>&lt; HSIL</td>
<td></td>
<td>454</td>
<td>41</td>
</tr>
<tr>
<td></td>
<td>HSIL</td>
<td></td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Acetowhiteness/Low-grade</td>
<td>&lt; HSIL</td>
<td></td>
<td>1524</td>
<td>298</td>
</tr>
<tr>
<td></td>
<td>HSIL</td>
<td></td>
<td>196</td>
<td>94</td>
</tr>
<tr>
<td>High-grade</td>
<td>&lt; HSIL</td>
<td></td>
<td>153</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td>HSIL</td>
<td></td>
<td>103</td>
<td>111</td>
</tr>
</tbody>
</table>

Evaluation of many fine strata before condensing to few simple categories
Currently discussed recommendations

• Importance of biopsies of any acetowhite area
• Random biopsies
• Fewer biopsies in women with <HSIL cytology and normal colposcopy
• Restricting of ECC to women with unsat colpo and women >40 years
• Low-risk threshold: 1-year return risk level
• Immediate treatment of women at highest risk possible

• Limitations:
  • Variability in colposcopy grading
  • How to define boundaries for risk strata?
Colposcopy Standards Project

Working Group 3: Colposcopy procedures and Adjuncts

How do you take a biopsy, what instruments
Saturday, April 16, 2016

Co-chairs: Alan Waxman; Candy Tedeschi

Members: Mark Schiffman, Barb Apgar, Warner Huh, Beth Stier and Christine Conageski
Goals/Charges

• Charge 1: Define colposcopy procedures
  • Equipment, approach, application of acetic acid, indication for Lugol’s solution

• Charge 2: Define standards for biopsy and ECC procedures
  • Instruments, procedures, etc.

• Charge 3: Evaluate colposcopy adjuncts,
  • How do you document? Is any required? Is taking a picture?
  • Integration in EMR
  • Products that help with colposcopic interpretation
Proposed objectives and methods

• Define elements of colposcopy procedure as performed in the U.S.
  • Very limited evidence for best practices
  • Survey sample of ASCCP members

• Literature review
## Example of survey

### Demographics

<table>
<thead>
<tr>
<th></th>
<th>&lt;30</th>
<th>31-40</th>
<th>41-50</th>
<th>51-60</th>
<th>&gt;60</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Your age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Years doing colposcopy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5</td>
<td></td>
<td>6-10</td>
<td>&gt;10</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type of Practice: Physician</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Family med</td>
<td></td>
<td>Ob/gyn</td>
<td>Gyn Oncology</td>
<td>Gyn Onc. Fellow</td>
<td></td>
</tr>
<tr>
<td><strong>Type of Practice: APC</strong></td>
<td></td>
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<tr>
<td>NP</td>
<td></td>
<td>CNM</td>
<td>PA</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td><strong>Type of practice-setting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private practice</td>
<td></td>
<td>Public clinic</td>
<td>Hospital based</td>
<td>Academic</td>
<td>Government (VA, DOD, IHS)</td>
</tr>
</tbody>
</table>
Example of survey: Colposcopy practice

When I do colposcopy the following describes my considerations / practice

<table>
<thead>
<tr>
<th>Precolpo evaluation</th>
<th>Always</th>
<th>Most of the time</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
<th>N/A not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review indications for colposcopy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluate for major comorbidities</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Assess LMP</td>
<td></td>
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<tr>
<td>Assess contraception</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assess pregnancy status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inquire / assess HIV status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inquire about smoking status</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Example of survey: Colposcopy practice

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<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
<th>N/A not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colposcopy with 3% acetic acid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colposcopy with 5% acetic acid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colposcopy of cervix with Lugols iodine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exam after timed interval after acetic acid wash: 60 seconds</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exam after timed interval: – &lt;60 seconds</td>
<td></td>
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<td>Exam after timed interval: &gt;60 seconds</td>
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<tr>
<td>I do not time exam after acetic acid</td>
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Survey synopsis

• Demographics
• Pre-exam evaluation
• Technique of exam in detail
  • Saline wash
  • Vinegar or acetic acid
  • Lugol’s
• Areas examined
  • Cervix
  • Vulva
  • Vagina
  • Anus
• Biopsies
  • Always, sometimes, never
  • How many
• ECC
  • Always, sometimes, never
  • Technique
  • Before or after biopsies
• Documentation
• Notification of patient
WG4: Quality Control

- **Leaders:** Mark Einstein and EJ Mayeaux
- **Members:** Phil Castle, David Chelmow, Kim Choma, Levi Downs, Francisco Garcia, Angela Liu, Akiva Novetsky, and Thea Papasozomenos
WG4: Quality Control

• *Quality assurance* is evaluating things as we do it
• *Quality control* is evaluating how well we did it
Many international guidelines that address QC:

- IFCPC, United Kingdom, Australia, New Zealand, European Federation of Colposcopy, Canada, IARC, French Society of Colposcopy and Cervicovaginal Pathology (SFCPCV)
WG4: Quality Control

Charges

• Review Quality Control (QC) measures
• Define set of meaningful QC parameters for the United States
• Discuss implementation of QC
QC Measures

• Can lump QC measures into the ‘buckets’ of:
  • Systems/individual provider
  • Technical/procedural
WG4: Quality Control

• Search the literature for QC in colposcopy
  • MESH search with MESH headings
    • ((( "Colposcopy/economics"[Mesh] OR "Colposcopy/education"[Mesh] OR
      "Colposcopy/organization and administration"[Mesh] OR
      "Colposcopy/standards"[Mesh] ))) AND implementation
  • Identified <100 articles - About 10% foreign language

• Obtained QC recommendations from Non-US National and International groups

• Extracted QC indicators

• Focusing on consistent indicators leading to the most optimal outcomes
  • Diagnosis of CIN 2+ and cancer from screening
QC Measures

**Systems Measurements** (Examples):

- Training
- Evaluating training of colposcopy Quality Assurance
- Time interval from abnormal cervical cancer screening tests to colposcopy
  - Stratified by degree of abnormalities interpretation
- In a system, % of women who had colposcopic-directed biopsy that shows clinically relevant disease (CIN2+, CIN3+), overall and stratified by screening tests interpretation.
  - Also age stratification
QC Measures

**Technical/procedural** (examples):

• How often do we actually perform at least one biopsy of more than one lesion
  • New referral patients
  • Follow-up (post initial colposcopy) patients
• Use of endocervical sampling with colposcopic adequacy
• Colposcopic adequacy stratified by age
WG4: Quality Control Discussion

Systems/individual provider questions for QC:

• Appropriate timing of abnormal cervical cancer screening tests and colposcopy appointments for patients
  • Knowing the additional healthcare determinants that go into this question
  • Measuring appointment time between significant abnormal screening tests and colpo appointment
    • By clinical significance and age
WG4: Quality Control Discussion

Systems/individual provider questions for QC:

• In a system or individual provider, do you think it is important to measure appointment time between abnormal screening tests and colpo appointment as a quality measure?

A. Yes
B. No
WG4: Quality Control Discussion

Systems/individual provider questions for QC:

• Would you stratify this appointment time by degree of abnormality (e.g., high grade disease completing colposcopy sooner)?

A. Yes
B. No
WG4: Quality Control Discussion

Systems/individual provider questions for QC:

• Do you think it is important to measure intervals or surveillance of conservatively followed/intentionally untreated lesions (e.g. persistent CIN I or CIN 2 in young women)?

A. Yes
B. No
WG4: Quality Control Discussion

Systems/individual provider questions for QC:

- What would be the time interval variation around guidelines you would expect to see as a quality indicator for follow-up of conservatively followed lesions (e.g., CIN I or CIN 2)?

A. ±3 months
B. ±6 months
C. ±9 months
D. ±12 months
Systems/individual provider questions for QC:

• In a system, do you think it is an important quality indicator to measure percent of high grade lesions not treated?

A. Yes
B. No
Systems/individual provider questions for QC:

• In a system, do you think it is important to measure appropriate referral to colposcopy (e.g., following guidelines)?

A. Yes

B. No
WG4: Quality Control Discussion

Training/maintenance of clinical skills measures for QC:

• We will be describing important benchmarks and metrics to measure for quality for:
  • Developing competency (training)
  • Maintaining proficiency (primary colposcopy providers)
Training/maintenance of clinical skills measures for QC:

• When maintaining proficiency, do you think it is important to perform colposcopy:
  
A. On average, at least one colposcopy per week
B. On average, at least one colposcopy per month
C. Over 50 per year
D. Over 100 per year
Pathology question for QC:

- Since we know outcomes and quality are related to clinically relevant lesions
  - Number/percentage of insufficient biopsies in a system or by provider