Quality Assurance in Colposcopy: CQUIP Pilot study

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Medical Director, VCCCR
Which of 3 arms of the screening program have quality assurance embedded in their conduct?

1. Cytology only
2. Histology only
3. Colposcopy only
4. Cytology & histology
5. All 3 arms
Quality assurance in the cervical screening program: Colposcopy

• Where are we now?
• Where do we want to go?
• How are we going to get there?
Quality Assurance in Cytology

• Quality standards include performance standards, which are numerical outcome measures set by the NCSP, in conjunction with the NPAAC
• Registries assist laboratories in provision of data
• All laboratories report using 2006 cytology coding schedule
Example: Impact of laboratory performance measures following QA program

Laboratory performance measure 3B  Positive predictive value of cervical cytology: Percent of laboratories outside the standard

Shield PW Pathology 2010 47(7)
Quality assurance - Pathology

• **RCPA Quality Assurance Program (QAP)**
  - Send samples for diagnostic assessment to laboratories – allowable limits of performance
  - Required to participate in technical proficiency modules
  - Required submit reporting numbers for benchmarking with other laboratories
Current colposcopy requirements Australia

• To access medicare benefits – must have a provider number.
• No requirement for any particular education, adherence to standards or participation in QAP
• The cervical screening program provides data on number of cervical biopsies performed & HIC data provides information on items numbers accessed
International Colposcopy QA

- BSCCP- \( \geq 50 \) new referrals, training and assessment
- Canada- \( >100 \) new cases, training program
- European Federation – developing audit
- Singapore - \( >30 \) new cases over 2 years, course attendance
- New Zealand – systematic collection of colposcopy data, independent monitoring
Standards in Colposcopy and Treatment

The Report of a RANZCOG and ASCCP Working Party
Standards in colposcopy & treatment
Document produced by joint working party of RANZCOG & ASCCP 2001

**Recommendations included:**
- NH&MRC guidelines be reviewed ✓
- No woman be treated w/o prior colposcopy
- High grade abnormalities in pregnancy ? 2nd opinion
- Excisional treatment be subject of audit
- Same standards in Colposcopy for Public & Private sectors
- Colposcopists regularly participate in relevant continuing education programs
Enter CQUIP....
Colposcopy Quality Improvement Program (RANZCOG)

Aim
• To improve the care of women who are referred for colposcopy and treatment of screen detected abnormalities.
• Develop certification and recertification programs for colposcopy.
• Developing audit tools for all health professionals practising colposcopy to support improved performance. Alternative options for data collection to be provided
• Providing a comprehensive online education program
Enter CQUIP....

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• Developing audit tools for all health professionals practising colposcopy to support improved performance. Alternative options for data collection to be provided

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CQUIP Draft performance measures and audit

• What do we want to measure?
• How will the data be collected?
• How will it be used?

Rule number 1: only collect the minimum data required
• "If you don't know where you are going, you will wind up somewhere else."
~Yogi Berra
CQUIP Draft performance measures and audit

• Considered measures used by BSCC, New Zealand, previous RANZCOG report, NHMRC guidelines
• Model of laboratory performance measures
• Selected draft diagnostic and therapeutic indicators for benchmarking and review
## Colposcopy audit

### Diagnostic performance standards

<table>
<thead>
<tr>
<th>Measures</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
<td></td>
</tr>
<tr>
<td>Number of colposcopies</td>
<td>75 per 3 years</td>
</tr>
<tr>
<td><strong>Level 2</strong></td>
<td></td>
</tr>
<tr>
<td>1. Perform biopsy &gt;95% HGA</td>
<td>&gt;95% (NHMRC)</td>
</tr>
<tr>
<td>2. % satisfactory biopsies</td>
<td>&gt;90% (NHMRC)</td>
</tr>
<tr>
<td>3a PPV colposcopy</td>
<td>No current benchmark</td>
</tr>
<tr>
<td>3b Yield of HGA on biopsy among women with HGA on cytology</td>
<td>No current benchmark</td>
</tr>
</tbody>
</table>
FIGURE 7.23: A dense acetowhite lesion with regular margin and coarse, irregular punctuation in a CIN 3 lesion.

FIGURE 7.22: A circumorificial dense opaque acetowhite area with coarse mosaics (CIN 3 lesion).

CIN3 histology
Colposcopy audit

- Therapeutic performance standards

<table>
<thead>
<tr>
<th>Measures</th>
<th>Standard</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of treatments</td>
<td>Required</td>
<td></td>
</tr>
<tr>
<td><strong>Level 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Biopsy prior to ablative treatment</td>
<td>&gt;95% (NHMRC)</td>
<td>Optional</td>
</tr>
<tr>
<td>2. Number women CIN2+ histo/Number treated</td>
<td>No current benchmark</td>
<td>Optional</td>
</tr>
<tr>
<td>3. % treatment failures of HGA</td>
<td>&lt;5% in 12 months NHMRC</td>
<td>Optional</td>
</tr>
<tr>
<td>4. Maximise 9 month followup after treatment for HGA</td>
<td>No current benchmark</td>
<td>Optional</td>
</tr>
</tbody>
</table>
Options for data collection

• Practice Management software
  – Low uptake at present
  – Range of options, would need to be modified
  – Uptake within cQUIP timeline uncertain

• QAP software
  – Web-based software (developed or existing)
  – Reasonable commitment required, esp data entry of histology. Optional participation
Options for data collection

• Pap test Registries
  – Legislation in place
  – Data security, privacy, confidentiality
  – Already collect cytology, histology, HPV
  – Colposcopy collected as part of PTR followup but not systematically
Advantages

– Data items already collected but colposcopy not systematic
– Infrastructure in place
– Would assist Registry followup as colposcopy or biopsy cease followup – fewer questionnaires!
– Modelled on Laboratory QA program
– General support from Cervical Screening program managers
Pilot study in Victoria: Aims

The VCCR pilot aims to determine:

• whether a simple data collection form is feasible and acceptable to practitioners
• the most user friendly format for reports
• benchmark and test the appropriateness of the proposed performance measures
• data specifications for possible software options
Pilot methods

• 3 month period May-July 2011
  – complete brief report form for each colposcopy or treatment episode
  – cc VCCR on histopath request form
  – Send forms in batches to VCCR

• Reports on performance indicators will be developed by VCCR and sent to colposcopists

• Only de-identified data sent to CQUIP for evaluation
COLPOSCOPY QUALITY ASSURANCE PILOT DATA COLLECTION FORM
Complete one form for each visit for colposcopy, treatment or both

Dr Jack Citizen
100 Nameless Lane
Clinic
MELBOURNE VIC 3000

PLACE PATIENT LABEL HERE OR
Name ........................................................
Address ........................................................
........................................................
DOB: .........../.........../............

COLPOSCOPY THIS EPISODE ☐ YES ☐ NO Date ........./...../......

INDICATIONS FOR COLPOSCOPY
☐ New patient with abnormal pap smear
☐ Follow-up of patient with previous abnormal smear at 0/12 or 12/12
☐ At time of treatment
☐ Other (specify) ........................................................

COLPOSCOPY FINDINGS: ☐ Normal ☐ LSIL
☐ HSIL (Specify) ☐ CIN 2 ☐ CIN 3
☐ Cancer ☐ Unsatisfactory
☐ Other (specify) .................................................

BIOPSY THIS EPISODE: ☐ YES ☐ NO (If yes, please cc VCCP on pathology request slip)

TREATMENT THIS EPISODE: ☐ YES ☐ NO Date ........./...../......

TYPE OF TREATMENT: ☐ LEEP ☐ Hysterectomy
☐ Ablative ☐ Cone Biopsy
☐ Other (specify) .................................................

Signature ............................................. Date ........./...../.....

Please send completed forms to:
Victorian Cervical Cytology Registry (CQuIP Pilot), PO Box 161, Carlton South Vic 3053
Colposcopist sends report form to Registry for each colposcopy/treatment event (in batches).

VCCR data entry/upload

Report to Colposcopist on Performance measures Assign participant number

De-identified reports collated at C-QuIP and VCCR Send back summary to colposcopists

Colposcopist sends de-identified report to C-QuIP

FEEDBACK ABOUT PILOT
Preliminary results of pilot

- 8 May- 31 July 2011
- 28 participants ASCCP members in Victoria (CPD points), 58 invited
- **1312** forms returned
- Mean= 46 forms (Range 6-160)
- 3 returned >100 forms
- 7 returned >50 forms
- 25 returned >20 forms
- Preliminary data mailed to participants 27.10.11
### AUDIT LEVEL 1

**Standard 2**
Documenting colposcopy occasions of service and maintaining skill level

<table>
<thead>
<tr>
<th>Number of colposcopy referrals during the pilot study</th>
<th>1212 referrals</th>
<th>Note: all colposcopies recertified on forms</th>
</tr>
</thead>
</table>

#### Indications for colposcopy

- New patient with abnormal smear
  - 12/21 (58%) of 21 referrals
  - 583 (44%) of 1332 referrals

- Followup of patient with abnormal smear at 6/12 or 12/12
  - 2/21 (10%) of 21 referrals
  - 413 (31%) of 1332 referrals

- At time of treatment
  - 3/21 (14%) of 21 referrals
  - 255 (19%) of 1332 referrals

### AUDIT LEVEL 2

Reducing failure of diagnosis and to improve diagnosis of high-grade abnormalities

**Standard 1**
Perform a biopsy in more than 50% of women with high-grade cytological abnormalities

- **Number of women with defined high-grade cytology who have punch or excisional biopsy**
  - 3/8 (100%) of 8 referrals
  - 60/110 (55%) of 110 referrals

**Ensuring quality of cervical biopsies**

- **Number of satisfactory biopsies/number of biopsies performed**
  - 16/16 (100%) of 16 referrals
  - 604/604 (100%) of 604 referrals

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### Standard 3e
Colposcopic findings should be correlated with histological findings to determine the predictive value of colposcopy for high-grade cervical abnormalities.

- **Number of women with histologically confirmed high-grade (CIN2+) within 6 months of colposcopy/Number of women with colposcopic findings CIN2+**
  - 122/178 (70%) of 178 referrals
  - Range 40-100% (where \( n \geq 5 \))

- **New patients only**
  - There is no set standard for this measure, recognizing that no benchmarks are currently available.

### Standard 39
The yield of high-grade abnormalities on biopsy among women referred with high grade cytology, as a reflection of the accuracy of targeting the appropriate area to biopsy.

- **Number of women with histologically confirmed high-grade (CIN2+) within 6 months of colposcopy/Number of women with high-grade cytology preceding colposcopy and biopsy**
  - 05/113 (72%) of 113 referrals
  - Range 50-90% (where \( n \geq 5 \))

- **New patients only**
  - There is no set standard for this measure, recognizing that no benchmarks are currently available.
## Level 1 Standard 1

### Number of referrals, Indications for colposcopy

<table>
<thead>
<tr>
<th>Indication</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>New patient with abnormal smear</td>
<td>583</td>
<td>(44%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20% prior smear HGA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>26% poss HGA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>43% LGA</td>
</tr>
<tr>
<td>Follow up at 6 or 12 mths</td>
<td>413</td>
<td>(32%)</td>
</tr>
<tr>
<td>At time of treatment</td>
<td>58</td>
<td>(4%)</td>
</tr>
<tr>
<td>Other</td>
<td>258</td>
<td>(20%)</td>
</tr>
</tbody>
</table>
Indications for colposcopy

- Follow Up
- New patient
- Other
- Treatment

% of all patients

Doctors 1-28
Perform biopsy in more than 95% of women with high-grade abnormalities

- NHMRC guidelines
- Prior Pap test is high-grade abnormality
- 99/110 (90%) women were biopsied
- If no biopsy performed, reasons included pregnancy, atrophic cervix
Level 2 Standard 2
Of all biopsies taken, more than 90% should be satisfactory

- NHMRC guidelines
- 99/110 (99%) biopsies were satisfactory for histological interpretation
Performance measure 3a: Positive predictive value for colposcopy

New patients only
PPV=71%  (Range 40-100%) if n>5
Performance measure 3a: n>5
Measure 3b: Yield of high-grade biopsies among women referred for high-grade cytology

PPV = 72% Range 50-90% if n>5
Measure 3b: Yield of high-grade biopsies among women referred for high-grade cytology

$n>5$
### Summary of measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Values for all participants</th>
<th>Comment</th>
</tr>
</thead>
</table>
| **Level 1, Standard 1**  
Number of colposcopy referrals | N= 1312  
Range (6-160)  
44% were new patients  
(of these 110 (20%) HGA | Mandatory |
| **Level 2, Standard 1**  
Perform biopsy in >95% of women with high-grade cytology | N=99/110 (90%) | Optional |
| Standard 2 90% biopsies satisfactory | N=656/660 (99%) | Optional |
| Standard 3a PPV colposcopy for high-grade histology | N= 72%  
Range 40-100% | New patients only |
| Standard 3b Yield of high-grade histology in women referred for high-grade cytology | N=73%  
Range 50-90% | New patients only |
### FEEDBACK FORM COLLATION

Colposcopy Quality Improvement Program (C-QuIP) Victorian Pilot Study with the Victorian Cervical Cytology Registry (VCCR)

**Number of forms returned: 9**

<table>
<thead>
<tr>
<th>Statement</th>
<th>1 Disagree</th>
<th>2 Neutral</th>
<th>3 Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I found participating in the pilot study useful to my practice</td>
<td>1</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>I believe the data collected for the pilot was relevant to my practice</td>
<td>1</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>I found the process of returning the completed colposcopy forms easy</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The final report provided was useful in understanding my performance</td>
<td>1</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>I would be interested in continuing to collect colposcopy data for my</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>practice in paper or excel form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would prefer to use data collection software for recording colposcopy</td>
<td>1</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>quality (Note: software would require recording prior cytology and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>subsequent histology results for each patient, either manually or auto</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>download, which may differ from the pilot which used VCCR data)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would like to be informed about any colposcopy data collection software</td>
<td>1</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>linked to the C-QuIP program that may be developed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Summary

• Colposcopists invited to certify and on-line learning are also being developed
• Roll-out of program early 2012
Summary

• If cQUIP participation to be maximised, data collection options need to be provided
• Pap test Registries already have a number of systems in place to facilitate QA
• Minimum data set and software options are being developed in parallel
• Data now available for review of draft performance standards and benchmarking
• Therapeutic standards to be developed
Acknowledgements

• Louise Farrell
• Marion Saville
• Lesley Rowlands
• Jordan Chrisp
• CQUIP steering committee