

Quality Assurance in Colposcopy: CQUIP Pilot study

Dorota Gertig
Medical Director, VCCR



Which of 3 arms of the screening program have quality assurance embedded in their conduct?

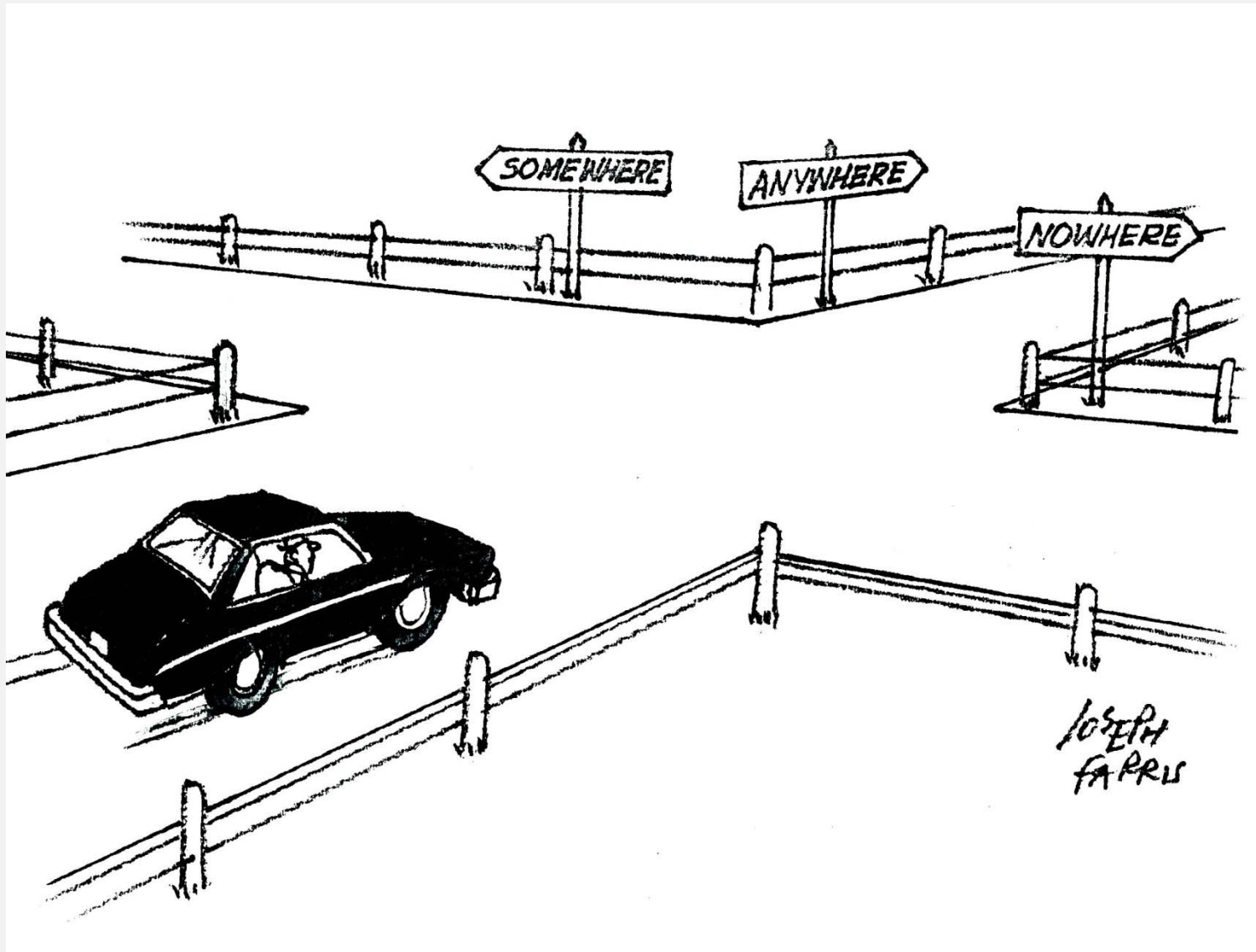
1. Cytology only
2. Histology only
3. Colposcopy only
4. Cytology & histology
5. All 3 arms



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?

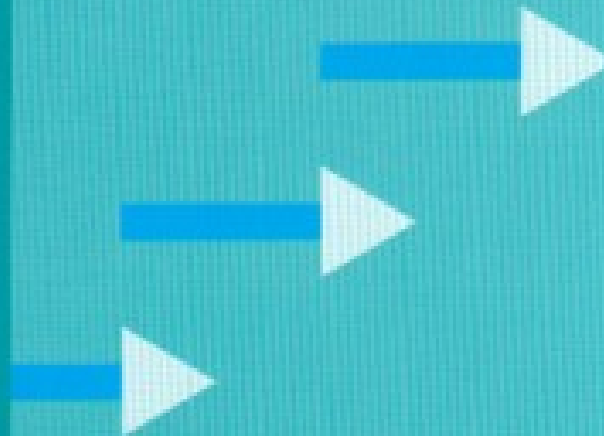




JOSEPH
FARRIS



PERFORMANCE MEASURES
FOR AUSTRALIAN LABORATORIES
REPORTING
CERVICAL CYTOLOGY



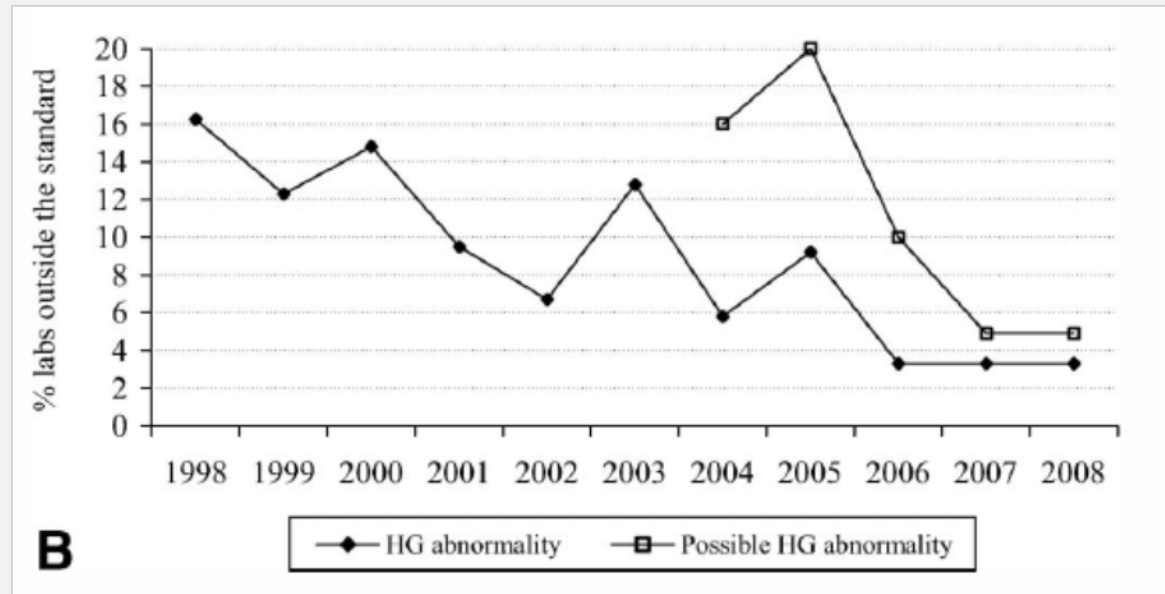
S T A N D A R D S



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

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 bench marking 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- ≥ 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....

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



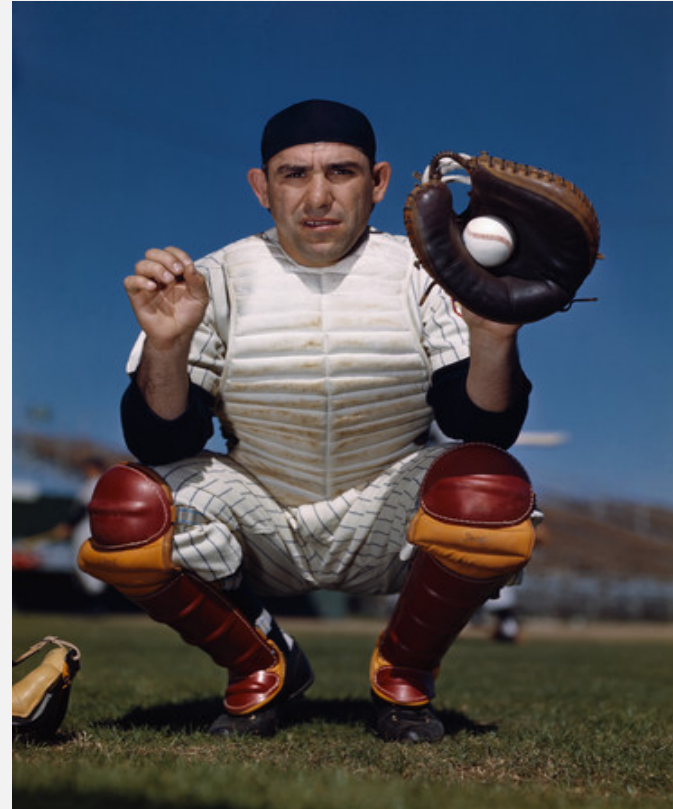
CQUIP Draft performance measures and audit

- 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

Measures	Standard	
Level 1		
Number of colposcopies	75 per 3 years	Required
Level 2		
1. Perform biopsy >95% HGA	>95% (NHMRC)	Optional
2. % satisfactory biopsies	>90% (NHMRC)	Optional
3a PPV colposcopy	No current benchmark	Optional
3b Yield of HGA on biopsy among women with HGA on cytology	No current benchmark	Optional

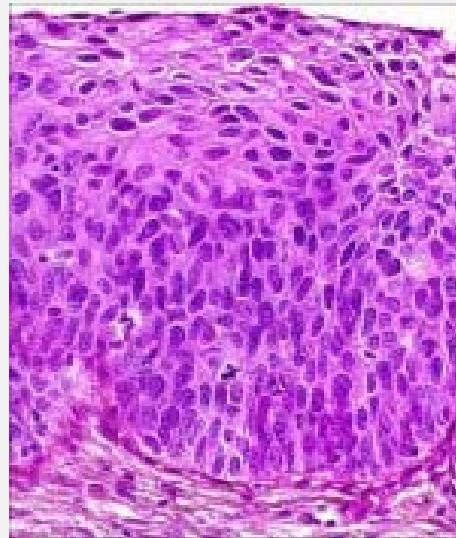


FIGURE 7.23: A dense acetowhite lesion with regular margin and coarse, irregular punctation in a CIN 3 lesion.



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

CIN3 histology



Colposcopy audit

- Therapeutic performance standards

Measures	Standard	Comments
Level 1		
Number of treatments		Required
Level 2		
1. Biopsy prior to ablative treatment	>95% (NHMRC)	Optional
2. Number women CIN2+ histo/Number treated	No current benchmark	Optional
3 % treatment failures of HGA	<5% in 12 months NHMRC	Optional
4. Maximise 9 month followup after treatment for HGA	No current benchmark	Optional

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 6/12 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 VCCR on pathology request slip)

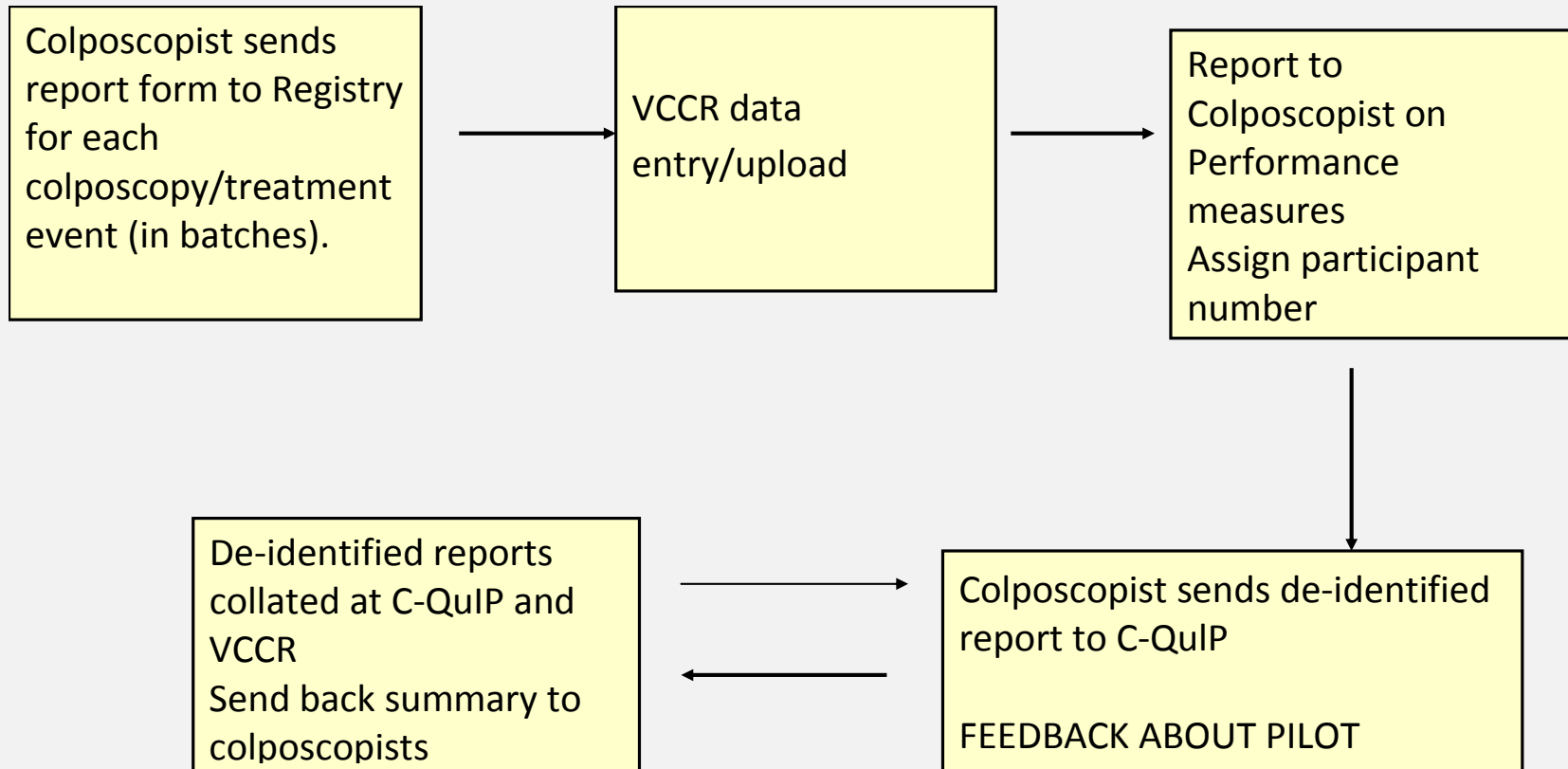
TREATMENT THIS EPISODE: YES NO Date/...../.....

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

Pilot flowchart



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

Your data for pilot 7/5/11 – 30/7/11		Values for all participants	Comments
AUDIT LEVEL 1			
Standard 1			
Documenting Colposcopy occasions of service and maintaining skill level			
Number of colposcopy referrals during the pilot study		1312 Range (6-160) Mean 46	Note these are all colposcopies recorded on forms
Indications for colposcopy			
<ul style="list-style-type: none"> New patient with abnormal smear 	18/21 (86%)	583 (44%)	Of the 583 new referrals 20% were for HGA cytology, 30% possible HGA and 45% for LGA.
<ul style="list-style-type: none"> Followup of patient with abnormal smear at 6/12 or 12/12 	2/21 (10%)	413 (31%)	
<ul style="list-style-type: none"> At time of treatment 		58 (4%)	
<ul style="list-style-type: none"> Other 	1/21 (5%)	258 (20%)	
AUDIT LEVEL 2			
Reducing failure of diagnosis and to improve diagnosis of high-grade abnormalities			
Standard 1			
Perform a biopsy in more than 95% of women with high-grade cytological abnormalities			
<ul style="list-style-type: none"> Number of women with definite high-grade cytology who have punch or excisional biopsy/ Number of women with referral for high-grade cytology 	3/3 (100%)	99/110 (90%)	Defined as where prior Pap is high grade for this pilot.
Ensuring quality of cervical biopsies			
Standard 2			
Of all biopsies taken, more than 90% should be suitable for histological interpretation			
<ul style="list-style-type: none"> Number of satisfactory biopsies/number of biopsies performed 	16/16 (100%)	684/691 (99%)	

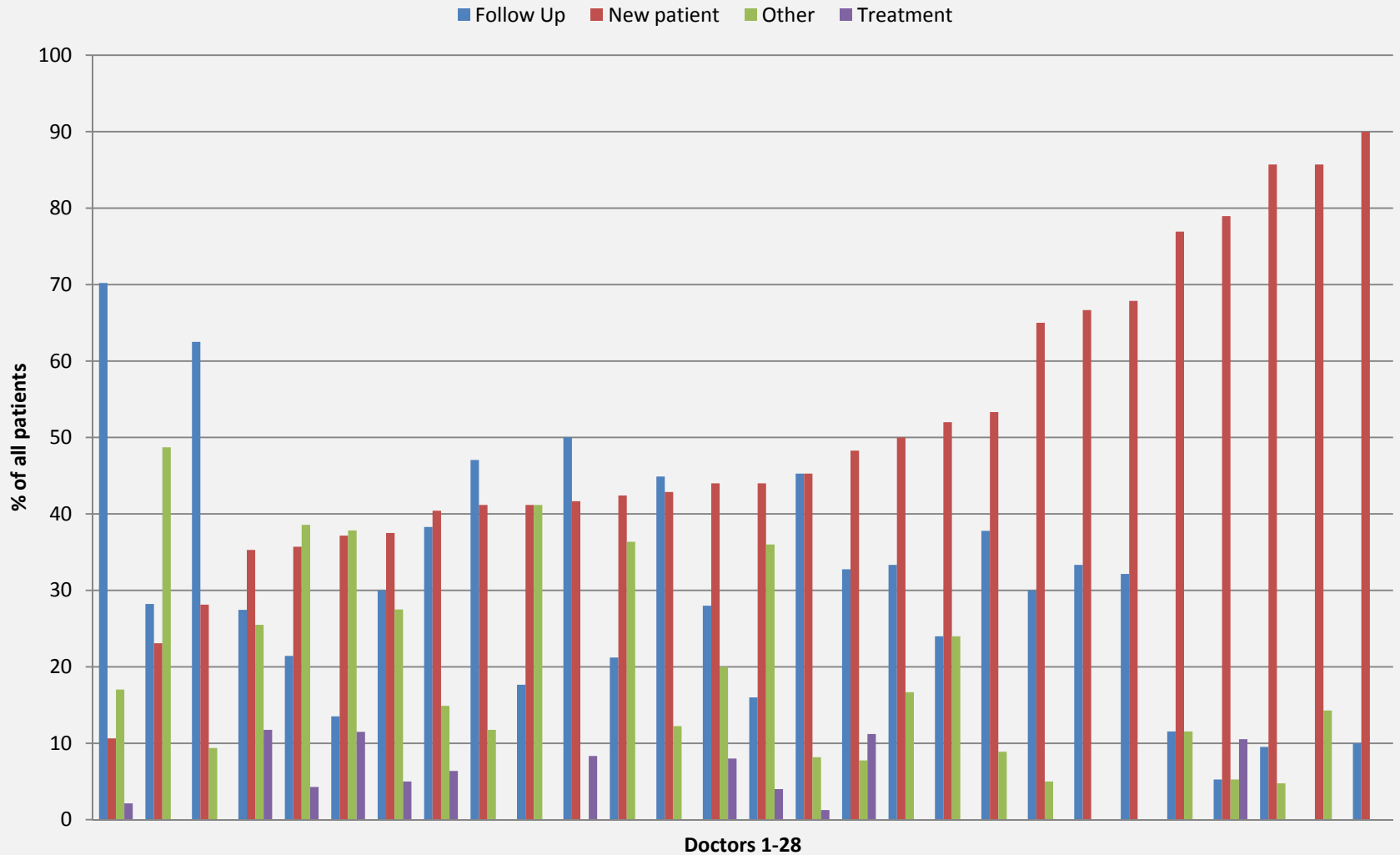
Standard 3a			
Colposcopic findings should be correlated with histological findings to determine the predictive value of colposcopy for high-grade cervical abnormalities.			
<ul style="list-style-type: none"> Number of women with histologically confirmed high-grade (CIN2+) within 6 months of colposcopy/Number of women with colposcopic findings CIN2+) 		122/178 (71%) Range 40-100% (where n ≥ 5)	New patients only There is no set standard for this measure, recognising that no benchmarks are currently available.
Standard 3b			
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.			
<ul style="list-style-type: none"> 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 		83/115 (72%) Range 50-90% (where n ≥ 5)	New patients only There is no set standard for this measure, recognising that no benchmarks are currently available.

Level 1 Standard 1

Number of referrals, Indications for colposcopy

Indication	Number	Percent
New patient with abnormal smear	583	(44%) 20% prior smear HGA 26% poss HGA 43% LGA
Follow up at 6 or 12 mths	413	(32%)
At time of treatment	58	(4%)
Other	258	(20%)

Indications for colposcopy



Level 2 Standard 1

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

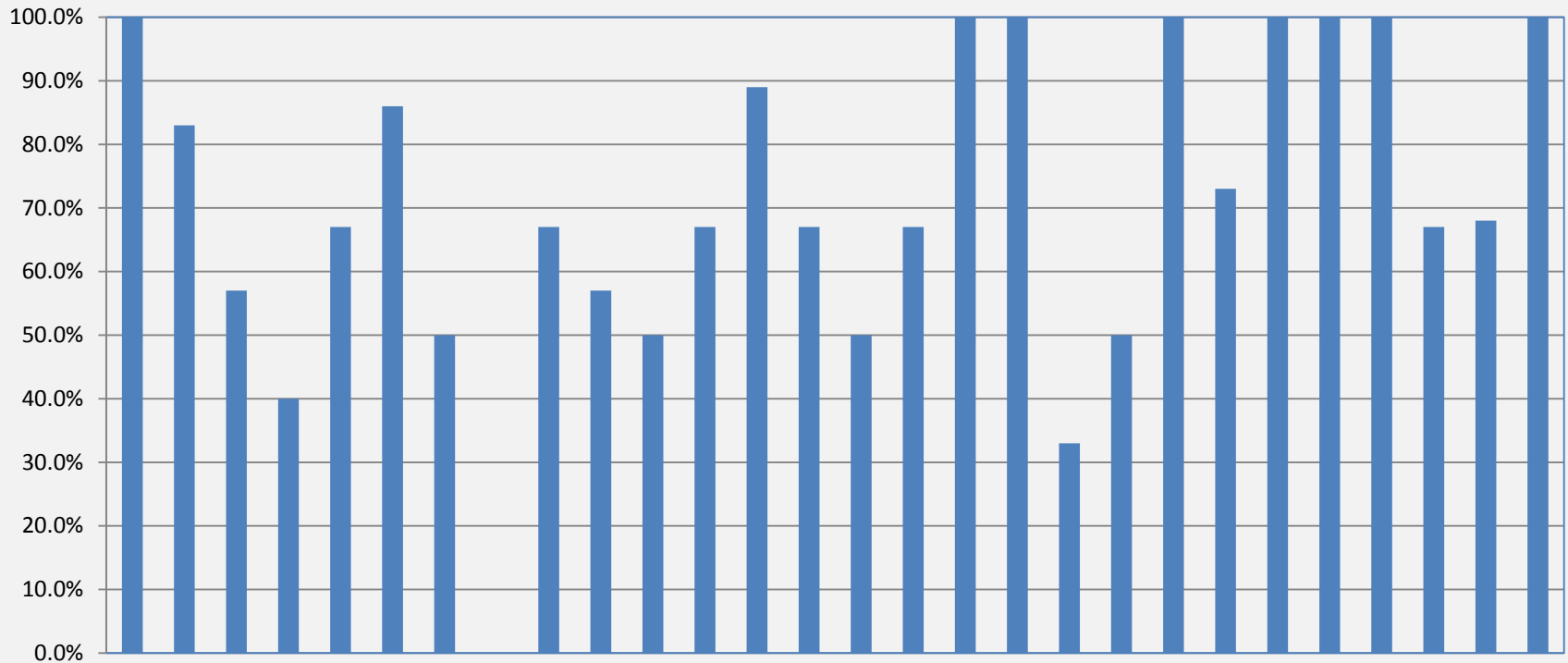
- NHMRC guidelines
- Prior Pap test is high-grade abnormality
- 99/110 (90%) women were biopsied
- If no biopsy performed, reasons included pregnancy, atrophic cervix

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

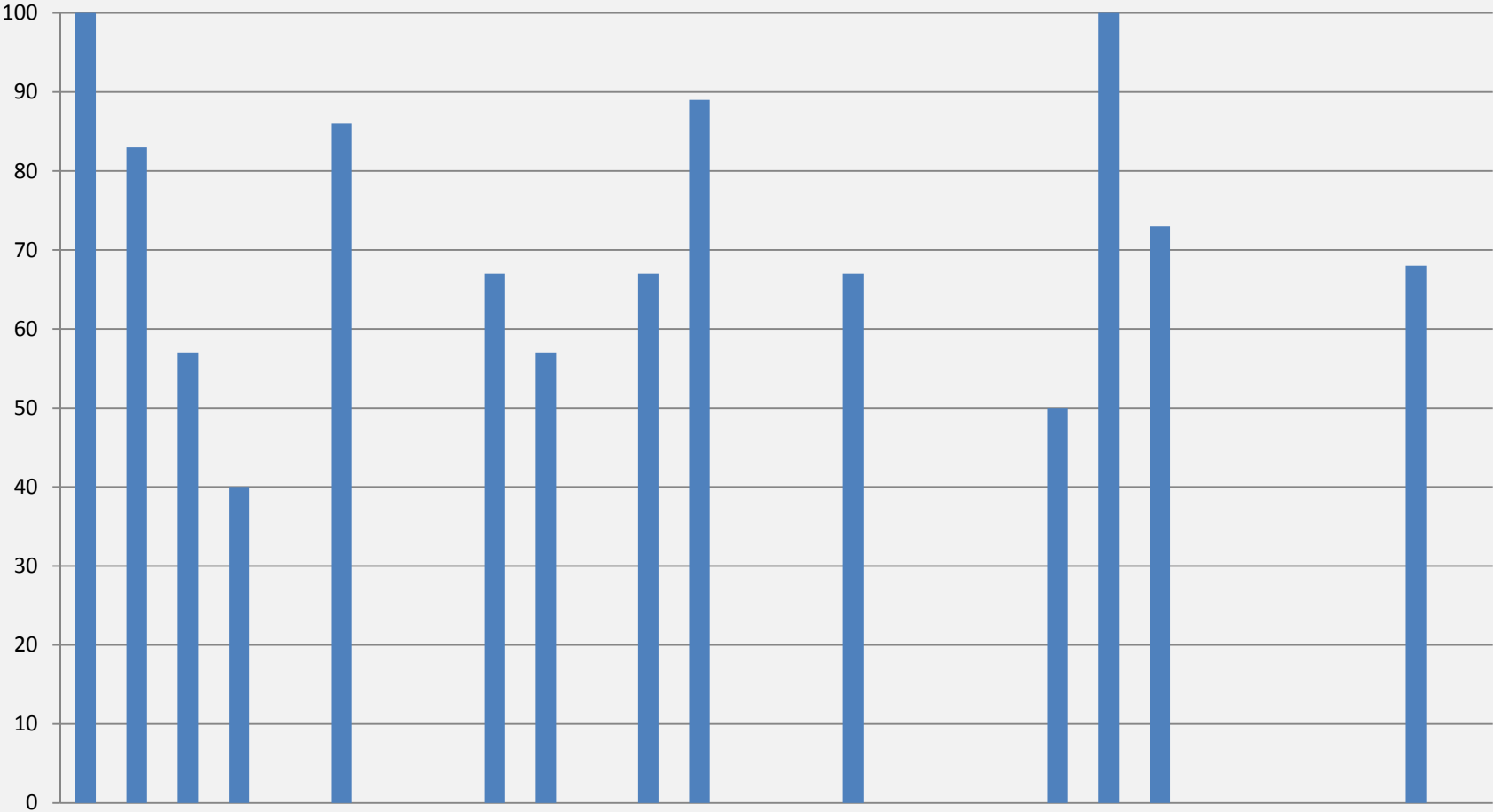
Performance measure 3a: Positive predictive value for colposcopy



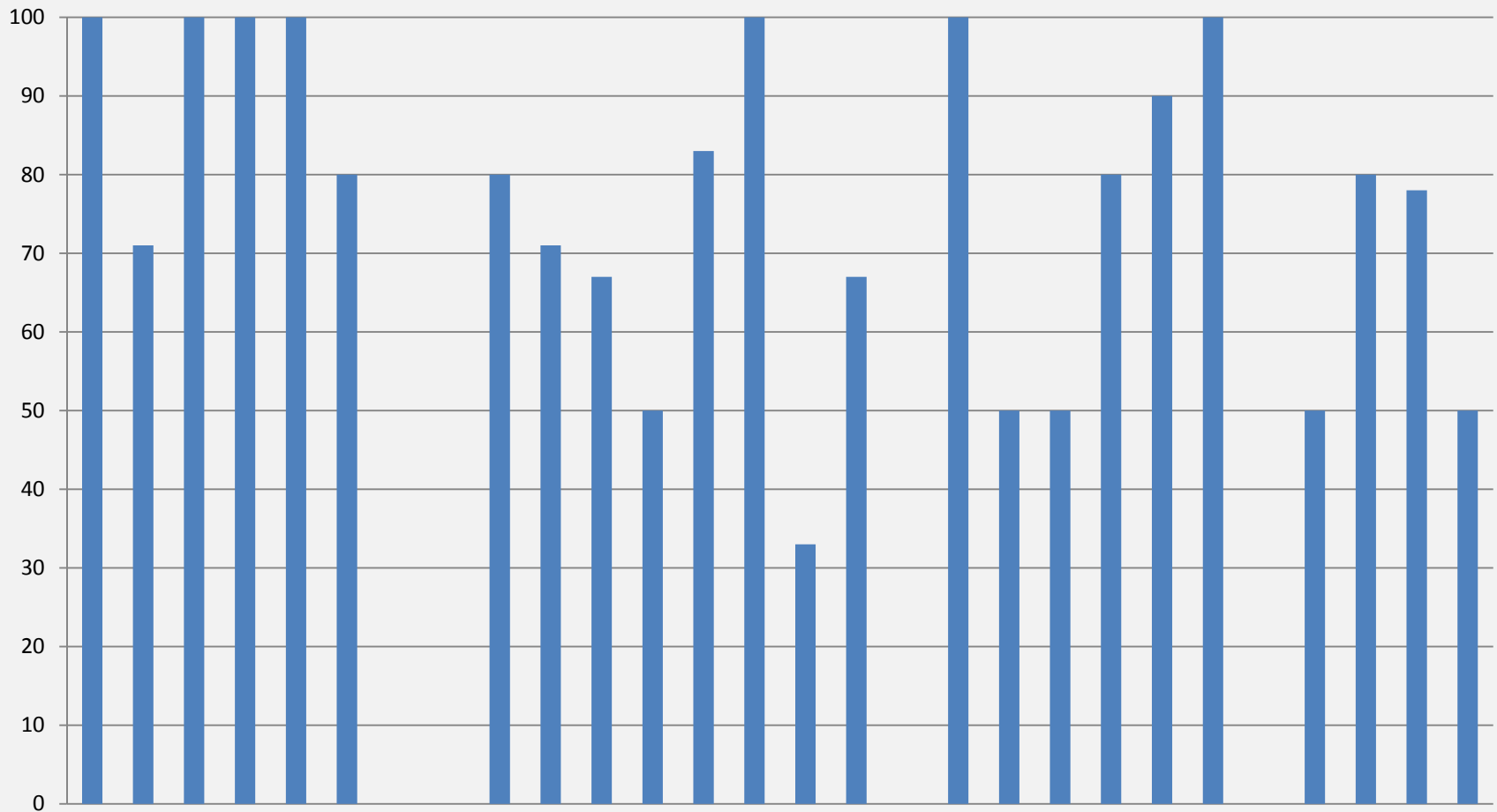
New patients only

PPV=71% (Range 40-100%) if n>5

Performance measure 3a: $n > 5$



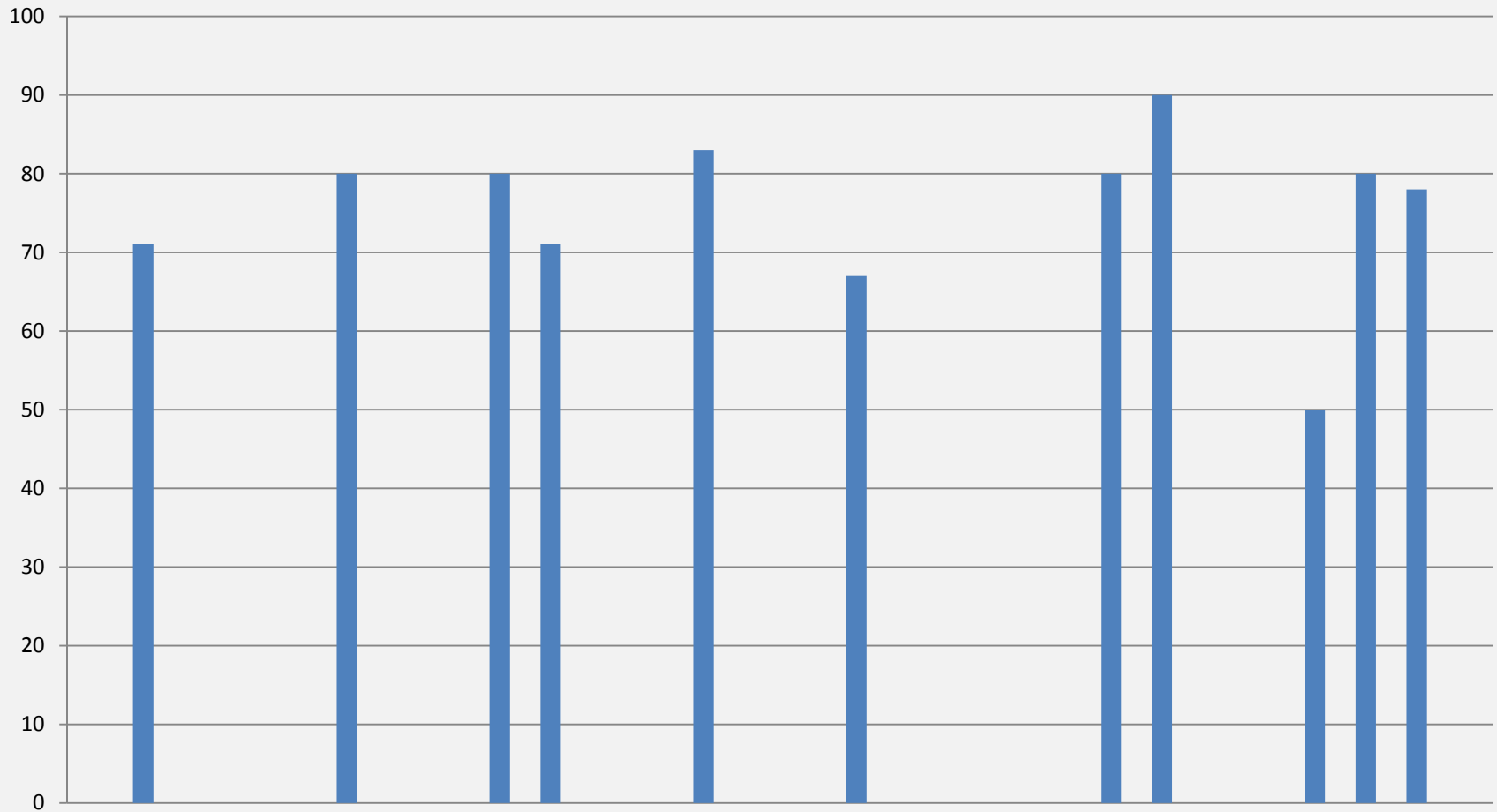
Measure 3b: Yield of high-grade biopsies among women referred for high-grade cytology



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

Measure	Values for all participants	Comment
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-QulP) Victorian Pilot Study with the Victorian Cervical Cytology Registry (VCCR)

Number of forms returned: 9

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

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