CHANGING COLPOSCOPY PRACTICE AND THE INTRODUCTION OF QUALITY ASSURANCE MONITORING

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Disclosures

- No financial relationships or conflict of interest to disclose

Cervical Cancer Prevention in Australia

- National Cervical Screening Program (NCSP)
  - Based on conventional Pap smear screening and has been highly successful.
  - Organised National Screening Program since 1991
- Cervical Cytology Registries in Australia (1989 Vic)
- HPV Vaccination program in Australia (Girls 2007, Boys 2013)
- National HPV Vaccination Program Register (2007)
- Government regulated Laboratory Quality Assurance for cytopathology
- NHMRC screening guidelines (1994, 2005)
- Renewal of guidelines with significant changes (2015/16)
- Quality and Safety Monitoring Committee (DoHA)
- National Cancer Screening Registry (2017)
- Renewal: Primary HPV screening from December 2017

National Cervical Screening Program Renewal

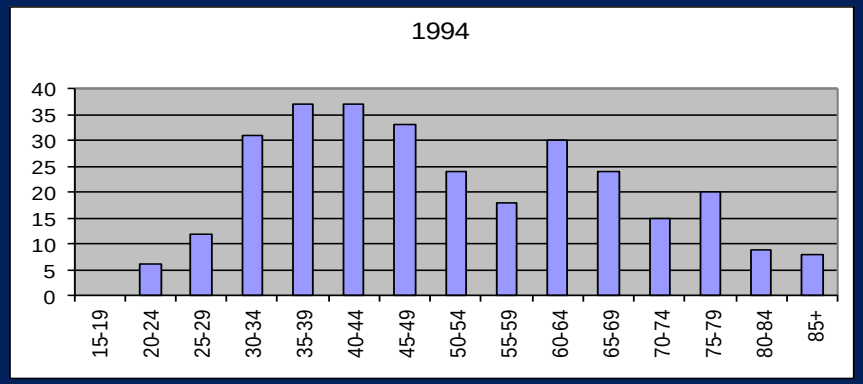
- **Renewal**
  - Draft of the new Clinical Management Guidelines for the Prevention of Cervical Cancer were made available for public consultation on 15 Feb 2016 and closed on 15 Mar 2016.
  - The final guidelines are expected to be launched on 1st December 2017.
  - It is expected that the new program will deliver a further 15-22% reduction in incidence and mortality from cervical cancer in Australian women.
- **National Cancer Screening Register**
  - The National Cancer Screening Register provides colposcopists with individual performance data benchmarked to national standards for quality improvement and certification purposes.
  - All diagnostic and therapeutic colposcopists will participate in a quality improvement programme in order to provide services for the NCSP.
  - Quality standards for colposcopy have been developed by the NCSP to provide guidance for individual performance review.
- **Certification** managed by RANZCOG
- **Quality and Safety Monitoring Committee**. (NCSP QSMC)
  - The QSMC has a role in monitoring the quality and safety of the NCSP and reports to the Standing Committee on Screening of the Australian Health Ministers' Advisory Council.
  - The QSMC is developing a quality and safety monitoring programme as part of a Quality Framework for the NCSP.

Primary HPV Screening and HPV Vaccination

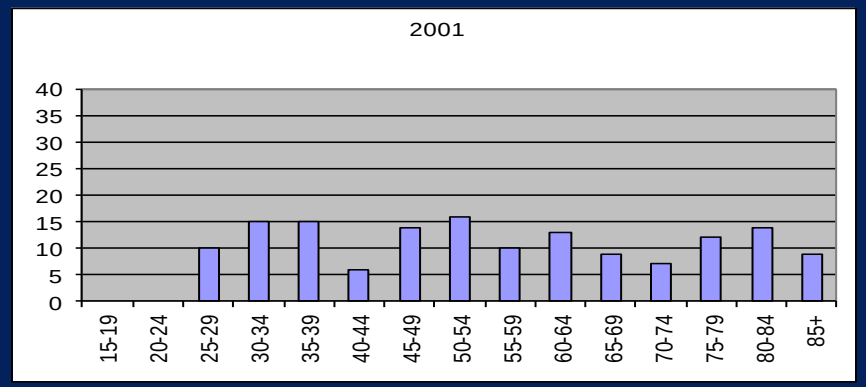
- Impact of National Cancer Screening Program in Australia.
- Impact on clinical practice.
- Impact on quality assurance in Australia.
- Future impact of clinical management guidelines, quality assurance in colposcopy, and Gardasil 9-valent.

Victorian Registry Data: Cervical Cancer incidence

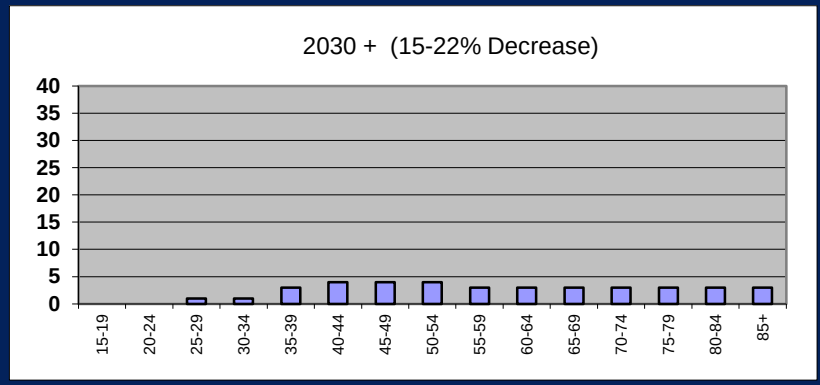
(1) Start



(2) Pre-Vaccination



(3) Post-Vaccination/HPV screening ??



Diagnostic and Therapeutic Colposcopists

Diagnostic and therapeutic colposcopy has been practised in the absence of any organised quality.

New NCSP Quality Framework.

Diagnostic Colposcopists

- Colposcopic assessment should be performed in a timely manner to ensure the safety of women at risk of cervical cancer pre-cursors.
- Women who are diagnosed with cervical cancer are appropriately referred to a certified gynaecological oncologist or gynaecological cancer treatment centre.
- All diagnostic colposcopists should participate in a colposcopy quality improvement programme in order to provide services for the NCSP. Quality standards for diagnostic colposcopists have been developed by the NCSP.
- Colposcopists provide the National Cancer Screening Register with data that will be benchmarked to the national standards for quality improvement and certification purposes. The performance data will be provided to colposcopists.

Therapeutic Colposcopists

- Treatment should be in accordance with the NCSP Clinical Management Guidelines.
- The quality of the therapeutic procedure is regularly assessed.
- All therapeutic colposcopists should participate in a colposcopy quality improvement programme in order to provide services for the NCSP.
- Quality standards for therapeutic colposcopy have been developed by the NCSP to provide guidance for individual performance review.
- The therapeutic colposcopist provides the National Cancer Screening Register with outcome data.
- Women are appropriately returned from colposcopic surveillance to routine screening in accordance with the clinical management guidelines.

Quality standards and targets for individual diagnostic and therapeutic colposcopists

(Awaiting Legislation. Not final).

Diagnostic Colposcopists

Colposcopists undertake a sufficient number of new patient colposcopies per year to maintain and improve skills in colposcopy practice (25 recommended).

The performance of a biopsy (punch or excision) in more than 95% of women with high grade cytological abnormalities (excluding pregnant women).

Of all punch biopsies taken, more than 90% should be suitable for quality histological examination.

For those with a satisfactory colposcopy:

a) the colposcopic diagnosis should be correlated with the histological diagnosis to calculate the PPV for CIN2 or greater, and this should be at least 65%;

b) predictive value of high grade cytology for high grade histology, for each colposcopist.

Quality standards and targets for individual diagnostic and therapeutic colposcopists

(Awaiting Legislation. Not final).

Therapeutic Colposcopists

All treatments must be recorded with type of treatment and include nature of anaesthesia.

All women having local ablative/destructive treatment must have had a cervical biopsy taken prior to treatment (100%).

There should be histological evidence of CIN2 or greater (biopsy or excisional specimen) in >80% of treated cases.

The number of women who are treated under local anaesthesia should be maximised (>50%).

The proportion of confirmed high grade histological abnormalities should not exceed 5% within 15 months of treatment.

Follow up of women who are treated for high grade histologic abnormality should be maximized, with at least 90% seen within 15 months of treatment.

It is expected that all colposcopists (diagnostic & therapeutic), who provide services to the NCSP, will participate in a cervical management quality assurance program

- Indication for colposcopy
- Type of Transformation Zone (Type 1, 2 or 3)
- Colposcopic impression
- Biopsy performed
- Pregnant (yes/no)
- Treatment performed (yes/no)
- Treatment modality
- Treatment anaesthetic
- Location of service

National Cancer Screening Registry

Submit minimum data set to NCSR (mandatory)

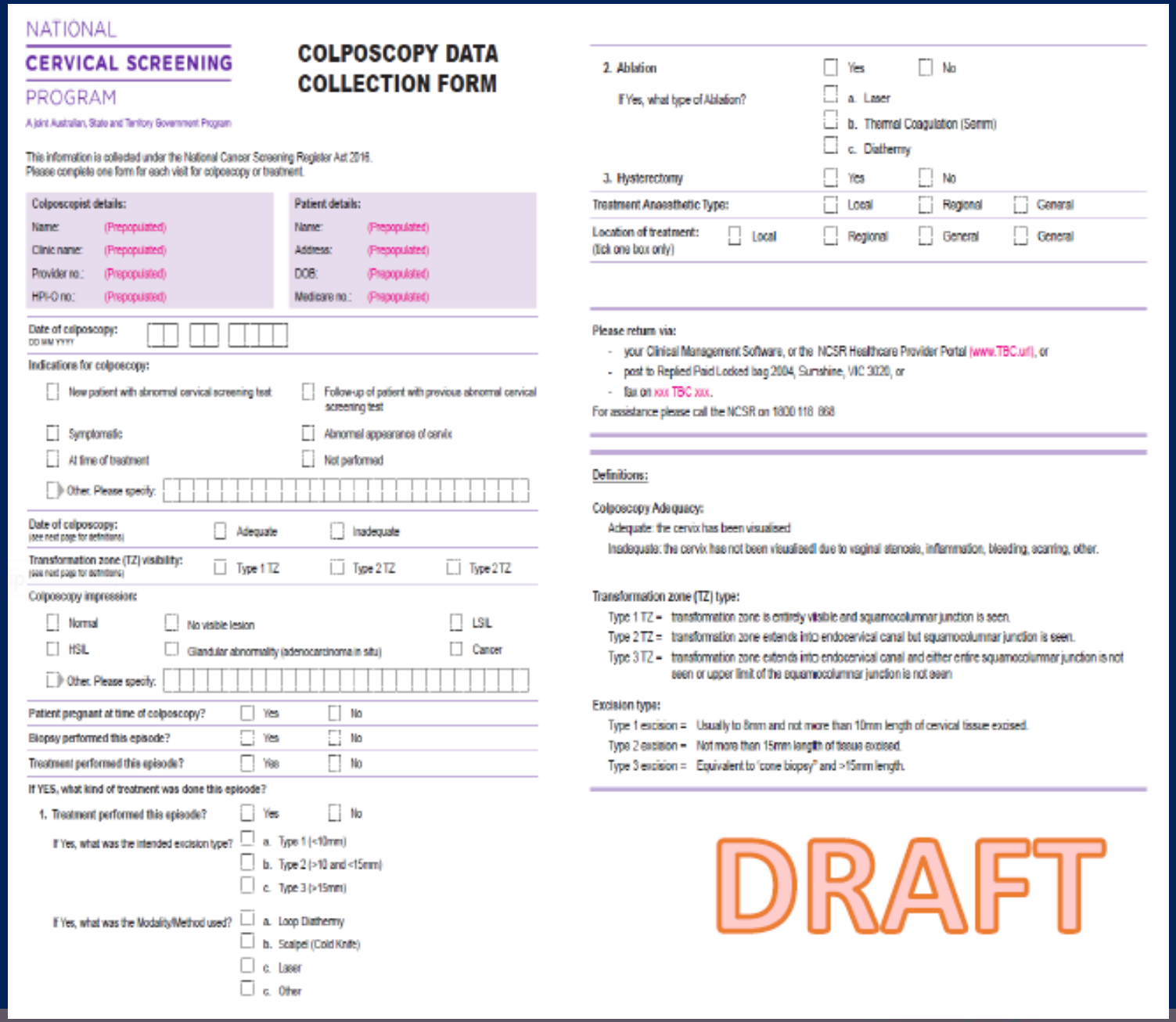
- Diagnostic and Therapeutic Colposcopy
- Electronic and paper submission

Will receive from NCSR

- Individual performance data
- Compared with peers
- Benchmarked to national standards

Participate in QA program (expected)

Colposcopy Data Collection Form
Early Provisional Draft – Awaiting Style Guide from Health



NATIONAL CERVICAL SCREENING PROGRAM

A joint Australian, State and Territory Government Program

COLPOSCOPY DATA COLLECTION FORM

This information is collected under the National Cancer Screening Register Act 2016.
Please complete one form for each visit for colposcopy or treatment.

Colposcopist details:
Name: (Prepopulated)
Clinic name: (Prepopulated)
Provider no.: (Prepopulated)
HPI-O no.: (Prepopulated)

Patient details:
Name: (Prepopulated)
Address: (Prepopulated)
DOB: (Prepopulated)
Medicare no.: (Prepopulated)

Date of colposcopy: DD MM YYYY

Indications for colposcopy:
- ☐ New patient with abnormal cervical screening test
- ☐ Follow-up of patient with previous abnormal cervical screening test
- ☐ Symptomatic
- ☐ Abnormal appearance of cervix
- ☐ At time of treatment
- ☐ Not performed
- ☐ Other. Please specify:

Date of colposcopy: (see next page for definitions) ☐ Adequate ☐ Inadequate

Transformation zone (TZ) visibility: (see next page for definitions) ☐ Type 1 TZ ☐ Type 2 TZ ☐ Type 2 TZ

Colposcopy impression:
- ☐ Normal
- ☐ No visible lesion
- ☐ LSIL
- ☐ HSIL
- ☐ Glandular abnormality (adenocarcinoma in situ)
- ☐ Cancer
- ☐ Other. Please specify:

Patient pregnant at time of colposcopy? ☐ Yes ☐ No

Biopsy performed this episode? ☐ Yes ☐ No

Treatment performed this episode? ☐ Yes ☐ No

If YES, what kind of treatment was done this episode?

1. Treatment performed this episode? ☐ Yes ☐ No
   If Yes, what was the intended excision type?
   - ☐ a. Type 1 (<10mm)
   - ☐ b. Type 2 (>10 and <15mm)
   - ☐ c. Type 3 (>15mm)
   If Yes, what was the Modality/Method used?
   - ☐ a. Loop Diathermy
   - ☐ b. Scalpel (Cold Knife)
   - ☐ c. Laser
   - ☐ c. Other

2. Ablation ☐ Yes ☐ No
   If Yes, what type of Ablation?
   - ☐ a. Laser
   - ☐ b. Thermal Coagulation (5mm)
   - ☐ c. Diathermy

3. Hysterectomy ☐ Yes ☐ No

Treatment Anaesthetic Type: ☐ Local ☐ Regional ☐ General

Location of treatment: (tick one box only) ☐ Local ☐ Regional ☐ General ☐ General

Please return via:
- your Clinical Management Software, or the NCSR Healthcare Provider Portal (www.TBC.url), or
- post to Replied Paid Locked bag 2004, Sunshine, VIC 3020, or
- fax on xxx TBC xxx.

For assistance please call the NCSR on 1800 118 868

Definitions:

Colposcopy Adequacy:
Adequate: the cervix has been visualised
Inadequate: the cervix has not been visualised due to vaginal stenosis, inflammation, bleeding, scarring, other.

Transformation zone (TZ) type:
Type 1 TZ = transformation zone is entirely visible and squamocolumnar junction is seen.
Type 2 TZ = transformation zone extends into endocervical canal but squamocolumnar junction is seen.
Type 3 TZ = transformation zone extends into endocervical canal and either entire squamocolumnar junction is not seen or upper limit of the squamocolumnar junction is not seen

Excision type:
Type 1 excision = Usually to 8mm and not more than 10mm length of cervical tissue excised.
Type 2 excision = Not more than 15mm length of tissue excised.
Type 3 excision = Equivalent to "cone biopsy" and >15mm length.

DRAFT

NCSP Quality Governance

Ensure that effective structures and processes are in place to ensure quality governance and management.

a) The Quality and Safety Monitoring Committee will **monitor the program** quality and safety and report to the Standing Committee on Screening

b) The Program Management Group will report to the Standing Committee on Screening

c) The NCSP Quality Framework is supported, implemented and monitored and there are processes for **ongoing continuous quality improvement**

d) A **periodic programme review** is embedded in the governance process to evaluate the NCSP and review current evidence.

Rapidly Changing Environment in Austraslia

- Renewal of Guidelines
- Screening 5 yearly with HPV test. Age 25-69 years.
- Call recall screening rather than opportunistic
- A National Cancer Screening Registry is being built.
- Colposcopists will be mandated to submit data to the NCSR from 1st December 2017.

- Introduction of Gardisil 9
- Therapeutic vaccines in phase 2 trials
- New HPV tests predicting HSIL

- Screening and Colposcopy:
  - Fewer HSIL cases
  - Quality monitoring, maintaining competence
  - Who should practice, who should treat, how will we treat in future?
  - Future of screening as we know it?