NATIONAL

CERVICAL SCREENING

PROGRAM

A joint Australian, State and Territory Government Program

Quality Framework

Australian Government

Endorsed by the Standing Committee on Screening at its 30 November 2017 meeting.

Contents

Introduction

The National Cervical Screening Program (NCSP) recommends participants aged 25 to 74 years of age have a five-yearly oncogenic human papillomavirus (HPV) test to prevent cervical cancer.

An effective population screening program requires comprehensive quality monitoring and evaluation systems in order to realise NCSP objectives of continued reductions in morbidity and mortality from cervical cancer. This Quality Framework defines how the NCSP is to be measured, monitored and evaluated, and how the high standards of program management and service delivery will be achieved and maintained.

The Quality Framework provides the principles and requirements that define the quality objectives for the NCSP and the suite of standards and benchmarks that will be used to monitor the performance and outcomes of the NCSP. It is for all individuals and organisations providing services as part of the cervical screening pathway.

The Quality Framework aims to:

- guide all service providers and organisations involved in the NCSP to provide high quality and safe screening services; and
- provide a comprehensive quality management system for the program in order to achieve high standards of program management, service delivery, monitoring and evaluation.

The Quality Framework will:

- support ethical practice and be consumer-centred;
- support and guide continuous quality improvement at a national, local and provider level;
- be evidence-based and informed by research;
- clearly describe the quality processes throughout the screening pathway;
- establish processes and outcomes that are measured and monitored at a program level; and
- provide accountability and transparency across the NCSP.

BACKGROUND

Since the introduction of the NCSP in 1991, there has been a 50 per cent reduction in the incidence of and mortality from cervical cancer. The policy of the screening program is underpinned by monitoring and evaluating of quality standards and jurisdictional 'Pap Test' Registers, so that all participants who participate in screening are followed up and sent reminders according to NCSP guidelines. This organised approach, along with high quality cervical cytology (Pap test) services with quality standards and a quality assurance program, has significantly contributed to the success of the NCSP.

In 2011, a renewal of the NCSP commenced. The 'Renewal' reviewed the policies and delivery of the NCSP in light of significant changes in science, technology and knowledge of the natural history of cervical cancer. Following a comprehensive review of the evidence and a modelled evaluation, in April 2014 the Medical Services Advisory Committee (MSAC) recommended that a five-yearly oncogenic primary HPV test replace the two-yearly Pap test.

In May 2015, the Australian Government accepted the recommendations of MSAC and agreed to implement the renewed NCSP. The planning for implementation of the MSAC recommendations commenced in July 2015 and the renewed NCSP policy was developed (Appendix A). The renewed screening pathway is depicted at Appendix B.

The renewed NCSP is supported by:

- a new Program governance framework;
- a new National Cancer Screening Register (NCSR) (ncsr.gov.au);
- Cancer Council Australia's *National Cervical Screening Program: Guidelines for the management of screen detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding* (2016 Guidelines) (wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening);
- the Quality Framework;
- the NCSP Program Performance Indicators (Appendix C);
- National Pathology Accreditation Advisory Council (NPAAC) *Requirements for laboratories reporting tests for the National Cervical Screening Program* (health.gov.au/internet/main/publishing.nsf/Content/npaac-cervical-screening) (Appendix D) and National Association of Testing Authorities (NATA) accreditation of pathology laboratories;
- Quality standards and targets for individual colposcopists (Appendix E) and Colposcopy Quality Improvement Program (C-QuIP);
- National competencies for cervical screening providers (Appendix F); and
- Royal Australian College of General Practitioners Standards for General Practice (racgp.org.au/your-practice/standards/standards-for-general-practices-(5th-edition/) and general practice accreditation.

The register function for the NCSP was also reviewed as part of the Renewal. Commonwealth, state and territory governments agreed that the register functions would be provided through the new NCSR. The NCSR records demographic details and test results for all participants across the country, so that all participants in the NCSP's target age range receive timely invitations, reminders and follow-up according to program guidelines. It also supports safety and quality monitoring and quality improvement processes for the NCSP.

A NEW ERA FOR CERVICAL SCREENING

The renewed NCSP is the advent of a new era for cervical screening in Australia where the primary screening test is now a disease risk marker for cervical cancer.

The HPV test will indicate a woman's risk of developing cervical cancer by detecting the presence of oncogenic HPV in the cells of the cervix. If oncogenic HPV is not detected, the woman is at low risk of developing significant cervical cancer precursors within the next five years.[1]

If oncogenic HPV is detected, the specimen will undergo a second test (reflex liquid based cytology) to determine whether the woman has a cervical abnormality and is at intermediate or higher risk of having a significant cervical abnormality.[2] Allocation of risk levels will determine what follow-up is required to prevent cervical cancer. Table 1 describes the risk levels and the screening pathway presented at Appendix B indicates the follow-up required for each risk level.[3]

Table 1: Definitions of risk levels

Risk level	Screening test results
Low risk	• Oncogenic HPV not detected
Intermediate risk	• Oncogenic HPV not 16/18 detected with no cervical abnormality detected on cytology; or • Oncogenic HPV not 16/18 detected with a possible or definite low grade abnormality detected on cytology
Higher risk	• Oncogenic HPV 16 and/or 18 detected (regardless of cytology result); or • Oncogenic HPV not 16/18 detected with a possible or definite high grade squamous or any glandular abnormality detected on cytology

[1] Shortened screening intervals in accordance with the 2016 Guidelines are recommended for immune-deficient (3-yearly) and women exposed to DES and their daughters if required (annually).

[2] For clinician-collected specimens, reflex Liquid Based Cytology (LBC) can be performed on the same cervical specimen (without requiring an additional request) and the pathology lab will issue the HPV test result, LBC test result and overall screening risk rating as a combined report. Self-collection of a vaginal sample can only be tested for HPV. A new pathology request will be required for the clinician-collected specimen for reflex LBC testing only. The pathology lab will then issue a combined report with the initial self-collect HPV test, LBC test result and overall screening risk rating as a combined report.

[3] Some HPV test platforms report HPV 18 and 45 together. For assays that do not distinguish between oncogenic HPV 18 and 45, a woman in whom type 18/45 is detected should be managed as for participants with a test result of oncogenic HPV (16/18) detected.

QUALITY FRAMEWORK

The NCSP aims to prevent cervical cancer by promoting cervical screening to asymptomatic participants. It is therefore paramount that the cervical screening pathway, from recruitment through to diagnosis, is supported by high quality services so that the benefits of screening outweigh the harms.

The Quality Framework outlines the principles of quality for the NCSP and how they should be applied as well as the requirements or actions that ensure service providers deliver safe and high quality services. Service providers across the cervical screening pathway include:

- healthcare providers;
- pathology laboratories;
- diagnostic and therapeutic colposcopists;
- Commonwealth and state and territory governments managing the NCSP; and
- NCSR operator/s.

PRINCIPLES OF QUALITY FOR THE NCSP

These principles provide the basis for achieving a high quality cervical screening program and have been informed by the Australian Safety and Quality Framework for Health Care.

1. The NCSP promotes ethical practice and is consumer-centred.
2. The NCSP is evidence-based and informed by research.
3. The NCSP is designed to protect the safety of participants.
4. The benefits of cervical screening in the screening population must outweigh the harms.
5. The NCSP aims to achieve equitable access to screening services for all eligible participants, irrespective of their geographic, socioeconomic, disability or cultural background.
6. All service providers across the screening pathway commit to delivering quality services, participate in continuing professional development and engage in quality improvement activities.
7. Continuous quality improvement is supported at a national, state and territory and provider level.
8. The governance framework will support the NCSP to remain safe, effective and cost-effective.
9. The performance and outcomes of the NCSP are monitored and evaluated on a regular basis.
10. Quality and safety is monitored across the entire screening pathway.

Table 2 (on pages 6–11) shows the principles of quality for the NCSP and how they are applied.

Table 2: Principles of quality for the NCSP and how they are applied

Principle	**1. The NCSP promotes ethical practice and is consumer-centred**	**Who is responsible?**
Relevant NCSP Policy Objectives	• *Provide cervical screening that is equitable, accessible and appropriate to Australian participants.*	
How the principles are applied within the NCSP	Providers deliver cervical screening services in accordance with the highest standards of professional behaviour and ethical conduct, so that participants are partners in all decision-making regarding their care and treatment.	• Healthcare providers • Therapeutic and diagnostic colposcopists (Colposcopists)
	Participant's experience with NCSP service providers will be consumer-centred, ethical, respectful, culturally safe and appropriate to her needs.	• All service providers
	Participant's informed consent will be obtained before each examination, investigation or treatment along the cervical screening pathway in accordance with relevant guidelines.[4] (Informed consent does not have to be in writing).	• Healthcare providers • Colposcopists
	The privacy and confidentiality of participants is maintained at all times.[5]	• All service providers
	Participants who are eligible and wish to undertake self-collection (policy provided at Appendix A) are adequately informed by the cervical screening provider or delegate on the risks and benefits of clinician-collected specimens and self-collected vaginal samples, and how to self-collect the specimen.	• Healthcare providers
	Healthcare providers offering the self-collection option should have an empathic understanding of the barriers and reasons why participants tend not to participate in cervical screening and utilise available and relevant resources to effectively address these barriers.	• Healthcare providers
	Participant's specimens are managed in accordance with guidelines.[6]	• Healthcare providers • Colposcopists • Pathology laboratories
	Information resources are available to participants regarding screen-detected abnormalities and follow up testing and treatment.	• Commonwealth, state and territory governments managing the NCSP • Healthcare providers
	The diagnostic and therapeutic colposcopist adequately informs the woman and her healthcare provider or delegate of any follow-up that may be required in accordance with the 2016 Guidelines.	• Colposcopists
	Healthcare providers or delegates and colposcopists notify participants of their cervical test results and recommendation in an appropriate and timely manner and follow up participants when they are due to have a follow-up test.	• Healthcare providers • Colposcopists
Principle	**2. The NCSP is evidence based and informed by research**	**Who is responsible?**
Relevant NCSP Policy Objectives	• Provide quality program management, monitoring, evaluation and accountability.	
How the principles are applied within the NCSP	The NCSP is developed from MSAC recommendations based on an independent evaluation of current evidence and supported through the listing on the Medicare Benefits Schedule (MBS).	• Commonwealth, state and territory governments managing the NCSP
	Participants are appropriately treated and returned from colposcopic surveillance to routine screening in accordance with the 2016 Guidelines.	• Colposcopists • Healthcare providers • NCSR

	NCSP policies are reviewed as new evidence, screening technologies and management guidelines become available by the Standing Committee on Screening (SCoS).	• Commonwealth, state and territory governments managing the NCSP • SCoS
	Monitoring and evaluation should be informed by research and evidence and utilised in planning and management. Research should also be generated to inform future activities.	• Commonwealth, state and territory governments managing the NCSP • SCoS
Principle	**3. The NCSP is designed to protect the safety of participants**	**Who is responsible?**
Relevant NCSP Policy Objectives	• *Minimise the harms of cervical screening.* • *Provide safe and effective services in accordance with the Quality Framework.* • *Provide quality program management, monitoring, evaluation and accountability.*	
How the principles are applied within the NCSP	The NCSR sends invitations and reminders to participants as they become due to screen or rescreen, and if relevant to complete further testing in accordance with the national follow-up protocols.	• NCSR
	The NCSR sends reminders to healthcare providers or delegate and participants, in accordance with the national follow-up protocols, when further testing becomes overdue.	• NCSR
	The NCSR maintains a record of all episodes of care delivered within the NCSP[7] including screening, assessment, treatment and follow up (up to and including a diagnosis of cervical cancer).	• Healthcare providers • Colposcopists • Pathology laboratories • NCSR
	The NCSR provides the screening history of participants to healthcare providers or their delegate and pathology laboratories to aid in clinical decision-making.	• NCSR
	Healthcare providers or delegates take responsibility for follow-up of unsatisfactory and abnormal test results and encourage participants to continue along the screening pathway until either they return to routine screening or are supported to transition into a treatment pathway.	• Healthcare providers
	Pathology laboratories adhere to the NPAAC *Requirements for laboratories reporting tests for the National Cervical Screening Program* to ensure the performance of the oncogenic HPV test is suitable for population based screening.	• Pathology laboratories
	For participants who require colposcopic assessment, appropriate referrals are provided by all eligible healthcare providers who are able to refer as well as advice on the recommended timeframe to have this follow-up test.	• Healthcare providers
	The NCSR provides colposcopists with individual performance data benchmarked to national standards for quality improvement.	• NCSR
	Colposcopic assessment should be performed in a timely manner to ensure the safety of participants at risk of cervical abnormalities.	• Private providers and public health clinics performing colposcopy services
	Participants who are diagnosed with cervical cancer are appropriately referred to a certified gynaecological oncologist or gynaecological cancer treatment centre for further assessment and/or treatment.	• Colposcopists • Healthcare providers

Principle	4. The benefits of cervical screening in the screening population must outweigh the harms	Who is responsible?
Relevant NCSP Policy Objectives	• *Reduce the mortality and morbidity attributable to cervical cancer.* • *Maximise the proportion of participants, 25 to 74 years, who are screened every five years.* • *Minimise the harms of cervical screening.* • *Provide safe and effective services in accordance with the Quality Framework.*	
How the principles are applied within the NCSP	The NCSP is developed from MSAC recommendations based on an independent evaluation of current evidence and supported through the listing on the MBS.	• Commonwealth, state and territory governments managing the NCSP
	Cervical screening is carried out in accordance with the policies and guidelines of the NCSP.	• Healthcare providers • NCSR
	Clinical decisions are evidence-based and informed by the 2016 Guidelines.	• Healthcare providers • Colposcopists • Pathology laboratories
	The benefits and harms are assessed through monitoring of Program Performance Indicators, Quality Standards, Safety Monitoring Parameters and other investigations to support Program operations are undertaken to support quality improvement activities.	• Commonwealth, state and territory governments managing the NCSP
Principle	**5. The NCSP aims to achieve equitable access to screening services for all eligible Australian participants, irrespective of their geographic, socioeconomic, disability or cultural background**	**Who is responsible?**
Relevant NCSP Policy Objectives	• *Maximise the proportion of participants, 25 to 74 years, who are screened every five years.* • *Provide cervical screening that is equitable, accessible and appropriate to Australian participants.*	
How the principles are applied within the NCSP	Active recruitment strategies are in place at national, state and territory, Primary Health Network and practice levels to encourage participation and improve equity of access in the NCSP, including specific activities for under-screened and never-screened participants.	• Commonwealth, state and territory governments managing the NCSP • NCSR • Healthcare providers
	Patterns of participation are monitored by socioeconomic, geographical, ethnic and cultural profiles to inform recruitment activities that target under-represented populations.	• Commonwealth, state and territory governments managing the NCSP
	Culturally sensitive resources are available for Aboriginal and Torres Strait Islander participants, and culturally and linguistically diverse participants.	• Commonwealth, state and territory governments managing the NCSP • Healthcare providers
	Culturally sensitive resources are available for participants with disabilities, low literacy and hearing or vision impaired.	• Commonwealth, state and territory governments managing the NCSP • Healthcare providers
	Participants are offered access to interpreter services when required (information on interpreter services can be accessed from www.tisnational.com.au) or teletypewriter (TTY) when required (information on interpreter services can be accessed from www. relayservice.gov.au).	• Commonwealth, state and territory governments managing the NCSP • NCSR • Healthcare providers • Colposcopists

Principle	6. All service providers across the screening pathway commit to delivering quality services, participate in continuing professional development and engage in quality improvement processes	Who is responsible?
Relevant NCSP Policy Objectives	• *Provide safe and effective services in accordance with the Quality Framework.*	
How the principles are applied within the NCSP	Healthcare providers maintain correct clinical practice and are appropriately trained in cervical screening, in line with the NCSP competency guidelines (Appendix F).	• Healthcare providers
	Pathology laboratories participate in an external quality assurance program for HPV testing and cervical cytology in accordance with the NPAAC *Requirements for laboratories reporting tests for the National Cervical Screening Program.*	• Pathology laboratories • Royal College of Pathologists of Australasia (RCPA) Quality Assurance Program (QAP) • Professional colleges and peak bodies
	Pathology laboratories provide healthcare providers with performance data to support their personal quality assurance and improved performance.	• Pathology laboratories
	The NCSR provides reports to laboratories and colposcopists with performance data for quality improvement and certification purposes.	• NCSR
	The quality of the colposcopic assessment and therapeutic procedure is regularly assessed. All diagnostic and therapeutic colposcopists should participate in a colposcopy quality improvement program. Quality standards for diagnostic and therapeutic colposcopists have been developed by the NCSP to provide guidance for individual performance review (Appendix E).	• Colposcopists • Royal Australian and New Zealand College of Obstetrics and Gynaecologists (RANZCOG) Colposcopy Quality Improvement Program (C-QuIP) • Professional colleges and peak bodies
	Service providers monitor and evaluate their own performance to maintain and where needed improve the services they provide.	• All service providers
Principle	**7. Continuous quality improvement is supported at a national, state and territory and provider level**	**Who is responsible?**
Relevant NCSP Policy Objectives	• *Provide safe and effective services in accordance with the Quality Framework.* • *Provide quality program management, monitoring, evaluation and accountability.*	
How the principles are applied within the NCSP	All program stakeholders use the Quality Framework for the NCSP for guidance on quality principles and requirements for delivery of the program.	• All stakeholders
	Program management at national and state and territory levels includes a focus on continuous quality improvement through monitoring and addressing issues, safety issues, trends and complaints and proactive identification of opportunities for improvement and innovation.	• Commonwealth, state and territory governments managing the NCSP
	The Quality Framework is reviewed and updated as required.	• Commonwealth, state and territory governments managing the NCSP
	Healthcare providers and laboratory staff engage in relevant professional development and quality assurance activities.	• Healthcare providers • Pathology laboratory staff

Principle	8. The governance framework will support the NCSP to remain safe, effective and cost effective	Who is responsible?
Relevant NCSP Policy Objectives	• *Provide safe and effective services in accordance with the Quality Framework.* • *Provide quality program management, monitoring, evaluation and accountability.*	
How the principles are applied within the NCSP	The NCSP has a governance structure that provides effective leadership and oversight of the organised approach to cervical screening.	• Commonwealth, state and territory governments managing the NCSP
	The governance structure supports appropriate monitoring and evaluation so that the program is safe and effective.	• Commonwealth, state and territory governments managing the NCSP
	Health services delivering cervical screening services have governance systems that actively manage the service(s) provided to maximise safety and minimise risk.	• Health services
	The health service identifies and assesses safety and risk at regular intervals and implements any identified needed change(s) to practice.	• Health services
Principle	**9. The performance and outcomes of the NCSP are monitored and evaluated on a regular basis**	**Who is responsible?**
Relevant NCSP Policy Objectives	• *Reduce the mortality and morbidity attributable to cervical cancer.* • *Maximise the proportion of participants, 25 to 74 years, who are screened every five years.* • *Provide quality program management, monitoring, evaluation and accountability.*	
How the principles are applied within the NCSP	The NCSR provides timely reports and register data to Commonwealth and state and territory health programs including participation rates by all participants and specified demographic groups to enable monitoring and evaluation of the NCSP and the development of recruitment strategies.	• NCSR • Quality and Safety Monitoring Committee (QSMC)
	The healthcare provider ascertains the woman's Indigenous status, language spoken at home and country of birth. These demographic data are recorded on the pathology request form where possible.	• Healthcare providers
	Pathology laboratories provide all cervical test reports to the NCSR. This includes associated demographic data such as a woman's Indigenous status, language spoken at home and country of birth where provided on the pathology request form.	• Pathology laboratories
	Colposcopists provide the NCSR with data in accordance with the minimum standards and targets as outlined at Appendix E.	• Colposcopists
	The incidence and mortality from cervical cancer are monitored by the NCSP and reported annually in accordance with the National Performance Indicators.	• Australian Institute of Health and Welfare (AIHW) • Commonwealth, state and territory governments managing the NCSP • QSMC
	Monitoring and evaluation are undertaken in a timely manner to ensure the ongoing quality and safety of the NCSP.	• Commonwealth, state and territory governments managing the NCSP • QSMC
	A current NCSP Data Dictionary is available for consistency in national reporting.	• Commonwealth, state and territory governments managing the NCSP • AIHW

	National Performance Indicators are reported annually and available to the public.	• Commonwealth, state and territory governments managing the NCSP • AIHW
	The NCSR provides timely high quality data, reports and information to enable research, monitoring and evaluation activities.	• NCSR
Principle	**10. Quality and safety is monitored across the entire screening pathway**	**Who is responsible?**
Relevant NCSP Policy Objectives	• *Provide safe and effective services in accordance with the Quality Framework.* • *Provide quality program management, monitoring, evaluation and accountability.*	
How the principles are applied within the NCSP	Standards and performance measures are monitored annually by the NCSP in accordance with the Quality Framework and the Program Performance Indicators.	• Commonwealth, state and territory governments managing the NCSP • QSMC
	Safety monitoring activities are undertaken to promote the safety of participants.	• Commonwealth, state and territory governments managing the NCSP • QSMC • NCSR
	The Quality Framework is maintained to guide and monitor the delivery of cervical screening services that promote safety, effectiveness and high quality.	• Commonwealth, state and territory governments managing the NCSP
	A QSMC will monitor the safety and quality of the NCSP.	• Commonwealth, state and territory governments managing the NCSP • QSMC
	Processes are in place at all steps of the screening pathway to obtain optimal data quality, completeness and integrity.	• Commonwealth, state and territory governments managing the NCSP • QSMC • SCoS • Pathology laboratories • NCSR

[4] The information that doctors need to give to patients is detailed in guidelines issued by the National Health and Medical Research Council (NHMRC, 2004. General Guidelines on for medical practitioners on providing information to patients; and NHMRC, 2004. Communicating with patients – advice for medical practitioners). The Australian Health Practitioner Regulation Agency requires health providers to adhere to relevant Board guidelines on code of conduct including obtaining informed consent from patients before an examination, investigation or treatment is undertaken.

[5] Adherence to current Federal and state legislation on privacy by all providers in the screening pathway

[6] Including the RCPA guidelines on 'The Ethical and Legal Issues in Relation to the Use of Human Tissue and Test Results in Australia'

[7] The NCSR will not maintain a record of participants who participate in the NCSP, who have opted-out of the NCSR.

QUALITY AND SAFETY IN PRACTICE

The NCSP has a clinical and corporate governance structure that is responsible for monitoring its achievement of NCSP aims and objectives. A detailed Governance Framework for the NCSP is being developed.

The SCoS of the Australian Health Ministers' Advisory Council has a role in providing leadership and national direction on policy, implementation and monitoring of the NCSP. The SCoS receives advice from the QSMC and the Program Management Group on quality and safety issues as they arise.

The NCSP monitors reports on program performance, quality and safety through its clinical and corporate governance structure. These reports can alert the NCSP to overarching program safety and quality issues. Operational issues at a national, jurisdictional, local or service provider level are also identified through the jurisdictional Program Management Group, the NCSR operator/s, service providers and participants.

In the event that a quality or safety concern is identified that impacts, or potentially could impact, on the safety of participants the process for managing quality and safety concerns will be put into action (Appendix G) by the QSMC and/or Commonwealth and state and territory Program Managers. The role of the Committee will primarily be to make sure this happens and the Program Managers will assist with implementation.

The Australian Safety and Quality Framework for Healthcare and associated resources and tools produced by the Australian Commission on Safety and Quality in Healthcare can be used to assist individuals and organisations understand their roles and responsibilities in providing safe and quality healthcare services including cervical screening.

The NCSP supports quality improvement by providing the performance data required for both individual performance review and submission to quality assurance and accreditation/certification programs. The NCSR provides annual reports to individuals and organisations against agreed standards and benchmarks compared to the national average. Individual service providers are encouraged to be responsible for undertaking their own quality improvement activities where the data indicates performance could be improved.

QUALITY OF PROGRAM REGISTER SERVICES

The NCSP is supported by the NCSR through the collection, storage, analysis and reporting of cervical screening and diagnostic data. It will facilitate invitations and reminders for screening, reminders for follow-up and support clinical decision making along the entire cervical screening pathway. Monitoring the quality of program register services is integral to ensuring the NCSP is delivered to a high standard.

The NCSR is delivered through a third party contractor under a Service Agreement with the Commonwealth Department of Health. Under the NCSP governance arrangements, the QSMC will have a role in providing advice on the quality of NCSR services through qualitative methods (TBD) and will report to SCoS and the Commonwealth.

It is expected that the NCSR facilitates the collection of all data required to support the NCSP and undertakes the necessary actions to support:

- participants along the cervical screening pathway;
- timely clinical decision making through the provision of screening histories to pathology laboratories and healthcare providers;
- the reporting requirements of the Commonwealth and state and territory governments;
- jurisdictional planning and evaluation of health promotion, recruitment and education initiatives; and
- research relating to cervical cancer and its prevention.

Quality reports will be produced by the NCSR as part of its day-to-day operations to review data quality, completeness and integrity and make improvements as required.

The NCSR operator will make sure agreed robust and transparent monitoring of its own performance and quality management systems are in place and report to the Commonwealth through the Service Level Agreements. Where required, the NCSP could seek an external review of NCSR services.

QUALITY OF PROGRAM DATA

The quality of program data is a key component for evaluating achievement of a high quality NCSP. The NCSR operator will undertake quality improvement activities as part of the continuous improvement outcome required in the contracted service; and work with the Commonwealth, state and territory governments managing the NCSP to remedy any quality concerns with program data. The following activities will be undertaken:

- The NCSR operator will monitor data quality, completeness and integrity and undertake activities to improve these over time;
- The NCSR operator will notify the Commonwealth and state and territory programs when data quality issues arise;
- Where data from providers and pathology laboratories are found to have quality issues the NCSR, Commonwealth, states and territories will engage with peak bodies to facilitate quality improvement; and
- The NCSP QSMC will monitor key program data quality measures (as listed in the Quality Standards) and provide advice to the NCSR operator and SCoS on improvement activities.

QUALITY STANDARDS, MEASURES AND BENCHMARKS

The following pages outline the quality standards, measures and benchmarks for the NCSP. The quality standards reflect a level of quality that should be attained by service providers and the program as a whole, and will be used to monitor delivery and outcomes of the NCSP. Standards can be qualitative or quantitative in nature. All the quality and safety standards will require data or information to be collected in order to be monitored by the NCSP.

The quality measures indicate how the quantitative standards will be measured. Qualitative standards will require a different monitoring process. In the early years of the renewed NCSP, complaints and queries through the NCSR and the Cancerscreening website will be monitored and it is intended that Patient Reported Experience Measures and Patient Reported Outcomes Measures (TBD) will also be used. These qualitative standards and a process for their monitoring are yet to be determined. The QSMC will develop this process as the renewed NCSP is established.

The quality benchmarks will be used to indicate whether the NCSP is reaching its goal to support high quality and safe services, and participation. As the renewed NCSP is a new screening paradigm, benchmarks will be calculated from NCSP experience. Some benchmarks are therefore listed as To Be Determined (TBD). Data collection and regular monitoring will be required to establish benchmarks for these standards. The standards, measures and benchmarks will be reviewed five years after implementation of the renewed NCSP to review existing benchmarks and establish benchmarks from collected data where none have been set.

Table 3 provides the quantitative standards, measures and benchmarks for the NCSP.

Table 3: Quantitative Quality Standards, Measures* and Benchmarks for the NCSP

* All measures will be broken down, where appropriate, by the following parameters: age, state and territory, Public Health Network, geographic area, socioeconomic status, Aboriginal and/or Torres Strait Islander status, culturally and linguistically diverse status and HPV vaccination status.

Standard		Measure	Benchmark
1.	The number of participants participating in the NCSP is maximised and access to cervical screening services is equitable.	Five-yearly participation rate (NCSP Program Performance Indicator 1)	TBD
2.	The response rate to invitations is maximised.	Proportion of participants who screen within 6 months of an invitation being sent (NCSP Program Performance Indicator 2).	TBD
3.	Compliance with the screening pathway in the recommended timeframes is maximised.	• Rescreen rate (NCSP Program Performance Indicator 3). • Proportion of participants who have a repeat oncogenic HPV test at 12 months following the index test, where this is indicated. • Proportion of participants with oncogenic HPV (any type) detected and cytology invasive or possible invasive cancer (squamous, glandular or other) having a colposcopy within 2 weeks of the primary screening test result. • Proportion of participants with oncogenic HPV (any type) detected and cytology HSIL or pHSIL having a colposcopy within 8 weeks of the primary screening test result. • Proportion of participants with oncogenic HPV (16/18) detected and cytology negative, LSIL or pLSIL having a colposcopy within 12 weeks of the primary screening test result. • Proportion of participants with oncogenic HPV (any type) detected on 12-month repeat test and cytology negative, LSIL or pLSIL having a colposcopy within 12 weeks of the repeat HPV test result. • Proportion of participants with oncogenic HPV (any type) detected on 12-month repeat test and cytology HSIL, pHSIL or glandular having a colposcopy within 8 weeks of the repeat HPV test result.	TBD
4.	Healthcare providers should collect a sufficient number of cervical specimens per year to maintain or improve skills in sample collection.	Proportion of healthcare providers collecting fewer than 30 specimens per year.[8,9]	TBD
5.	Minimise the proportion of ineligible participants accessing self-collection.	Proportion of ineligible participants who self-collect outside of the self-collect eligibility criteria is at Appendix A.	TBD
6.	The unsatisfactory rate of screening tests is minimised.	Frequency and proportion of screening episodes reported as 'unsatisfactory' as defined in the 2016 Guidelines[10] (NPAAC Performance Measure 1) Stratify by: • HPV NAT unsatisfactory or reflex LBC unsatisfactory • If HPV NAT unsatisfactory, stratify by HPV test type • screening episode eg 'routine screening', 'self-collection' or 'other (includes symptomatic individuals, test of cure, etc)' • healthcare provider type[11]	TBD
7.	Pathology laboratories meet the NPAAC Performance Measures and Standards.	Proportion of pathology laboratories meeting the NPAAC Performance Measures by each measure.	TBD[12]

8.	Participants who have oncogenic HPV (any type) detected from a self-collected sample have a follow-up test within the recommended timeframe according to the 2016 Guidelines.	Proportion of participants with oncogenic HPV (any type) detected in the self-collection pathway who: • have a reflex LBC test; and • have a colposcopy within six months (AIHW Performance Indicator 8 and 9).	TBD
9.	Colposcopists should manage a sufficient number of new cases per year to maintain and improve skills in colposcopy practice.	Proportion of colposcopists managing less than 25 new cases per year[13].	TBD
10.	Colposcopists meet the individual standards and targets for diagnostic and therapeutic colposcopy practice.	National average for each individual diagnostic and therapeutic colposcopy standard per year.	TBD
11.	The cytological prediction of a high grade abnormality should be correlated with the histological diagnosis to calculate the PPV for HSIL.	Proportion of LBC specimens reported as possible HSIL/HSIL where cervical histopathology, taken within six months, confirms the abnormality as HSIL, AIS or cervical malignancy (NPAAC Performance Measure 3a and 3b).	TBD
12.	Participants who have oncogenic HPV (any type) detected, with a cytology report of adenocarcinoma in situ or possible high grade glandular abnormality who undergo excisional treatment according to the 2016 Guidelines.	The proportion of oncogenic HPV (any type) detected participants with a cytological report of adenocarcinoma in situ or possible high grade glandular abnormalities who undergo excisional treatment.	100%
13.	Participants diagnosed with HSIL are treated within the recommended timeframe according to the 2016 Guidelines.	Proportion of oncogenic HPV (any type) detected participants with HSIL, excluding pregnant participants, who are treated within 12 weeks[14] of histological confirmation.	90%
14.	The number of participants diagnosed with cervical cancer is minimised.	Incidence (Performance Indicator 19).	6.8
15.	Data quality, integrity and completeness in the NCSR are maximised.	• Proportion of eligible participants opting out of the NCSR by type: - Opt out of the NCSR; or - Opt out of NCSR correspondence. • Proportion of participants for whom Aboriginal and/or Torres Strait Islander and culturally and linguistically diverse data are held in the NCSR compared to ABS estimates. • Proportion of colposcopy data not submitted within 2 months. • Proportion of Return to Sender (RTS) flags within 3 months. • Proportion of unmatched/possible matched records to DHS/IHI data	TBD

[8] Caveat re update and use of provider identifier HPI-I, ie intended to identify test taker.

[9] This is not for monitoring individuals.

[10] The NCSP considers unsatisfactory screening results may occur either because the HPV test cannot be performed or because LBC, when indicated, cannot be evaluated.

[11] This is intended to refer to the test taker.

[12] Prior to the development of benchmark need to have the proportion of laboratories reporting all required data against the NPAAC Performance Measures.

[13] The NCSP considers 25 new cases per year to be the minimum number of cases required to ensure skills are maintained in the clinical management of participants referred to colposcopy.

[14] This timeframe is not based on a clinical requirement but considered reasonable to reduce the potential anxiety caused to participants requiring treatment.

SAFETY MONITORING PARAMETERS

There is strong evidence supporting transitioning from two-yearly Pap testing to five-oncogenic yearly HPV testing. The NCSP will monitor safety parameters to ensure the NCSP remains safe and meets its expected outcomes throughout transition period and beyond. Parameters monitored will include:

Parameter	Safety monitoring protocol
Test performance	1 Monitor the performance of the screening test by HPV positivity rate, measured quarterly: a) using COMPASS data to inform expected HPV positivity rates in the first round of screening; and a) using modelled predictions to inform expected HPV positivity rates in future.
Participants who have an oncogenic HPV not detected test result	2 Introducing a time-limited early recall for a proportion of HPV negative participants at 2.5 years to retest a random population sample in a single jurisdiction.
	3 Review expected rates at different time frames using historical data from the jurisdictional Pap Test Registers direct estimate of longitudinal HSIL (CIN2 and CIN3) rates in cytology negative participants.
2016 Guidelines recommendations for intermediate risk participants	4 Safety monitoring methodology for the 2016 Guidelines recommendations for intermediate risk participants: a) using COMPASS data to inform expected intermediate risk rates in the first round of screening; and a) using modelled predictions to inform expected intermediate risk rates in future.
2016 Guidelines recommendations for higher risk participants	5 Safety monitoring methodology for the 2016 Guidelines recommendations for higher risk participants: a) using COMPASS data to inform expected higher risk rates in the first round of screening; and a) using modelled predictions to inform expected higher risk rates in future.
Cervical cancer case reviews	6 National cervical cancer case review of the screening history of participants diagnosed with cervical cancer: a) classification of screening history; and a) classification of vaccination history.

ABBREVIATIONS

AIHW	Australian Institute of Health and Welfare
AIS	Adenocarcinoma in situ
C-QuIP	Colposcopy Quality Improvement Program
DES	Diethylstilboestrol
DHS	Department of Human Services
HSIL	High-grade squamous intraepithelial lesion
HPV	Human papillomavirus
HPV NAT	Human papillomavirus nucleic acid testing
IHI	Individual Healthcare Identifier
LSIL	Low-grade squamous intraepithelial lesion
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NATA	National Association of Testing Authorities
NCSP	National Cervical Screening Program
NCSR	National Cancer Screening Register
NPAAC	National Pathology Accreditation Advisory Council
pHSIL	Possible high-grade squamous intraepithelial lesion
pLSIL	Possible low-grade squamous intraepithelial lesion
PPV	Positive predictive value
RANZCOG	Royal Australian College and New Zealand College of Obstetricians and Gynaecologists
RCPA	Royal College of Pathologists of Australasia
RTS	return to sender
SCoS	Standing Committee on Screening
QAP	Quality Assurance Program
QSMC	Quality and Safety Monitoring Committee
TBD	To be determined
TIS	Translating and Interpreting Service
TTY	Teletypewriter
2016 Guidelines	National Cervical Screening Program: Guidelines for the management of screen detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding

GLOSSARY

Abnormality	Unusual cell changes.
Aboriginal and/or Torres Strait Islander person	An Aboriginal and/or Torres Strait Islander person is a person of Aboriginal and/or Torres Strait Islander descent who identifies as an Aboriginal and/or Torres Strait Islander person and is accepted as such by the community in which he or she lives.
Active recruitment strategies	Strategies designed to actively use opportunities to target participants to participate in and complete routine screening.
Benchmark	A standard or point of reference against which performance may be compared. Can be either qualitative or quantitative in nature and are used to help participants to commit to quality improvement.
Biopsy of the cervix	Removal of a small piece of the cervix for examination.
Cervical cancer precursors	A histologically confirmed abnormality of the cervix that may lead to the development of cervical cancer.
Cervical Cancer Prevention Data Dictionary	Defines the structure of data within a database to control and maintain large databases.
2016 Guidelines	The 2016 Guidelines have been developed to assist participants and healthcare providers to achieve the best outcomes in the management of abnormal HPV test results and for individuals who have symptoms.
Colposcopist	Any health professional who is qualified to perform a colposcopy. They may be qualified to only perform a diagnostic colposcopy examination (diagnostic colposcopist) or they may also be qualified to perform treatment procedures (therapeutic colposcopist).
Colposcopy	The examination of the cervix and vagina with a magnifying instrument called a colposcope to check for abnormalities.
Consumer	A generic term for a patient, potential patient, carer, organisation representing consumers' interests, or member of the public, who is the target of the NCSP.
Culturally and linguistically diverse	Culturally and linguistically diverse communities are those made up of individuals for whom English is not their primary language, or who were born into a culture significantly different to the dominant Australian culture.
Cytology	The study of cells, their origin, structure and function.
Gynaecological oncologist	A gynaecologist who has had special training in caring for individuals with gynaecological cancers.
Gynaecologist	A specialist in the health of individuals and their reproductive organs.
Healthcare provider	Healthcare providers include appropriately trained medical practitioners and specialists in cervical screening as well as non-medical providers such as midwives, nurse practitioners, registered and enrolled nurses, and Aboriginal health workers; or non medical providers such as registered and enrolled nurses, and Aboriginal health workers in the public health system.
Health services	Includes all services involved in dealing with the screening, diagnosis and treatment of disease, or the promotion, maintenance and restoration of health.
High grade abnormalities	May indicate more serious changes in the cells of the cervix that require further investigation by a specialist. High grade abnormalities can be treated easily and successfully, if detected early. If left untreated, they have a greater chance of developing into cervical cancer.
Higher risk for cervical cancer or precursors	May indicate a high grade abnormality or HPV infection with types 16 and/or 18 that requires treatment in line with the 2016 Guidelines. If left untreated, these conditions have an increased risk of developing into cervical cancer.
Histology	The study of body tissue structure using a microscope.
Human papillomavirus (HPV)	A common viral infection of humans that may infect the reproductive tract and affects both males and females. HPV is passed from person to person through sexual activity. HPV is eradicated from the body in most cases within 12–24 months. Persistent infection can lead to cell changes in the cervix and this may lead to the development of cervical cancer or its precursors.
HPV partial genotyping (HPV testing)	A method of testing for the most frequent types of HPV that can lead to cervical cancer or its precursors.
HPV types 16, 18 +/- 45	The most frequent specific types of HPV that can lead to cervical cancer or its precursors.
Individual Healthcare Identifier (IHI)	A unique 16 digit number used to identify individuals receiving healthcare services in the My Health Record system.

Informed consent	A person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved.
Intermediate risk for cervical cancer or precursors	This is determined by the combination of an oncogenic HPV not 16/18 result and the absence of a cytological high grade abnormality, and requires follow-up testing in 12 months in accordance with the 2016 Guidelines.
Liquid-based cytology (LBC)	A laboratory test method which involves analysing cells from a woman's cervix (or vagina) that have been stored in a liquid preservative solution. These cells are then extracted from the solution and put on a slide for microscopic cytological examination.
Low grade abnormalities	Indicate changes in the cells of a woman's cervix that are most likely caused by the presence of a HPV infection. Most low grade abnormalities do not require treatment and usually resolve over time. It is important that low grade abnormalities are assessed in line with the 2016 Guidelines.
Low risk for cervical cancer or precursors	Indicates a negative HPV test result where the chance of a woman developing cervical cancer or a high grade abnormality which requires treatment over the next five years is very low.
Medicare Benefits Schedule	A listing of the Medicare services subsidised by the Australian government.
National Cancer Screening Register (NCSR)	A national population based screening register that supports the NCSP by collecting and storing cervical screening data to enable issuing of cervical screening invitations, reminders and follow-up.
Opportunistic screening	The offering of a cervical screening test to women when they present to a health care practitioner for reasons unrelated to cervical screening.
Participant	The NCSP recommends all individuals with a cervix aged 25 to 74 years of age have a five-yearly oncogenic human papillomavirus (HPV) test to prevent cervical cancer. This includes participants who identify as lesbian or bisexual as well as transgender men with a cervix. It is important to note symptomatic individuals can be tested at any time.
Pap smear/Pap test	A test developed by George Papanicolaou in the 1940s in which cells are scraped from the cervix, smeared onto to a microscope slide and then examined microscopically for abnormalities that could indicate cervical cancer or pre-cancer. These terms are used interchangeably throughout the document.
Program Performance Indicators	A set of quantifiable measures that are used to gauge or compare performance in terms of meeting the National Cervical Screening Program's strategic and operational goals.
Rescreen	A screening test on a woman returning for routine screening according to the recommended screening interval.
Retest	A follow-up test performed on participants at intermediate risk of cervical cancer according to the 2016 Guidelines.
Quality Assurance Program	A way of systematically monitoring and evaluating the various aspects of a program to ensure that standards of quality are being met.
Quality and Safety Monitoring Committee (QSMC)	Monitor issues relating to the quality and safety of the NCSP and 2016 Guidelines.
Quality Management System	A quality management system is a collection of business processes focused on achieving a quality policy and quality objectives. It is expressed as the organisational structure, policies, procedures, processes and resources needed to implement quality management.
Quality measure	Quality measures are tools that help measure or quantify outcomes and goals.
Screening pathway	The screening pathway includes all activities from identification of the target population to diagnosis. It includes invitation, having the test, receiving test results, assessment and diagnosis.
Service provider	An organisation, body or business that provides services to the public.
Socioeconomic status	An indication of disadvantage or advantage in terms of individual's access to material and social resources as well as their ability to participate in society.
Self-collection	A process of collecting a vaginal sample for HPV testing for the purposes of improving participation in cervical screening among under-screened and never screened participants. The availability and requirements of the self-collection test is outlined in the NCSP Self-collection Policy.
Standard	A level of quality that should be attained and will be used to provide a basis for comparison and monitoring.
Transformation zone	The zone on the cervix at which the squamous epithelium and columnar epithelium meet. The transformation zone changes location in response to a woman's hormonal status.
Unsatisfactory test result	An unsatisfactory test result occurs when the sample of a woman's cells was not able to be tested properly, or that the test may not have been collected or prepared properly.

APPENDIX A – NCSP POLICIES

The renewed NCSP policies are based on the recommendations of the Medical Services Advisory Committee that were formed following a comprehensive and robust evidence review and modelling evaluation (MSAC, 2014 – Application 1276).

NATIONAL CERVICAL SCREENING POLICY

The National Cervical Screening Program (NCSP) aims to reduce morbidity and mortality from cervical cancer. This will be achieved through an organised population-based screening pathway to detect pre-cancerous cervical abnormalities in asymptomatic participants.[15]

The renewed national policy[16] recommends:

1. Cervical screening should be undertaken every five years in asymptomatic participants, using a primary human papillomavirus (HPV) test with partial genotyping and reflex liquid based cytology triage;
2. Individuals who have ever been sexually active should commence cervical screening at 25 years of age;
3. Individuals aged 25 years or older and less than 70 years will receive invitations and reminders to participate in the program;
4. Individuals will be invited to exit the program by having a HPV test between 70 years or older and less than 75 years of age and may cease cervical screening if their test result is negative;
5. Individuals 75 years of age or older who have either never had a cervical screening test or have not had one in the previous five years, may request a cervical screening test and can be screened;
6. An alternative screening process is available for participants who are under-screened or never-screened and have declined invitations and reminders for conventional screening (see Self-collection Policy)[17];
7. All participants, both HPV vaccinated and unvaccinated, are included in the program;
8. Participants with positive cervical screening test results should be followed up in accordance with the cervical screening pathway and the *NCSP: Guidelines for the management of screen detected abnormalities, screening women in specific populations and investigation of women with abnormal vaginal bleeding (2016 Guidelines)*[18]; and
9. Monitoring and evaluation of the program will be in accordance with the Quality Framework.

[15] Participants with symptoms require diagnostic testing and should be managed in accordance with the 2016 Guidelines.

[16] The NCSP policy is in accordance with the Medical Services Advisory Committee recommendations, April 2014 (Application 1276).

[17] For the purposes of the National Policies alternative screening refers to cervical screening on self-collected vaginal samples and conventional screening refers to cervical screening on practitioner collected cervical samples.

[18] The *2016 Guidelines* include recommendations on how to manage participants who have HPV detected in their screening test; how to test individuals with symptoms, a previous abnormality or individuals in specific populations (who may be at higher risk of cervical cancer than the average population); and will advise when participants who have been treated for an abnormality can resume screening as per the national policy.

SELF-COLLECTION POLICY

This Self-Collection Policy aims to improve participation in screening by providing an alternative screening process for asymptomatic participants[19] who are under-screened or never-screened and have declined conventional screening via invitations and reminders from health providers[17] and the National Cancer Screening Register. The vast majority of cervical cancer in Australia occurs among this group of participants. Healthcare providers offering the self-collection option should have an empathic understanding of the barriers and reasons why participants tend not to participate in cervical screening and utilise available and relevant resources to effectively address these barriers. Healthcare providers should promote conventional screening, but inform and support participants who decline conventional screening to undertake the alternative screening process.

The self-collection policy recommends:

1. self-collection of a sample for cervical screening for HPV testing is available for:
   - participants who have never participated in the NCSP and are 30 years of age or over; or
   - participants who are overdue for cervical screening by two years or longer[20] and are 30 years of age or over.
2. self-collection for cervical screening must be facilitated and requested by a healthcare professional[21] who also routinely offers cervical screening services;
3. the self-collection device and the HPV test, when used together, must meet the requirements of the National Pathology Accreditation Advisory Council (NPAAC) Standards and Performance Measures.[22]

Participants with positive HPV test results from a self-collected sample will require further tests and should be followed up in accordance with the *NCSP: Guidelines for the management of screen detected abnormalities, screening women in specific populations and investigation of women with abnormal vaginal bleeding (2016 Guidelines)*.

[19] Individuals with symptoms are advised to have a gynaecological examination (self-collection is not recommended).

[20] During the early years of transition to the renewed program this includes both Pap and HPV tests ie greater than four years since last conventional Pap test or greater than seven years since last HPV test.

[21] Healthcare providers that provide cervical screening services may include but are not limited to medical practitioners and specialists as well as non-medical providers such as nurse practitioners, registered and enrolled nurses and Aboriginal health workers under the supervision of a medical practitioner; or non-medical providers such as registered and enrolled nurses and Aboriginal health workers in the public health system.

[22] The performance of an HPV test can be different on self-collected cervical samples compared to clinician-collected samples therefore the HPV test and the self-collect device must be compatible in a way that the performance of the HPV test meets the requirements of NPAAC.

POLICY ON TRANSITIONING PARTICIPANTS TO THE RENEWED NATIONAL CERVICAL SCREENING PROGRAM (NCSP)

Policy objectives

- To provide advice on how participants already participating in the program[23] will be transitioned from two-yearly Pap smear cervical screening to five-yearly primary HPV screening.

Policy

Transition arrangements from 1 December 2017:

- Participants who are already participating in the program, and were aged 23 years or older and less than 70 years when they had their last Pap test, will be invited to screen at or within three months of the date when they would have been due for their two yearly Pap test.
- Participants who are already participating in the program, and were younger than 23 years of age when they had their last negative Pap test, will be sent a letter advising them of the changes to the NCSP and that they will receive an invitation to screen close to their 25th birthday.
- Conventional Pap tests collected after 30 November 2017 will no longer attract a MBS rebate.[24] A woman who has a conventional Pap test taken in the transition period after 30 November 2017 with a negative result will be invited to return for a HPV test in two years.
- Participants who have participated in the program, are overdue for their Pap test by less than two years, and are aged 25 years and over, will be advised that they are overdue for their screening test and will be reminded to screen.
- Participants who have participated in the program, are overdue for their Pap test by two years or more, and are over 30 years of age, will be invited to screen and will also be advised that they are eligible (if they would prefer) to self-collect a vaginal sample for screening under the guidance of their healthcare provider.
- Participants who have participated in the program and are aged 70 years or older and less than 75 years, will be invited to have an exit screening test.
- Participants who are already participating in the program and who have been treated for a cervical precancerous lesion will be invited to screen as recommended by the *NCSP: Guidelines for the management of screen detected abnormalities, screening women in specific populations and investigation of women with abnormal vaginal bleeding (2016 Guidelines)*.
- All participants regardless of age who are undergoing follow-up and/or treatment for a cervical precancerous lesion will be followed up in accordance with the NCSP Protocol of Actions (transition and business as usual).

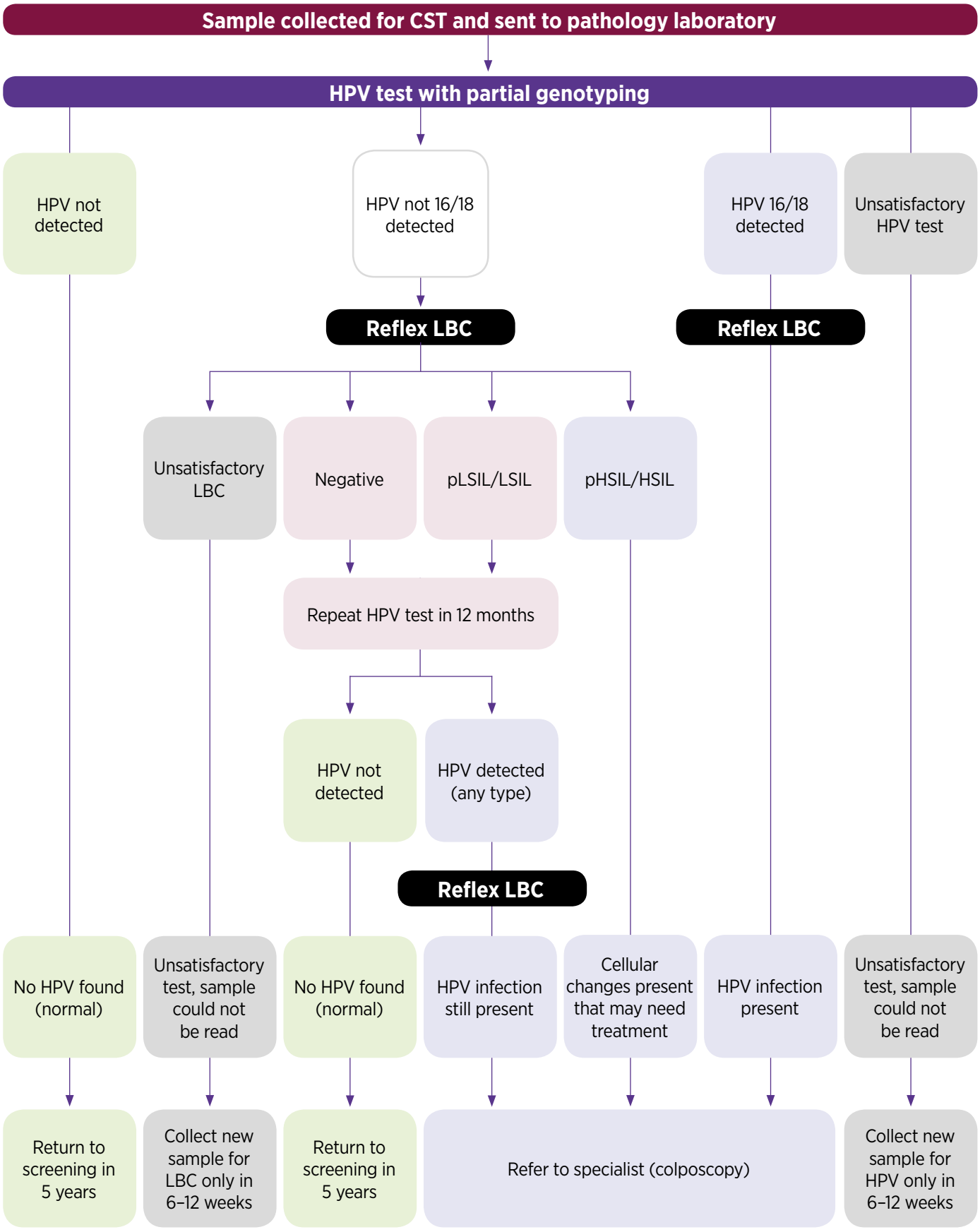
[23] Individuals who have never participated in the NCSP (have never had a cervical screening test) and who are over the age of 30 years will be invited to screen and will be advised that they are eligible to self-collect a cervical sample for screening under the guidance of their healthcare professional.

[24] All effort will be made to ensure healthcare providers are adequately informed about the replacement of the Pap test with an HPV test for cervical screening and the associated Medicare rebates in the lead up to 1 December 2017.

APPENDIX B – SCREENING PATHWAYS

NATIONAL CERVICAL SCREENING PATHWAY

Figure 1: Cervical screening pathway for clinician-collected sample



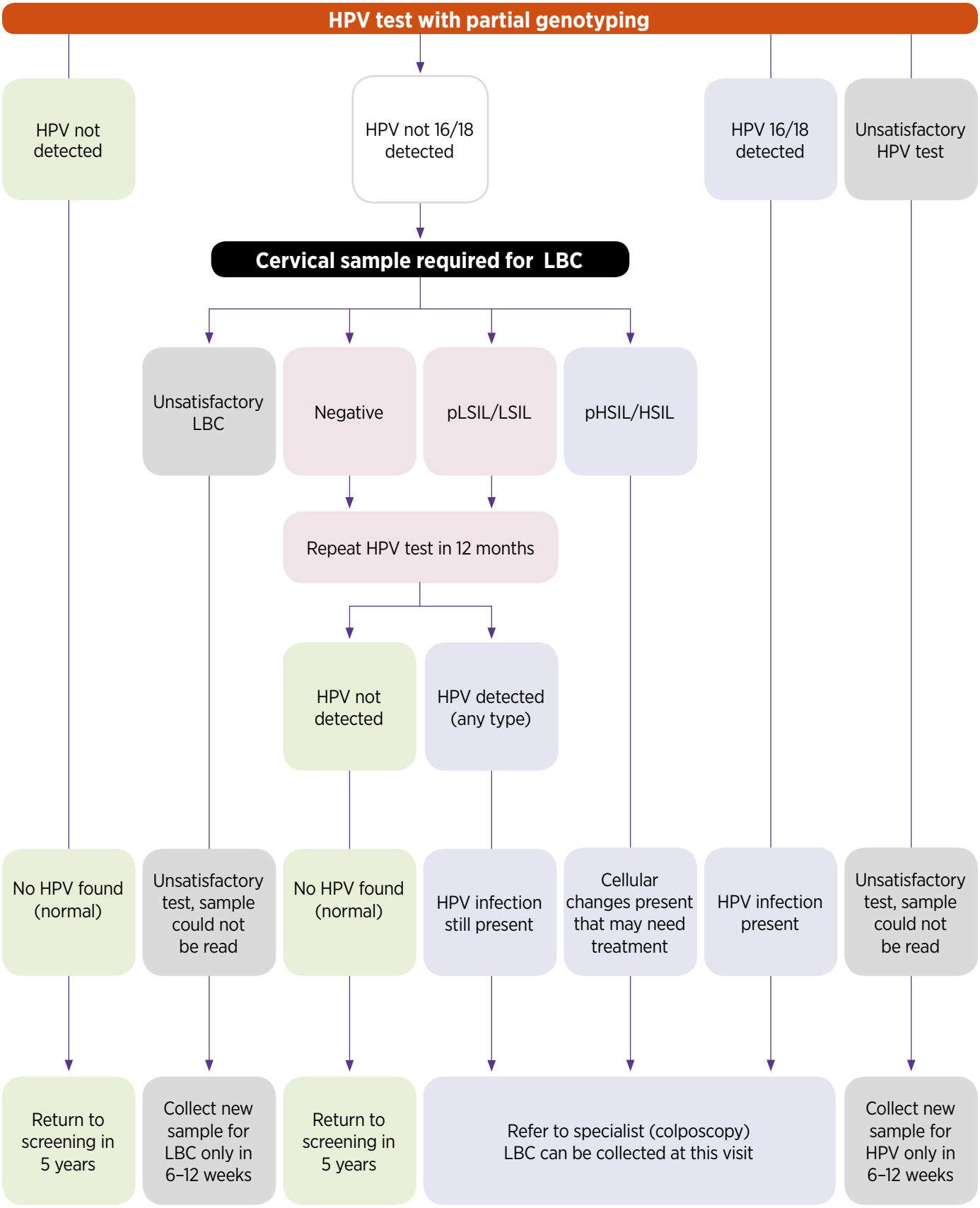
Legend Low | Intermediate | Higher

Risk of cervical cancer precursors in the next five years.

Definitions: CST = Cervical Screening Test HPV = Human papillomavirus; LSIL = low-grade squamous intraepithelial lesion; HSIL = high-grade squamous intraepithelial lesion; LBC = liquid-based cytology.
Diagram adapted from 2016 Guidelines.

SELF-COLLECTION SCREENING PATHWAY

Figure 2: Cervical screening pathway for self-collected vaginal sample



Legend Low | Intermediate | Higher

Risk of cervical cancer precursors in the next five years.

Definitions: HPV = Human papillomavirus; LSIL = low-grade squamous intraepithelial lesion; HSIL = high-grade squamous intraepithelial lesion; LBC = liquid-based cytology.

Diagram adapted from 2016 Guidelines.

APPENDIX C – PROGRAM PERFORMANCE INDICATORS

The new performance indicators for the NCSP are outlined below.

Screening pathway	Performance indicator
Recruitment	1 Participation
	2 Response to invitation
	3 Rescreening
Screening	4 Screening results
	5 Correlation of screening results
Screening HPV test performance	6 Screening HPV test positivity
	7 Cervical cancer diagnosed after a low risk screening test result
Self-collection	8 Self-collection participants positive for oncogenic HPV (not 16/18) who have an LBC test within 6 months
	9 Self-collection participants positive for oncogenic HPV 16/18 who have a colposcopy within 6 months
Follow-up	10 Adherence to recommendation for follow-up
	11 Follow-up results
Assessment	12 Colposcopy rate
	13 Time to colposcopy
	14 Biopsy rate
	15 Yield of high grade abnormalities on biopsy among participants who attend colposcopy with higher risk screening results
	16 Positive predictive value of colposcopy
Diagnosis	17a High grade cervical abnormality detection rate
	17b Cervical cancer detection rate
Outcomes	18 Cervical cancers diagnosed by time since last screen
	19 Incidence of cervical cancer
	20 Mortality from cervical cancer

Further information on the new Program Performance Indicators can be found at Part 5 of the NCSP Data Dictionary v1.0 (aihw.gov.au/publication-detail/?id=60129559625).

APPENDIX D – NPAAC PERFORMANCE MEASURES

The new NPAAC Performance Measures for HPV and LBC testing in the NCSP are outlined below.

Performance Measure	Standard*
1	The number and percentage of screening episodes reported as 'unsatisfactory' must be reported to the RCPAQAP.
2a	Laboratories must provide the proportion of all technically satisfactory screening episodes reported in the categories low risk, intermediate risk and higher risk.
2b	Laboratories must provide a breakdown of the HPV NAT and LBC results of all other episodes.
3a	The proportion of LBC specimens reported as HSIL where cervical histopathology, taken within six months, confirms the abnormality as HSIL, AIS or cervical malignancy must be reported to the RCPAQAP.
3b	The proportion of LBC specimens reported as possible HSIL where cervical histopathology, taken within six months, confirmed the abnormality as HSIL, AIS or cervical malignancy must be reported to the RCPAQAP.
4	The proportion of participants with histological diagnosis of HSIL or malignancy which were originally reported as low risk with a primary screening HPV NAT within the last 63 months must be reported.

*Commentary on these Standards is available in the NPAAC *Requirements for laboratories reporting tests for the National Cervical Screening Program*

Further information on the NPAAC Requirements for the NCSP can be found at health.gov.au/internet/main/publishing.nsf/Content/npaac-cervical-screening

APPENDIX E – QUALITY STANDARDS AND TARGETS FOR INDIVIDUAL COLPOSCOPISTS

These are the NCSP recommended standards and targets for individual diagnostic and therapeutic colposcopists to guide best practice and quality improvement.

Colposcopists	Quality standards and targets
Diagnostic	1 Colposcopists undertake a sufficient number of new patient colposcopies per year to maintain and improve skills in colposcopy practice.
	2 The performance of a biopsy (punch or excision) in more than 90% of participants with high grade cytological abnormalities (excluding pregnant participants).
	3 Of all punch biopsies taken, more than 90% should be suitable for quality histological examination.
	4 For those with a satisfactory colposcopy: a) the colposcopic diagnosis should be correlated with the histological diagnosis to calculate the PPV for HSIL, and this should be at least 65%; and a) predictive value of high grade histology, for each colposcopist.
Therapeutic	1 All treatments must be recorded with type of treatment in accordance with the nomenclature provided in the 2016 Guidelines and include nature of anaesthesia.
	2 All participants having local ablative/destructive treatment must have had a cervical biopsy prior to treatment (100%).
	3 Of all excisional biopsies taken, more than 90% should be suitable for quality histological examination.
	4 There should be histological evidence of HSIL (biopsy or excisional specimen) in > 80% of treated cases.
	5 The number of participants who are treated under local anaesthesia should be maximised.
	6 The proportion of confirmed high grade histological abnormalities should not exceed 5% within 15 months of treatment.
	7 Follow up of participants who are treated for high grade histologic abnormality should be maximised, with at least 90% seen within 15 months of treatment.

Where colposcopy data is provided to the National Cancer Screening Register, the register will be able to provide reports to individuals with their own data compared to the national average in order to review their own performance. This data could also be used to assist in the certification/recertification process managed by RANZCOG.

APPENDIX F – NATIONAL COMPETENCIES FOR CERVICAL SCREENING PROVIDERS

COMPETENCY GUIDELINES FOR CERVICAL SCREENING PROVIDERS IN THE RENEWED NATIONAL CERVICAL SCREENING PROGRAM

Background

In Australia, cervical screening is offered by medical and non medical[25] healthcare providers. Historically the education and training undertaken by these healthcare providers has been varied including inter-state differences within the same discipline. In addition, practice guidelines applicable to providers who offer cervical screening services have been largely non-existent.

National competencies are critical to supporting the delivery of high quality services. The following competencies aim to support high quality cervical screening through facilitating consistent provider training and providing guidance for clinical practice. This will support Cervical Screening Providers in taking the steps that are necessary to develop and maintain their skills as well as promoting quality and safety in practice.

The development of these national competencies was timely as they support the implementation of, and provide guidance for, providers within the renewed National Cervical Screening Program (NCSP).

These competencies were drafted following consultation with a wide range of Australian stakeholders with expertise in providing cervical screening and with reference to the 1997 *National Standards for Nurse Pap Smear Providers*. These competencies have been considered and endorsed by the Standing Committee on Screening, the Commonwealth and state and territory governments' governing body for the National Cervical Screening Program, with the intention that they will inform education and clinical practice.

National competencies: objectives

To support the provision of high quality cervical screening services, and meet the requirements of the renewed NCSP, this document describes recommended national competencies to:

- Guide the development of new education and training programs and revisions to existing programs
- Ensure ongoing quality assurance activities are embedded in clinical practice
- Support jurisdictions that continue to offer a Cervical Screening Provider credentialing program in their initial and subsequent assessments of the competency of credentialed providers.

[25] 'Non-medical cervical screening providers' is an umbrella term, used to describe all healthcare professionals who are not medical practitioners and who offer a cervical screening service. This includes Aboriginal Health Workers, Aboriginal and Torres Strait Islander Health Practitioners, Registered Nurses, Nurse Practitioners, Enrolled Nurses, Registered Midwives, Eligible Midwives and Endorsed Midwives.

Cervical screening provider competencies: guiding principles

It is expected that *Cervical Screening Providers* will uphold the following principles[26] of practice:

- Accurate contemporary knowledge to support safe and high quality cervical screening service delivery
- Comprehensive health assessment and interpretive skills to achieve optimal care for participants[27]
- Protection of the rights of participants, including maintaining the rights of participants to make informed decisions, which may include refusal to be screened
- Recognition of personal ability, scope of practice, level of provider competence, appropriate referral and/or seeking assistance and learning opportunities as needed
- Enhancement of the dignity and integrity of participants through the maintenance of a physical and psychosocial environment which promotes safety, security and optimal healthcare
- Multidisciplinary collaboration with other healthcare providers as needed to achieve optimal outcomes for participants
- Undertake cervical screening service delivery with cultural sensitivity.

Education and training: minimum initial competency requirements

The purpose of these national education and training competency requirements is to describe the minimum standards that training organisations can use to develop theoretical and clinical course content.

At a minimum, theoretical training must include, and participants are required to demonstrate an understanding of:

- Anatomy of the female pelvis and cervix
- Human papillomavirus and natural history of cervical cancer and precursors
- Primary prevention of cervical cancer and the role of the National HPV Vaccination Program
- Secondary prevention of cervical cancer and the role of population based screening
- National Cervical Screening Program
  - Role of the Register
  - Program policy
- A quality cervical sample – what it is and how it is taken
- Screening test results and their interpretation
- 2016 Guidelines for participants with screen-detected abnormalities, including an understanding of colposcopy and treatment options
- Management of symptomatic individuals and/or participants with an abnormality detected on visual cervical examination
- Cervical screening in specific/vulnerable populations of participants (e.g. participants with disabilities, participants with a history of abuse/trauma including sexual, physical, emotional)
- Eligibility requirements for self-collection in the renewed program and how to support participants who choose this option
- Effective communication techniques, including history-taking and notification of results
- Culturally sensitive practice to ensure services are appropriate to participants of all cultures and backgrounds
- Personal attitudes, values and communication skills (being open and non-judgemental) when discussing sensitive issues
- Medico-legal issues related to screening.

[26] Based upon the *National Standards for Nurse Pap Smear Providers* (1997).

[27] Cervical screening should meet the needs of all people with a cervix, including women who identify as lesbian or bisexual as well as transgender men with a cervix

Clinical practicum training must include opportunities for trainee-observed and preceptor-supervised clinical consultations and speculum examinations, including taking cervical screening samples. This competency-based clinical training must be adaptive and responsive to the participant learning needs of healthcare providers. The number of required consultations, inclusive of the taking of cervical screening samples, will vary greatly. In *most* cases training should include *at least* five supervised consultations and cervical sample collections; however, this number must be tailored to the participant to ensure, that at the end of clinical training, healthcare providers demonstrate competency in:

- Effective communication skills that facilitate the participant's ability to give informed consent by ensuring the participant has a clear understanding of the screening procedure
- Ensuring the participant is as physically and psychologically comfortable, throughout the procedure, as possible
- Visualising the cervix (differentiating normal, variations of normal and abnormal) with minimal discomfort to the participant
- Adequate sampling of the transformation zone
- Correct specimen preparation and handling
- Appropriate documentation of the consultation and procedure and completion of pathology request forms
- Communication of screening test results and recommended follow-up.

Clinical practice: minimum on-going competency requirements

Healthcare providers will maintain competency in their practice through:

- Reflecting on feedback from participants undergoing cervical screening
- Complying with legislative data collection requirements (e.g. Aboriginal and Torres Strait Islander)
- Reflection on practice and cervical screening statistics (in comparison to the averages reported by the examining laboratory) to support:
  - Implementation of strategies to improve theoretical understanding and/or clinical competence, should a need be identified
  - Participation in appropriate quality assurance and provider development activities.

APPENDIX G – PROCESS FOR MANAGING QUALITY AND SAFETY CONCERNS

IDENTIFY THE ISSUE

There are a number of channels where a quality and safety issue could be identified including:

- Quality and Safety Monitoring Committee review of quality and safety monitoring data
- State and territory program monitoring of local data
- Standing Committee on Screening
- NCSR data analysts
- Peak body or clinical College
- NATA advice on pathology standards
- Individuals

ALERT RELEVANT STAKEHOLDERS

Any notifications regarding quality issues received by the Commonwealth or state and territory programs should be provided to the QSMC for consideration and advice provided to the Standing Committee on Screening.

INVESTIGATION OF THE ISSUE AND RISK ANALYSIS

QSMC will provide advice to the Standing Committee on Screening on what actions need to be undertaken by the NCSP to investigate the issue which may include but should not be limited to activities to confirm the issue is real and the potential cause, data analysis, seeking feedback from stakeholders (peak bodies, experts) and a risk analysis.

ADDRESS THE ISSUE

A report should be provided by the investigating organisation (to be agreed by SCoS) to the QSMC for feedback and advice on how to manage the issue. The combined report and QSMC advice should be provided to SCoS for action.

COMMUNICATION

Any safety or quality concerns should be raised with relevant and affected stakeholders to ensure they are aware of the issue and can support any actions that may be required to address the issue.

MONITORING

The issue should be monitored by QSMC through data review until resolution and systems are in place to prevent the issue occurring again.