National Cervical Screening Program

A joint Australian, State and Territory Government initiative

Renewal of the National Cervical Screening Program

Pathology Laboratory Renewal Update July 2016

This is the first of regular Pathology Laboratory Renewal Updates outlining the latest information relevant to the transition of pathology laboratories during the implementation of the changes to the National Cervical Screening Program (NCSP). While not all the answers are yet available, we hope the following information is useful. Any feedback and/or questions on the update and renewal activities can be directed to CervicalRenewal@health.gov.au.

The Steering Committee for the Renewal Implementation Project (SCRIP), chaired by Professor Ian Hammond, has initiated this update in order to provide more regular and detailed communication with pathology laboratories during the implementation phase.

Summary of changes

- In May 2015, the Australian Government announced it had accepted the evidence-based Medical Services Advisory Committee's (MSAC) recommendations and agreed to implement a renewed NCSP from **1 May 2017**.
- The recommendations include replacing the two yearly Pap test with a five yearly human papillomavirus (HPV) test with partial genotyping and reflex liquid based cytology (LBC).
- The age range for screening will also change from 18 to 69 years, to women aged between 25 and 74 years.
- New cervical screening MBS items will be available from 1 May 2017. LBC testing can be done on a reflex basis and is Pathologist Determinable.
- Until 1 May 2017, conventional Pap tests every two years are recommended.
- More information on the MSAC recommendation may be found on the MSAC website (www.msac.gov.au Application 1276) and Cancerscreening website (www.cancerscreening.gov.au).

New cervical screening pathway

- The new cervical screening pathway includes the recommendations from MSAC and the *National Cervical Screening Program: Guidelines for the management of screen detected abnormalities, screening in specific populations and investigation of abnormal bleeding* (the 2016 NCSP Guidelines).
- The new pathway is a risk based approach to cervical screening. Women are managed according to their risk of developing cervical cancer which is determined by their HPV test result and subsequent reflex LBC result, if indicated.
- The cervical screening result must be reported as low, intermediate or higher risk of significant cervical abnormality, or as unsatisfactory for evaluation, based on both the HPV test and (where indicated) reflex LBC.
- The screening pathway at Attachment A incorporates the clinical management of women at low risk, intermediate risk and higher risk.

- The pathways following colposcopy may be found in the 2016 NCSP Guidelines to be publicly released in early 2017. Pathology laboratories will be provided with embargoed documents early to assist pathology transition.

Implementation date

- The new MBS items supporting primary HPV testing and reflex LBC tests will be available on 1 May 2017.

New MBS Items for cervical screening

- The Department is working with the Pathology Clinical Committee and Business Group to finalise the item descriptors and fees to support the renewed NCSP. The Business Group met on 16 June 2016 to discuss methodologies to support fee setting.
- It is understood that many pathology laboratories require the item descriptors and fees to undertake modelling for administration, system and business planning purposes and the Department will release this information once the details are finalised.

Pathology Workforce Project

- The Royal College of Pathologists Australasia (RCPA) is managing a Pathology Workforce Project. The project aims to:
  - Develop and deliver on-line training for liquid based cytology to complement existing training resources;
  - Work with the Australian Society of Cytology to ensure appropriate educational resources for diagnostic liquid based gynaecological cytology are available to new cytologists;
  - Provide support for existing cytologists through the provision of Transition Services and Support to complement employer-based programs; and
  - Undertake regular communication activities to inform the pathology workforce of the changes to the NCSP.
- Updates on the progress if this project may be found at https://www.rcpa.edu.au/Library/Practising-Pathology/NCSP

Pathology standards and performance measures for cervical screening

- The National Pathology Accreditation Advisory Council's (NPAAC) Cervical Screening Drafting Committee, chaired by Associate Professor Paul McKenzie, is currently drafting the quality standards for cervical screening tests, including human papillomavirus (HPV) testing.
- The draft Requirements for Pathology Laboratories Performing Cervical Screening Tests is expected to be finalised shortly. Subject to consideration by NPAAC, the draft document is expected to be released for public consultation in the near future.
- All stakeholders will be advised by NPAAC Secretariat when the draft document is available. You may also wish to check the NPAAC website (http://www.health.gov.au/npaac) for any updates, or email the NPAAC Secretariat at npaac@health.gov.au

HPV test platforms

- The NPAAC *Requirements for Laboratories reporting cervical screening tests* will provide the quality and performance standards related to HPV tests used as part of the National Cervical Screening Program.

- The Medical Services Advisory Committee provided some initial recommendations regarding all HPV tests used as part of a population based cervical screening program utilising primary HPV testing, including they must:
  1. comply with the TGA regulatory framework for IVD medical devices and each manufacturer must provide evidence that it's product complies with the TGA framework in order for its product to be claimed through the MBS;
  2. be valid, according to the guidelines developed by Meijer *et al* (2009);
  3. provide a pooled result for all high risk HPV genotypes and partial HPV genotyping for at least HPV16 and HPV18; and
  4. not be an in-house HPV test.
- In February 2016, the MSAC Executive agreed that commercial HPV tests performed on self-collected samples should be exempt from the 2014 MSAC recommendations that in-house tests should not be approved or considered for use in the NCSP. Under the *Therapeutic Goods (Medical Devices) Regulations 2002* commercially supplied IVDs become in house IVDs when they are not used in accordance with the manufacturer's instruction and stated intended use. Currently, the stated intended use for commercial HPV tests limits specimen collection of cervical cells to liquid based mediums.

Managing transition volumes

- It has been recognised that since the release of the publication from Smith *et al* (2016), on resource implications for transitioning from two yearly screening to five yearly cervical screening, pathology laboratories have concerns regarding the impact on business including the cytology workforce in the second round of screening.
- The Steering Committee for the Renewal Implementation Project has been considering transitioning issues since May 2015 when the Australian Government committed to fund the implementation of the Renewal in the 2015 Commonwealth Budget.
- SCRIP last met on 28 June 2016 and discussed the concerns of the pathology sector. Members agreed to undertake further analysis to inform potential options for reducing the severity of the fluctuating test volumes and to work with the pathology sector to manage the workforce issues.

National Cancer Screening Register and IT requirements

- Telstra Health will establish the National Cancer Screening Register (the Register). The Register is a piece of national digital health infrastructure for the collection, storage, analysis and reporting of cancer screening data for both the renewed National Cervical Screening Program and the National Bowel Cancer Screening Program. The Register is an integral part of cervical screening service delivery: it will facilitate invitations and reminders for screening, and support clinical decision-making for this program.
- Telstra Health has commenced consultation with the pathology sector and is holding a National Cancer Screening Register Pathology Workshop on 28 July 2016 in Sydney. The RCPA, Pathology Australia and National Coalition of Public Pathology (NCOPP) have been invited to attend. Interested parties should contact the RCPA or their relevant peak body for further information.

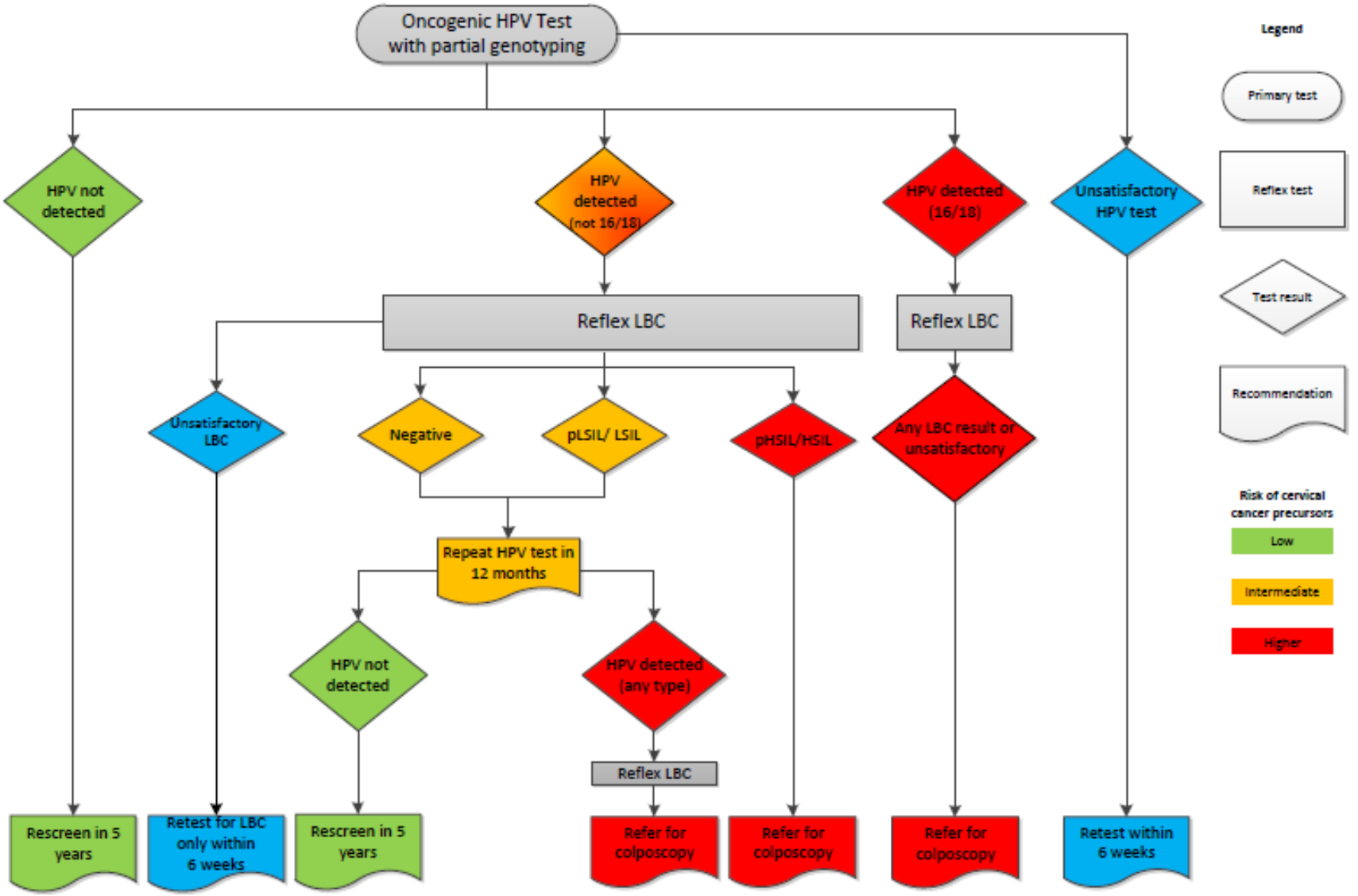
Communication with referring practitioners

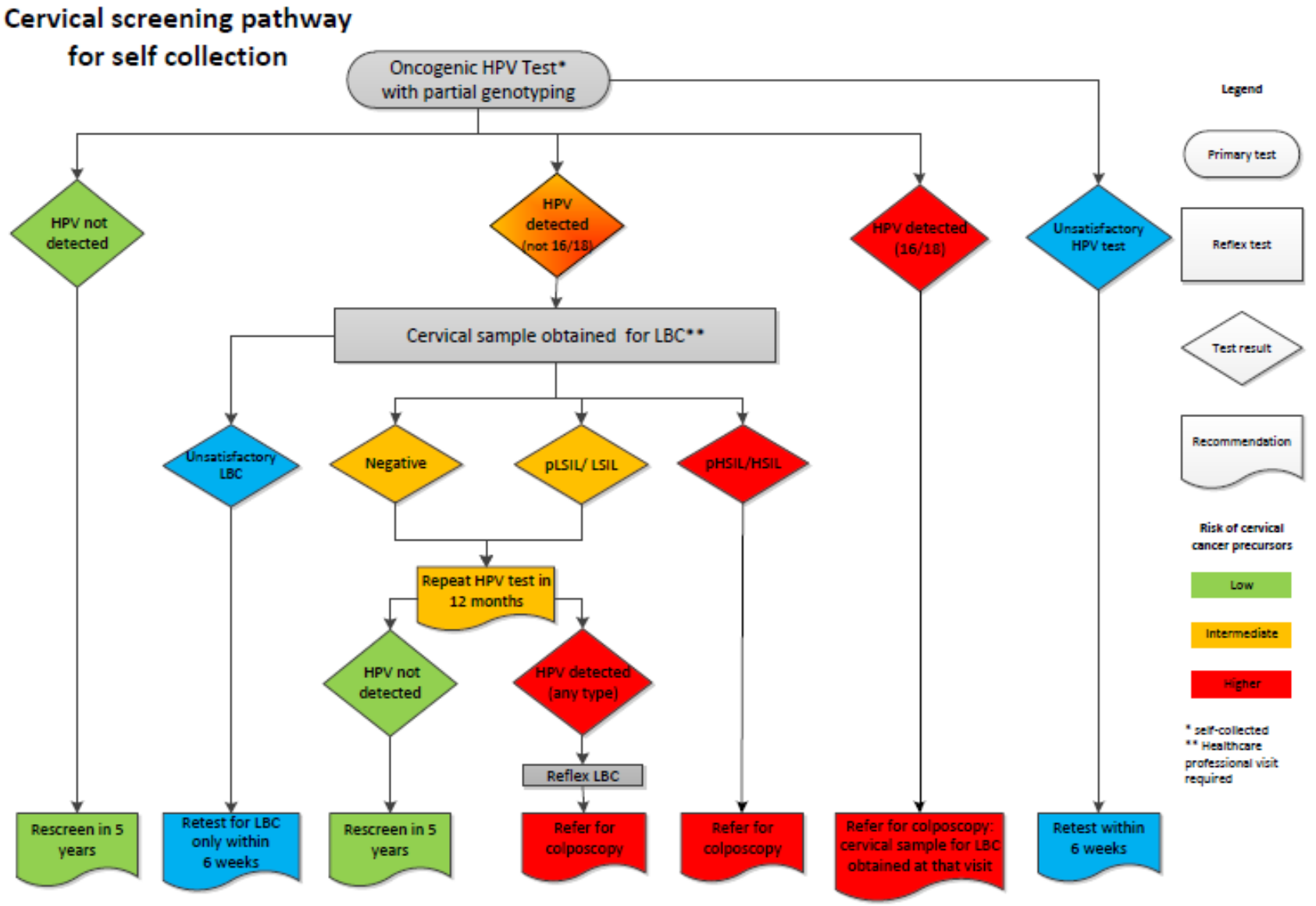
- Attached is a Health Professional Information Sheet that you might like to distribute to your referring practitioners to assist with responding to queries being received about the changes to cervical screening.

Further information

- Renewal information may be found at www.cancerscreening.gov.au
- Medical Services Advisory Committee (MSAC) recommendations may be found on the MSAC website (www.msac.gov.au Application 1276)
- NPS MedicineWise special edition of RADAR released in October 2015 explaining the evidence based changes (access at: https://www.nps.org.au/radar/articles/changes-to-the-national-cervical-screening-program)
- Interested parties may also register for regular newsletter updates on the implementation of the new program at CervicalRenewal@health.gov.au

Cervical screening pathway




Cervical screening pathway for self collection
Oncogenic HPV Test* with partial genotyping
HPV not detected
HPV detected (not 16/18)
HPV detected (16/18)
Unsatisfactory HPV test
Cervical sample obtained for LBC**
Unsatisfactory LBC
Negative
pLSIL/ LSIL
pHSIL/HSIL
Repeat HPV test in 12 months
HPV not detected
HPV detected (any type)
Reflex LBC
Rescreen in 5 years
Retest for LBC only within 6 weeks
Rescreen in 5 years
Refer for colposcopy
Refer for colposcopy
Refer for colposcopy: cervical sample for LBC obtained at that visit
Retest within 6 weeks
Legend
Primary test
Reflex test
Test result
Recommendation
Risk of cervical cancer precursors
Low
Intermediate
Higher
* self-collected
** Healthcare professional visit required