Abstract

Objectives: Australia was one of the first countries to make the transition from cytology-based to HPV-based cervical screening. This analysis of the national program's transition to a new model looks at the lessons learnt that can provide valuable insights to other settings.

Type of program: Australia's National Cervical Screening Program (NCSP).

Methods: Following an extensive policy review, in December 2017 the NCSP transitioned from 2-yearly cytology-based screening in women from age 18, to 5-yearly primary HPV screening from age 25.

Results: Some changes were more complex than initially anticipated. Building and implementing the National Cancer Screening Register was a more demanding and specialised project than expected. Regulatory requirements for self-collection were unexpectedly onerous, because self-collection was not formally included as an intended use by HPV test manufacturers. This delayed the rollout of a key measure to improve participation and equity.

Colposcopy demand was expected to increase substantially but exceeded expectations. Uncertainty about appropriate clinical management or testing outside guideline recommendations may have contributed to the excess demand, highlighting the importance of training providers in the rationale for guidelines as well as the content.

Lessons learnt: Although the changes were evidence based, there were nevertheless some concerns among women and healthcare providers, especially about the longer interval and later starting age for screening. These could have been reduced through earlier and more extensively delivered information to healthcare providers, who play a key role in addressing community concerns. Improved coordination of stakeholder support between government and nongovernment organisations may also have extended both the reach and credibility of communication about the program changes.

Key points

- Australia’s cervical screening program underwent major changes in December 2017 that have been largely well accepted
- Transition challenges arose in implementing the National Cancer Screening Register, regulatory requirements for self-collection, meeting demand for colposcopy (especially in public clinics) and communication about the changes
- Australia’s experiences in transitioning a major screening program provide valuable lessons to other countries
- Improving systems and communications, and thereby screening participation, are key to increasing equity and eventually eliminating cervical cancer
Transcending a well-established program is challenging, not only because of the changes required, but also because the existing program must continue to function until the transition. Delays may be hard to avoid, but early communication will enable better forward planning, especially by service providers. Since delays can reduce wider confidence in the changes, proactive communication is critical.

Achieving high and equitable screening coverage is a key element if Australia and other countries are to succeed in eliminating cervical cancer as a public health problem. Improving screening program confidence and participation remain important ongoing work. Lessons from Australia will provide valuable insights for other countries making similar changes.

Introduction

The renewed National Cervical Screening Program (NCSP) commenced in December 2017. The major evidence-based changes to the program included a new cervical screening test, based on primary testing for oncogenic types of human papillomavirus (HPV) with liquid-based cytology triage; extending the screening interval from 2 to 5 years; a later starting age of 25 years and an exit test for women aged 70–74; and the introduction of self-collection of a vaginal sample for cervical screening in never- and under-screened women.1

The new NCSP has been well accepted by most women and health professionals. However, there have been some major implementation challenges and several important lessons learnt, which should inform future efforts to implement similar programs.

Delays due to lack of a national register

The development of a National Cancer Screening Register (NCSR) to support both the cervical and bowel screening programs was an essential component of the NCSP changes. The NCSR would actively invite women to participate in the NCSP, including inviting women to commence screening shortly before they reached age 25. This replaced a system that sent reminders to previously screened women who were 3 months overdue, but did not actively send invitations to never-screened women. Two months before the initially scheduled transition date of 1 May 2017, the Australian Government Department of Health announced that the new NCSR was not ready, and delayed the NCSP transition until 1 December 2017. This caused significant confusion among consumers and healthcare providers. It was also a major problem for the laboratory sector, which, in planning for an expected May 2017 transition, had reduced cytology staff and geared up to commence large-scale HPV testing. This led to a costly financial subsidy from the government to the laboratories to enable them to continue providing the cytology-based screening program.2,3 The delay also caused a prolonged period of uncertainty regarding the program and concerns about when the NCSR would be “fit for purpose”.

Lessons

A likely delay in the NCSR was clear long before February 2017. It would have been preferable for the consequent delay in the NCSP transition to be announced much earlier to allow more effective forward planning and clearer communication to healthcare providers and women.

Unfortunately, delays in building, testing and implementing the NCSR also led to concerns about other unrelated aspects of the new program which, according to anecdotal stakeholder feedback, have not yet completely dissipated.

A major lesson from the experience is that IT projects to develop health registers are complex, and differ from other IT projects because these registers provide a myriad of inter-related functions beyond being a database repository. Providers of such IT systems need to include multidisciplinary teams, including public health and laboratory professionals, in addition to health information managers with relevant experience and IT professionals. Other countries (e.g. the UK and New Zealand) have faced similar issues.4,5

Delays in implementing self-collection due to regulatory requirements

A welcome feature of the renewed NCSP was the introduction of self-collection, explicitly aimed at improving participation among never- and under-screened women.1 There was particular emphasis on specific populations with documented lower participation rates and high cervical cancer burden, including Aboriginal and Torres Strait Islander and culturally and linguistically diverse women, who may avoid speculum vaginal examination for various reasons and find self-collection more acceptable.6

Despite intensive education around self-collection and enthusiasm from health professionals, self-collection was not available until January 2018, and full implementation has still not been achieved. The delay was due to an unanticipated regulatory issue: because self-collection was not listed as an ‘intended use’ by HPV test manufacturers, the Therapeutic Goods Administration...
required each laboratory to validate the specific collection device used for self-collected HPV tests. Only one laboratory (VCS Pathology) had undertaken this process before December 2017. This caused major concerns for providers who had developed strategies to encourage women to ‘self-collect’ only to discover that the test could not be processed unless sent to the single approved pathology provider, using a specific swab that they had validated. Some laboratories were reluctant to promote self-collection or act as a conduit for testing. This led to significant delays in improving participation in under-screened women.

Lessons

Lack of clarity around regulatory approval for self-collection and the inability to overcome regulatory hurdles delayed its implementation, causing confusion among clinicians, pathologists and women. The regulator was not convinced by arguments that never- and under-screened women would benefit even if using a test that was not technically ‘approved’, because the test in question was far better than no test at all. It is unlikely that full implementation of self-collection will occur until commercial HPV test products include self-collection as an ‘intended use’. This is of critical importance, not only in Australia but globally, especially in countries where self-collection is likely to have a major role in rapidly expanding cervical screening to coverage levels required to achieve elimination of cervical cancer. Adopting a standard, widely used device (e.g., Copan flocked swab 522C) reduces the need for clinics to stock special kits.

Unexpected ‘blow out’ in colposcopy referrals

Modelling predicted a transient 60% increase in colposcopy referrals in the first 2 years of the renewed program. This increase however appears to have been unevenly distributed. Much larger increases, some over 100%, have been reported in some jurisdictions, particularly in public clinics, whereas MBS data suggest the increase in the private sector has been smaller. This has resulted in long waiting times for colposcopy in public clinics, which have reported difficulty in seeing patients within recommended timeframes, and therefore resulted in the potential for inequity in women being able to access appropriate follow-up in a timely way, and also psychosocial impacts on women experiencing delays.

The NCSR has estimated that the proportion of cervical screening tests with a laboratory recommendation for colposcopy has more than doubled since December 2017, with the greatest increases in women aged under 20, 20–25 and over 50 years (in whom the rate of recommendations for colposcopy has tripled). The NCSR reports that approximately 500 women aged under 25 years are having a cervical screening test each week.

An increase in colposcopy was anticipated due to the change to a more sensitive primary (HPV) test, but there may be other drivers of this larger than expected increase in demand. Most likely is that healthcare providers are not adhering to the NCSP Guidelines and are:

- Screening women aged under 25 years, who are more likely to be HPV-positive and referred for colposcopy
- Co-testing (i.e. ordering an adjunct cytology test to be performed, regardless of HPV test result) ‘symptomatic’ women, in particular those aged under 25 years, to attract a Medicare rebate for a younger woman, or to access a rebate for liquid-based cytology (which is not generally reimbursed in conjunction with a routine screening test unless HPV is detected), or due to a lack of understanding of symptoms of cervical cancer
- Referring women of intermediate risk (low-grade cytology) to colposcopy, rather than recommending a repeat HPV test in 12 months.

Other reasons that may have increased colposcopy demand include:

- Unclear or confusing laboratory recommendations
- GP software that is inconsistent with the NCSP Guidelines
- Healthcare providers’ distrust of the new program, resulting in them screening younger women and offering women both old and new tests
- Women demanding testing outside NCSP guidelines.

Lessons

Modelling is dependent on expected behaviours, and it appears that healthcare provider behaviour has been unexpected. It seems likely that some health professionals are uncomfortable with the later starting age for screening and are not convinced of the safety of the cervical screening test, and were using low thresholds for ‘symptoms’ to circumvent NCSP guidelines. It is unlikely that a single driver will be discovered, so it is important that targeted educational strategies are developed. These should include information, resources and training around:

- Transitioning women with a prior abnormality
- Appropriate ordering of co-tests
- Implications for women when providers state ‘symptoms’ that are vague and not necessarily related to cervical cancer
- Supporting healthcare providers in dealing with women who request testing outside the NCSP guidelines.
Value of Wiki format for new NCSP Guidelines

Unlike previous NCSP management guidelines, the current guidelines use an online Wiki format, which allows for easy access, rapid document navigation, and most importantly, updating as new evidence becomes available. However, it is important that strategies and resourcing to review and update the evidence and guidelines are in place at the time of guidelines publication. This formal process was not in place at commencement of the renewed program and led to some difficulties in correcting inadvertent omissions and errors that became apparent as the guidelines were 'operationalised'.

Lessons

The Wiki format for such documents is a major advance and should be considered for documents in other disciplines, as paper documents are difficult and costly to update and often outdated soon after publication. Healthcare providers appreciate and print out flowcharts, so consideration needs to be given to ensuring these are updated when appropriate.

Education of healthcare providers and consumers

Despite various educational strategies, some healthcare providers and women remain concerned about the new program. Some organisations educating women and health professionals about the transition appear to have had minimal content knowledge, drawing heavily on unpaid support from experts working in the field. In February 2017, community concerns reached the level of a change.org petition with more than 70,000 signatures, started by a woman whose healthcare provider had expressed apprehension to her about the changes. Despite various educational strategies, some healthcare providers and women remain concerned about the new program. Some organisations educating women and health professionals about the transition appear to have had minimal content knowledge, drawing heavily on unpaid support from experts working in the field. In February 2017, community concerns reached the level of a change.org petition with more than 70,000 signatures, started by a woman whose healthcare provider had expressed apprehension to her about the changes.18 Evidence-based responses to the concerns being raised were possible, but apparently not known or understood by all providers.

Several nongovernment organisations stepped in to fill what they saw as information gaps (in particular for women), or to produce information tailored to particular groups. However, these organisations could have provided more timely information had they been aware of the Department of Health’s communication strategy and timing.

Lessons

Care should be taken to ensure organisations appointed to provide education about program changes have a proven track record in the area and are able to demonstrate appropriate content knowledge. Education of health professionals should begin well in advance of program changes, as they play an important role in explaining changes to the community. Many community-based or nongovernment organisations have proved willing to support the NCSP and fill communication gaps. Involving them more actively and earlier could have extended the reach of the Department of Health’s communications strategy and provided endorsement for NCSP changes from a variety of trusted voices.

The future

Self-collection is likely to play a key role in addressing one of the main barriers to further reducing cervical cancer in Australia: participation that was suboptimal, inequitable and declining. In Australia, self-collection is offered through a clinic-based model (rather than mailouts or home visits). At present, this model is unusual, and Australia’s experience will be of wide interest. Local pilots of this approach found very high acceptance of self-collection when there was appropriate support and training of healthcare providers, and community engagement with hard-to-reach groups.6 Identifying optimal approaches to triaging and managing HPV-positive women is the subject of much active research. In Australia, women who test positive to HPV types 16 and 18 are managed differently to those in whom only non-16/18 types are detected. This allows the program to automatically adapt to the effects of Australia’s HPV vaccination program, and introduce HPV screening from age 25 while avoiding over-referral in younger women. The cytology workforce has been reducing, and so sustainability of cytology triage in the longer term is uncertain. Other approaches under active investigation (including in the Australian trial, Compass)15,19 include use of more detailed genotyping information or tests that look for molecular features indicative of transforming infections.

Australia is well positioned to eliminate cervical cancer as a public health problem within 20 years as a result of its cervical cancer prevention programs.20 Successfully implementing the screening changes is crucial to achieving this goal.21 To ensure this can occur, it is vital to ensure all systems work effectively, confidence in the screening program is maintained, improvements are ongoing and participation becomes more equitable.

Peer review and provenance

Externally peer reviewed, commissioned.

Competing interests

MSm was a member of the team that undertook the modelled analysis that formed part of the policy evaluation for the Australian Medical Services Advisory Committee, was part of the technical team for the Cervical Cancer Screening Guidelines Working Party, and has performed other modelled analyses for the Australian Department of Health.
IH and MSa sat on expert advisory groups that supported the decision-making and policy implementation process around changes to cervical screening policy in Australia, as follows. IH chaired the Renewal Steering Committee, the Steering Committee for the Renewal Implementation Project, and the Cervical Cancer Screening Guidelines Working Party. MSa was a member of Renewal Steering Committee, the Steering Committee for the Renewal Implementation Project and was deputy chair of the Cervical Cancer Screening Guidelines Working Party.

MSa is co-principal investigator of an investigator-initiated trial of cytology and primary HPV screening in Australia (‘Compass’), which is conducted and funded by the VCS Foundation, a government-funded health promotion charity. MSa’s institution, VCS Foundation, has received equipment and a funding contribution for the Compass trial from Roche Molecular Systems and Roche Tissue Diagnostics. MSm is on the Compass study team, but neither MSm nor her institution (Cancer Council NSW) receive direct funding from industry for the Compass trial or any other project.

Author contributions

MSm, IH and MSa drafted, reviewed and approved the final version of the article.

References


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