



Implementation of Australia's primary human papillomavirus (HPV) cervical screening program: The Stakeholders Opinions of Renewal Implementation and Experiences Study

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ABSTRACT

In this study, we aimed to document stakeholders' experiences of implementing Australia's renewed National Cervical Screening Program. In December 2017, the program changed from 2nd yearly cytology for 20–69 year olds to 5 yearly human papillomavirus (HPV) screening for women 25–74 years. We undertook semi-structured interviews with key stakeholders including government, program administrators, register staff, clinicians and health care workers, non-government organisations, professional bodies, and pathology laboratories from across Australia between Nov 2018 - Aug 2019. Response rate to emailed invitations was 49/85 (58%). We used Proctor et al's (2011) implementation outcomes framework to guide our questions and thematic analysis. We found that stakeholders were evenly divided over whether implementation was successful. There was strong support for change, but concern over aspects of the implementation. There was some frustration related to the delayed start, timeliness of communication and education, shortcomings in change management, lack of inclusion of Aboriginal and Torres Strait Islander people in planning and implementation, failure to make self-collection widely available, and delays in the National Cancer Screening Register. Barriers centred around a perceived failure to appreciate the enormity of the change and register build, and consequent failure to resource, project manage and communicate effectively. Facilitators included the good will and dedication of stakeholders, strong evidence base for change and the support of jurisdictions during the delay. We documented substantial implementation challenges, offering learnings for other countries transitioning to HPV screening. Sufficient planning, significant and transparent engagement and communication with stakeholders, and change management are critical.

1. Introduction

The National Cervical Screening Program (NCSP) is one of Australia's three national cancer screening programs, which follow the criteria of Australia's Population Based Screening Framework ([Commonwealth of Australia as represented by the Department of Health, 2018](#)). The NCSP has halved cervical cancer incidence and mortality in Australia since its commencement in 1991 using 2nd yearly cervical cytology.

However, a plateau in impact has been observed since 2002, with a slow decline in program participation across most age groups (2nd yearly participation 2016–2017 in the target age group 20–69 years was 56%) ([Smith and Canfell, 2016](#); [Australian Institute of Health and Welfare, 2019](#)). The program also had limited acceptability and reach to some priority population groups such as Aboriginal and Torres Strait Islander people, who have twice the incidence of cervical cancer and nearly four times the mortality rate ([Australian Institute of Health and Welfare,](#)

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2019).

In 2011, on the basis of emerging international evidence about the superior effectiveness of human papillomavirus (HPV) nucleic acid testing for cervical screening (Dillner et al., 2008; Ronco et al., 2014) and in the context of Australia's national HPV vaccination program, Australia's health department established a Renewal Steering Committee tasked with reviewing the NCSP. The Committee oversaw a systematic literature review and modelled evaluations and then made a referral to the Medical Services Advisory Committee (MSAC), which appraises new medical services proposed for public funding, and provides advice to Government on whether such a service should be publicly funded based on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence (Media release 21/4/2022; Saville, 2016). In April 2014, MSAC recommended that Australia move to a screening program based on testing every 5 years using an HPV test with partial genotyping and reflex liquid based cytology triage for HPV-vaccinated and unvaccinated women ages 25 to 69 years plus an additional exit test for women up to age 74 years. They also recommended that Australia initiate population based invitations to screen, rather than only recalls/reminders as previously, and include a self-collection pathway for never- and under-screened women and people with a cervix (hereafter respectfully referred to as people), intended to improve participation and reduce inequities (Web page. MSAC application, 1276). The new program was predicted to be more effective and to cost less, with an expected further reduction in incidence and mortality from cervical cancer by 20–30% (Lew et al., 2017). A Steering Committee for the Renewal Implementation Project (SCRIP) was established which focused on three implementation priorities of (i) revised clinical guidelines, (ii) pathology/laboratory standards and measures and (iii) register capability. The 2015/16 national budget committed funds for implementation and for a new National Cancer Screening Register (Webpage). The timeline aimed for launch of the new program, referred to locally and herein as the renewed NCSP (rNCSP), and Register in May 2017 (see Timeline, online Appendix.) On 1st December 2017 (following a 7-month delay relating primarily to the lack of readiness of the Register), the NCSP commenced. Key program changes involved in the rNCSP are outlined in Table 1.

The rNCSP is organised and implemented through the Australian Department of Health, State and Territory health departments and local Primary Health Networks. It is supported by a National Cancer Screening Register (the Register) which replaced eight longstanding jurisdictional registers, which had served a similar function of systematic data collection to support and monitor the program but only for participants within their State or Territory. The previous State based registers had only provided reminders to those who had previously screened, with the national register using a national population denominator (Medicare enrolments) for the first time in order to allow it to send invitations. As previously, the program is delivered through general practice and other primary health care services, such as community health services and Aboriginal Medical Services, as well as by pathology laboratories and gynaecologists in both the public and private sectors. As previously, the cost of screening (attendance in primary care, costs of pathology, diagnostic and treatment services in the public sector) is subsidised for participants by Medicare, which is Australia's universal health insurance system, noting that over time complete subsidisation of such costs ('bulk billing') has become less available. The Australian Department of Health was responsible for the commissioning, coordination, and communication of activities necessary to facilitate, and prepare stakeholders for rNCSP. Table 1 summarises the anticipated impacts and sectors primarily impacted by the rNCSP changes.

The aim of this study was to document the experiences and perspectives of key stakeholders about whether the rNCSP was implemented successfully and the main barriers and facilitators to its implementation. These reflections were collected 11–20 months after the launch of the new program so reflect initial experiences in the first 1–2 years of the new 5-year screening interval.

2. Methods

2.1. Design

The STakeholders Opinions of Renewal Implementation and Experiences Study (STORIES) aimed to document stakeholders' initial experiences in implementing the rNCSP through semi-structured interviews. To inform the design of the interview guide, a workshop was convened with the investigator team to identify and document program changes and possible impacts across stakeholder groups. These changes and impacts were considered against eight implementation outcomes of Proctor et al.'s "Conceptual Framework for Implementation Outcomes" (Proctor et al., 2011) (acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability.) The interview guide was tailored to each stakeholder group, including probes in areas specific to the participant's role. (see Online Appendix A) An Advisory Committee of 11 purposefully selected Australian experts provided guidance on the study, interview guide and suggested potential study participants.

2.2. Participant recruitment

Individuals with roles in the program, provider or laboratory sectors were invited to participate. Selection aimed to achieve broad diversity among participants by role and location and included Aboriginal and Torres Strait Islander stakeholders.

Participants were emailed an invitation with a link to a plain language statement explaining the study and their role and seeking written informed consent to participate. If the participant consented, the participant was contacted to organise an interview time.

2.3. Data collection

Interviews were conducted face-to-face, online or by phone by the authors (TM, JB, DM, MS, NR, HS, MK) following the interview guides. The participant was asked to describe their role in cervical screening; their opinion about and experiences to date of the rNCSP; their perceptions of its acceptability to the broader community, providers and other stakeholders; any challenges in the implementation process and its impact (specific to their area); opinions on how any areas of concern could have been addressed differently; and perceived strengths of the renewed program. Interviews were digitally recorded, transcribed verbatim and imported into NVivo 11 for coding and storage.

2.4. Data analysis

Thematic analysis using a combination of inductive and deductive coding was used to identify, analyse and report patterns (themes) within the data (Braun and Clarke, 2006; Fereday and Muir-Cochrane, 2006). First, two authors (TM and KP) independently analysed five interview transcripts. The resulting coding trees were compared and refined through discussion, leading to an agreed coding tree that was then reviewed by a third author (MK). The remaining transcripts were coded by one author (TM), and additional codes added as needed. The team collaboratively and iteratively reviewed and discussed the list of themes. A second analysis round was conducted for greater specificity. Data were re-coded by the authors (MK, JB, MS, DM, KP, TM, HS, CN, CJ, CZ, AP) to generate more specific sub-themes issues mapped to the Proctor implementation outcomes framework (Proctor et al., 2011) as a structured template. The current paper focuses on reporting the barriers, facilitators and overall experiences of implementing the rNCSP. In-depth analysis of some themes will be reported in separate publications.

Ethical approval

Ethics approval for the study was granted by the Human Research

Table 1

Key changes between Australia’s 1991–30 Nov 2017 cytology-based National Cervical Screening Program (NCSP) and the renewed NCSP (rNCSP) from 1 Dec 2017.

Components	Cytology-based NCSP	Renewed NCSP	Key changes and potential impacts	Sectors/stakeholders primarily impacted
1. Primary screening test	Cytology	HPV (also known as the cervical screening test (CST))	<ul style="list-style-type: none"> • HPV test more sensitive – more screen positives requiring referral • Objective, automatable test with different cost and different workforce required 	<ul style="list-style-type: none"> • Pathology sector • Primary care • Specialists
2. Age range	20-69 years	25-74 years <ul style="list-style-type: none"> • no screening for those <25 • exit testing for 70-74 years of age 	<ul style="list-style-type: none"> • No longer screening under 25- need to communicate and explain why and manage those who were in follow up of positive screening tests at the time of transition • Explicit exit test and older exit age, including planned recall of previously exited women 	<ul style="list-style-type: none"> • Participants • Primary care • Specialists • Register provider
3. Invitation	State and Territory registry based reminders when overdue (for women screened at least once previously)	National register sends pro-active invitations and reminders (for all Medicare-enrolled women)	<ul style="list-style-type: none"> • Women receive invitations and reminders to participate, including never-screened women enrolled in Medicare • (Primary care retain own independent local reminder systems, which need updating) 	<ul style="list-style-type: none"> • Register provider • Participants • Primary care
4. Screening interval	2-yearly	5-yearly	<ul style="list-style-type: none"> • Less frequent • Fluctuating screening volumes during transition as most women expected to attend in first 2-3 years 	<ul style="list-style-type: none"> • Pathology sector • Primary care • Specialists
5. Self-collection	Not available	Available for never and under-screened women aged 30 and over (2 years or more overdue)*	<ul style="list-style-type: none"> • New pathway providing a choice for some participants to improve access and equity • Required primary care to assess eligibility and offer vaginal self-collection and pathology to process 	<ul style="list-style-type: none"> • Primary care • Pathology sector • Participants
6. Sample collection	Slide preparation	Liquid based	<ul style="list-style-type: none"> • Different collection media and process to prepare to send to lab – requires primary care education • Storage issues/hazards for flammable media 	<ul style="list-style-type: none"> • Primary care • Pathology laboratories
7. Screening register	Separate jurisdictional registers	National register	<ul style="list-style-type: none"> • Large piece of work vital to program delivery, support and monitoring with challenging timelines <ul style="list-style-type: none"> o New legislation to support new national data set o New registry provider and register build to support program pathways o Need to merge existing jurisdictional registry data o New use of Medicare data and planned incorporation of HPV vaccination data o New interfaces with laboratories and providers 	<ul style="list-style-type: none"> • Register provider • Commonwealth government • State and Territory govts • Laboratories • Primary care • Specialists
8. Responsibilities	Joint Commonwealth/State program	Joint Commonwealth/State program	<ul style="list-style-type: none"> • Screening register is now Commonwealth instead of state responsibility 	<ul style="list-style-type: none"> • Commonwealth Govt • State and Territory Govts
9. Symptomatic women	Symptomatic women screen in usual way (cytology) with referral to specialist if indicated	Symptomatic women eligible for a co-test (HPV & liquid based cytology (LBC)) with referral to specialist if indicated	<ul style="list-style-type: none"> • New pathway with an additional test provided (HPV & LBC) depending on the symptoms (provider needs to decide at time of test that co-test is or is not indicated by symptoms – education need) 	<ul style="list-style-type: none"> • Primary care providers • Laboratory sector • Specialists
10. Program guidelines and referral pathways	Dependent on cytology results	Dependent on HPV test results +/- cytology test results in some cases (triage or co-testing)	<ul style="list-style-type: none"> • New referral and management pathways dependent on HPV and reflex LBC test results (education and training needs for providers, laboratories, registry to ensure correct pathway followed and correct algorithms used in software and making recommendations) • Specific pathways for those in transition (previous abnormalities under cytology-based program) 	<ul style="list-style-type: none"> • Primary care providers • Laboratory sector • Specialists
11. Laboratory QA system	Laboratory QA systems in place for cytology	Laboratory QA systems set up for HPV testing; QA systems for cytology maintained	<ul style="list-style-type: none"> • New test and new requirements/standards (need to be developed, agreed and disseminated) 	<ul style="list-style-type: none"> • Laboratory providers
12. Program performance indicators	National quality and safety monitoring committee; routine monitoring by AIHW	National quality and safety monitoring committee; routine monitoring by AIHW	<ul style="list-style-type: none"> • New quality and safety indicators • New program performance indicators or new definitions of existing indicators (require data from register to generate indicators) 	<ul style="list-style-type: none"> • Registry provider • Commonwealth
13. Colposcopy	Colposcopy not routinely reported to registers or analysed for national QA	Colposcopy data collection mandated	<ul style="list-style-type: none"> • New program data element (need to develop all elements including data items, data transmission, collation and use) 	<ul style="list-style-type: none"> • Specialists • Registry provider
14. Medicare rebates	Rebates received for cytology testing by labs	New rebates for HPV tests and reflex cytology	<ul style="list-style-type: none"> • Differing costs/rebate structures. • Restrictions on when items can be claimed (e.g. restrictions by age and on minimum interval between claims for some items) 	<ul style="list-style-type: none"> • Pathology providers • Primary care

(continued on next page)

Table 1 (continued)

Components	Cytology-based NCSP	Renewed NCSP	Key changes and potential impacts	Sectors/stakeholders primarily impacted
15. Ethnicity data	Not systematically collected	Indigenous status and country of birth data to be collected and stored on NCSR	<ul style="list-style-type: none"> • Potential for improved monitoring of program equity and of interventions for specific population groups 	<ul style="list-style-type: none"> • Registry provider • Laboratory providers • Primary care • Specialists • Participants

*From July 2022, all screening eligible participants will be able to participate using self-collection.

Ethics Committee of the University of Melbourne (HREC ethics ID: 1852257). The study complies with Australia’s National Statement on Ethical Conduct in Human Research, which safeguards the protection of human subjects in relation to safety and privacy.

3. Results

3.1. Participants

We invited 87 stakeholders to participate; 36 either declined, did not reply or failed to schedule an interview despite at least two reminders, and two emails were undeliverable.

Interviews were conducted with 49 stakeholders (response rate 58%) between November 2018 and August 2019 (professional groupings shown in Table 2). Interviews averaged 41 min in length (range 20–69 min).

3.2. Key themes

High level themes identified were: the national Register, communication and education, Aboriginal and Torres Strait Islander inclusion, self-collection, clinical guidelines, age range and screening interval, laboratories/pathology sector, colposcopy, and Culturally and Linguistically Diverse (CALD) populations. The subthemes identified are presented using illustrative quotes in Appendix B.

3.3. Overall views of rNCSP implementation

There was a very high level of support across all stakeholder groups for the changes to the program, which centred around the move to HPV-based cervical screening. Stakeholders felt the program was very appropriate, supported by good evidence, and provided opportunities to improve equity in the program by reaching under- and never-screened people, and would facilitate the elimination of cervical cancer in Australia.

Around half of the participants felt the program had been successfully implemented (successfully implemented as defined by the individual), given the magnitude of the changes, although with caveats including that the complexity and scale had been underestimated. Some participants felt that implementation had relied heavily upon the goodwill and commitment of the medical community, pathology labs, and existing program staff.

The remaining half of the participants felt the rNCSP had not been

Table 2

Professional groups of participants in the STORIES studyⁱ, 2018–2019, Australia.

Professional group	n
Healthcare provider (eg GP, nurse, gynaecologist)	18
Program /Policy (Commonwealth, State/Territory, Primary Health Care Network, Registry providers)	11
Pathology sector	10
Advocacy/Education/Research	6
Other*	3

ⁱ ‘Other’ category includes: a consumer representative, a medical student and a medical intern.

successfully implemented or were unsure. These participants expressed disappointment in the implementation, feeling it was rushed and without adequate support. They voiced concerns that the delays in the start date and the national register implementation had been detrimental to screening participants and under-screened people and had concerns about quality and safety. They felt there was a lot more work to be done (especially on the Register) and were anxious about how the new program would work with current shortcomings. The overall implementation was perceived as having let down Aboriginal and Torres Strait Islander people because it had not consulted adequately and built in features to increase Aboriginal and Torres Strait Islander participation.

As a nationally funded and organised program, penetration of the structural changes to routine screening practices was near universal. Participants expressed concern that screening participants may have only become aware of the change through their provider. The penetration of self-collection was sub-optimal, with laboratories required to go through onerous processes before they could process self-collected specimens, and only one laboratory was able to do so by January 2018 (Smith et al., 2019). Consequently, self-collection was not well promoted, and interview participants felt that provider awareness and confidence in implementing self-collection remained low. The perceived consequences of this low penetration of self-collection included missed opportunities and delays in reducing inequity.

Stakeholders identified short-, medium- and long-term implications of the changes. Short-term implications included workforce and health system changes, some confusion and transition issues, and increased colposcopy demand. Medium-term issues included fluctuations in screening and colposcopy numbers (and HPV and disease detection over time) as participants transition from 2-yearly to 5-yearly recall; keeping people engaged with screening; and reviewing and updating the guidelines as evidence emerges about the optimal management of people (including older people) with HPV positive results, to reduce over-treatment. Long-term themes were reductions in cervical cancer and high-grade changes, better outcomes for participants, and better equity and participation in the program.

3.4. Facilitators and barriers

Facilitators and barriers to implementation raised by stakeholders are summarised in Fig. 1 and Box 1, with two illustrative quotes below.

“.. I think it’s worth emphasizing the enormous amount of work that a lot of people have put into making this a success. People who it’s not their job to do it, I mean; they’ve gone above and beyond what they’re being paid for, because they care about the program. And I think that’s at all levels. I can’t imagine where we’d be if all of that goodwill hadn’t been put in.” (P37, Program stakeholder).

“The biggest barrier was no doubt the delay in the register implementation because it was such a pivotal part of how you go about inviting participants and it also underpinned trust in the program itself.” (P10, Program stakeholder).

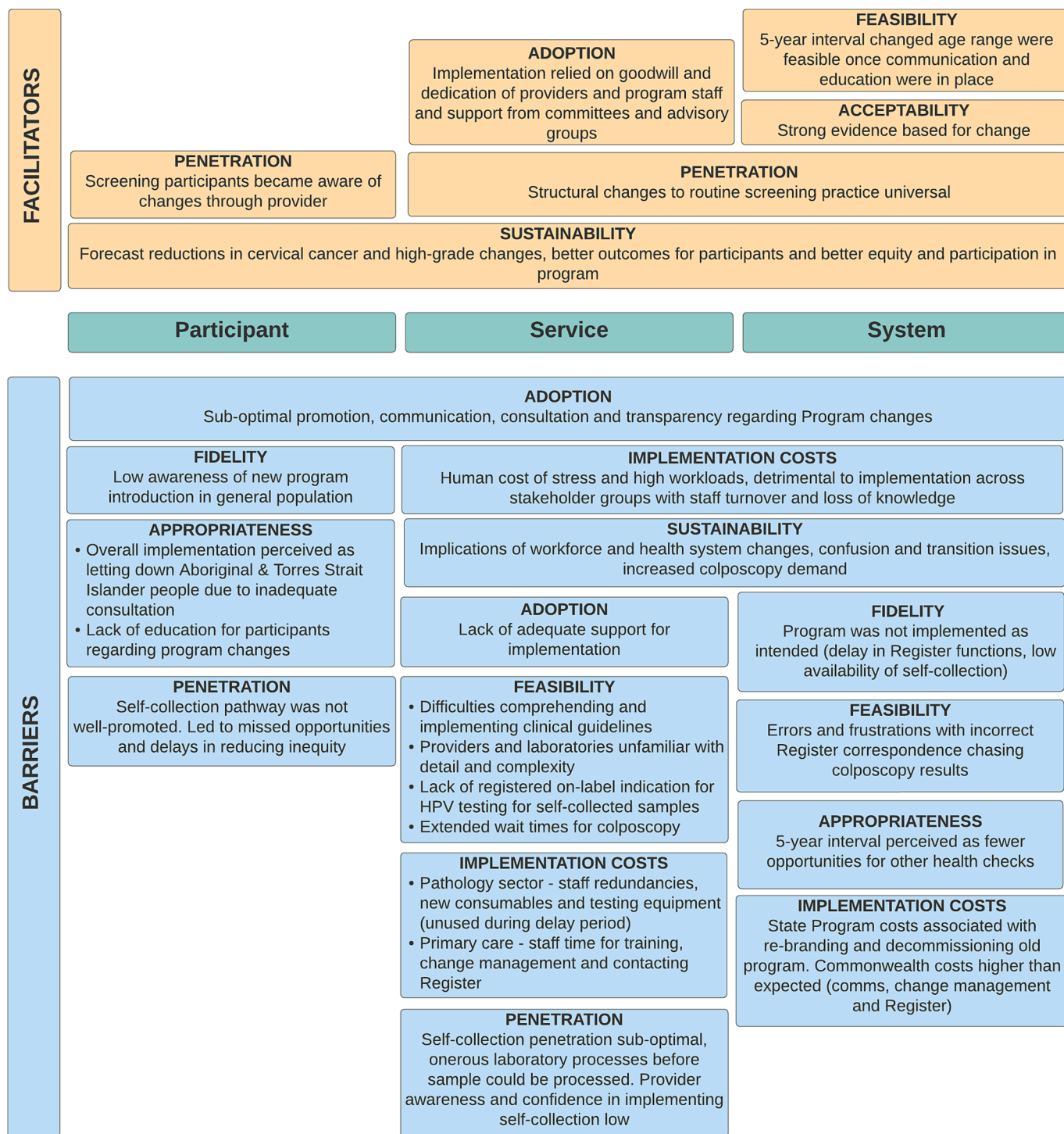


Fig. 1. Facilitators and barriers according to the domains of Proctor et al.’s implementation outcomes framework grouped by impact on screening participants, services and systems, as identified by 49 key stakeholders, Australia 2018–2019.

4. Discussion

We conducted interviews with key program stakeholders 11 to 20 months into the rNCSP. Stakeholders reflected on the significant change that had occurred over a protracted period with large impacts. There was strong support for the change to HPV-based screening, but concern over numerous aspects of implementation. There was some frustration related to the delayed start, timeliness of communication and education, shortcomings in change management, lack of inclusion of Aboriginal and Torres Strait Islanders in the planning and implementation, failure

to make self-collection widely available, and Register delays. Participants were divided on whether implementation could be considered as successful overall. Identified facilitators to implementation included stakeholder support and dedication, and the strong evidence base for change. Barriers centred around a perceived failure to appreciate the enormity of the change and building a national register, and consequent failure to resource, project manage and communicate effectively. Stakeholders were concerned that failure to identify and address some of the challenges experienced in implementation could already have delayed the potential benefits of the program in increasing equity and

further reducing the cervical cancer burden. This is the first study to capture the views of diverse stakeholders and our findings provide vital data to identify how barriers and facilitators might be addressed in future.

The main strength of our study is that it is the first to comprehensively assess the views of the diverse range of stakeholders involved in implementation, including those within programs, government and pathology. Documenting the experience of such a major program transition from multiple perspectives (including senior policy makers speaking frankly on condition of anonymity) may be useful for other national programs undergoing major change or for future programs being established, such as the proposed lung cancer screening program (Australia, 2020). Previous studies have documented the perceptions and experiences of clinicians at a similar time point to our study (1–2 years into the rNCSP) with similar findings of majority in principle support, but some challenges in accessing and using the Register and new guidelines, and implementing self-collection. Sultana et al documented an increase in confidence and knowledge about the program amongst primary care clinicians, predominantly GPs, in the months before and after Renewal, but an ongoing deficit in understanding and use of self-collection (Sultana et al., 2020). Sweeney et al surveyed primary care providers in NSW in late 2018, finding that about 10% did not receive any education about the rNCSP, did not know where to locate the guidelines, and that about one third of practitioners had rarely or never used them (Sweeney et al., 2022). Obermair et al surveyed general practitioners, obstetricians and gynaecologists two years into the rNCSP and found that, whilst over 80% were comfortable with the main program changes to start age, interval and test type, one third did not view self-collection as a reasonable alternative to clinician-collection (Obermair et al., 2021). Just under half had used the Register, many identified that they had further training needs relating to rNCSP pathways, and long colposcopy wait times were noted.

The major limitation of our study, and the previous surveys (Sultana et al., 2020; Sweeney et al., 2022; Obermair et al., 2021 Jun), is that they document a snapshot in time of what is an ongoing implementation through the first 5-year screening interval, with projected peaks and troughs in volume and revisions to policy over time (Smith et al., 2016; Smith et al., 2022). Program monitoring data, derived from the Register, informed an adjustment to the intermediate risk screening pathway from February 2021 (Smith et al., 2022). Now in the sixth year of the rNCSP, it is noteworthy however that not all issues identified by stakeholders have been clearly resolved and significant implementation challenges remain. In late 2020, the Register launched an integrated portal to some of the commonest primary care medical software, with slowly increasing uptake. An annual program indicator report is now published, showing that 62% of women aged 25–74 years had a cervical test in the three years 2018–2020, but planned reporting of indicators by Indigenous status and CALD status has not yet been achieved nor has a comprehensive colposcopy quality assurance program (Australian Institute of Health and Welfare, 2021; Whop et al., 2019). Data reporting how the rNCSP is meeting the needs of a wider range of under-screened groups is limited. From July 2022, self-collection became a choice for all screening participants (Media release 8/11/, 2021) in a transition that will reduce some of the current implementation barriers. The change will overcome barriers relating to the restricted eligibility criteria, which have resulted in laboratory rejection of self-collected specimens (Brotherton et al., 2022) and a lack of confidence in implementing self-collection in practice (Sultana et al., 2020; Obermair et al., 2021 Jun; Creagh et al., 2021), and will be facilitated by on-label self-collection to ensure all laboratories can process self-collected specimens. It is anticipated that a timely education and communication strategy for providers and the community will raise awareness and confidence in its use (Media release 21/4/2022). This study provides valuable insights into the immediate implementation experience of the rNCSP. Further research to explore the long-term implementation experience will be essential to understand how the program has overcome initial implementation

barriers and the experience through the second 5-year screening cycle and the policy change expanding access to self-collection.

Given that HPV screening is the recommended screening approach in all settings (WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization, 2021; World Health Organization, 2020), with emerging experiences from early adopters (such as the Netherlands Webpage, 2021) and many other countries planning transition, the implementation challenges we have documented in Australia provide useful information for other countries, both those with a similar high-income setting and also for low-middle income countries where implementation of HPV screening is vital in order to address the current inequitable global burden of cervical cancer. Key facilitators of success identified were detailed cross sector engagement and comprehensive planning; early attention to communication, education, and regulatory issues; and transparency with all stakeholders if timelines for implementation are delayed. Our findings highlight that prioritising engagement and stakeholder consultation with never- or under-screened populations (for example Indigenous, CALD, and lesbian, gay, bisexual, transgender, queer and intersex populations) from the outset is critical to ensuring elements that will reduce inequity are embedded in the program. A phased approach, such as a regional onboarding or pilot implementation experiences, may be preferred and certainly more manageable; however, the ethical implications of not offering HPV screening to all may be increasingly problematic given its universal recommendation as a key pillar of the World Health Organization's cervical cancer elimination strategy (WHO, 2021; World Health Organization, 2020; Castañon et al., 2019).

Responding to new evidence and recognising opportunities to increase equity, Australia made the decision to renew a very successful cervical screening program. The STORIES findings highlight substantial implementation challenges that offer learnings that are relevant for other countries transitioning to HPV based testing, and also for future health system changes in Australia, including the policy change regarding the availability of self-collection.

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All authors had full access to all of the data.

CRedit authorship contribution statement

Julia M.L. Brotherton: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, Writing – review & editing, Supervision. **Tracey McDermott:** Investigation, Writing – review & editing, Project administration. **Megan A. Smith:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Dorothy A. Machalek:** Investigation, Writing – review & editing. **Hannah Shilling:** Investigation, Writing – review & editing. **Khic-Houy Prang:** Methodology, Writing – review & editing. **Chloe Jennett:** Writing – review & editing. **Claire Nightingale:** Writing – review & editing. **Claire Zammit:** Visualization, Writing – review & editing. **Amy Pagotto:** Writing – review & editing. **Nicole M. Rankin:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Margaret Kelaher:** Conceptualization, Methodology, Investigation, Supervision, Funding acquisition.

Declaration of Competing Interest

The authors declare the following financial interests/personal

relationships which may be considered as potential competing interests: The CRE is a collaboration led by the Daffodil Centre (Cancer Council NSW and University of Sydney), the Australian Centre for the Prevention of Cervical Cancer (ACPCC), the University of Melbourne and the Kirby Institute, University of NSW. Both Cancer Council NSW and ACPCC participated in the implementation of the rNCSP and employees/representatives of these organisations were represented on the research team and invited to participate as stakeholders in the interviews. Where

such potential conflict of interests could have arisen between interviewer/interviewee, interviews were conducted by people who were not conflicted and all interviews were analysed deidentified and consistently through thematic, coded analysis. The study was overseen by a scientific advisory committee.

Box 1

Facilitators and barriers to the implementation of Renewal identified by 49 stakeholders, 2018-2019

Facilitators to date

- 1) Strong evidence base for change
- 2) Goodwill and dedication of stakeholders, including ongoing advice and support from committees and advisory groups
- 3) Ability of State and Territory programs to continue/ resume pre-Renewal operations (eg ongoing registry functions, program management and communications) during delay in transition and national registry operations

Perceived future facilitators

- 1) Clear communications to participants and providers, including data to show the program is working
- 2) Getting the National Register up to full functionality, including:
 - a. invitations, reminders, follow-up, and ready access to screening histories
 - b. improving data completeness and quality
 - c. using it to monitor and drive improvement
 - d. moving away from paper-based communications and faxes
 - e. improving integration with laboratory and practice management systems
 - f. ensuring its algorithms provide clinical safety
- 3) Good governance and planning, with sufficient capacity and dedicated resources.
- 4) Specific improvements suggested included:
 - a. simplifying some processes (such as colposcopy data collection and the layout of the guidelines)
 - b. providing more support and information for practitioners
 - c. timely guideline updates
 - d. continuous education and raising awareness in the population, including targeted campaigns for Aboriginal and Torres Strait Islander people
 - e. expanding who can provide cervical screening, especially in rural and remote areas

Barriers

1. Failure to appreciate the enormity of the change and register build
2. Importance of change management not acknowledged early enough
3. Expertise of States and Territories not utilised adequately
4. Absence of consistent central oversight, leadership and project management
5. Workload of those responsible for implementing change was very high, with staff turnover and loss of knowledge
6. Human cost of stress across all stakeholder groups
7. Delays and issues with Register meant other important aspects of the rNCSP were insufficiently addressed
8. Suboptimal communication, consultation, and transparency
9. Late communication, particularly the announcement to delay the program.
 - a. Program delay created operational issues, due to staff redundancies for State registers and cytologists in pathology labs, which happened too early
 - b. Delay commonly conflated by the public with the belief that the program itself was flawed, creating mistrust
 - c. Some practitioners had already told patients that their next screen would be the new test, or had patients hold off screening for the new test, only to have to explain to them on their return that it was not yet available
10. Insufficient education for providers and the public.
 - a. Not consistent or well-timed communication or education to support practitioners implementing the program
 - b. Lack of clear and timely communication with the public
11. Other practitioner level barriers included:
 - a. Insufficient time to discuss cervical screening in consultations
 - b. Loss of the nurse led cervical screening MBS number
 - c. Difficulties implementing new clinical guidelines when providers and laboratories were not yet familiar with the detail and complexity (especially for people with previous abnormalities)
 - d. Errors and frustrations with incorrect Register correspondence chasing colposcopy results
12. Lack of a registered on-label indication for HPV testing on self-collected samples, creating lack of test availability which limited access
13. Length of colposcopy waiting lists and associated delays in women being seen at colposcopy

Data availability

The authors do not have permission to share data.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.pmedr.2023.102213>.

References

- Australia, C., 2020. Report on the Lung Cancer Screening Enquiry. Cancer Australia, Surry Hills, NSW.
- Australian Institute of Health and Welfare 2019. Cervical screening in Australia 2019. Cancer series no. 123. Cat. no. CAN 124. Canberra: AIHW.
- Australian Institute of Health and Welfare 2021. National Cervical Screening Program monitoring report 2021. Cancer series 134. Cat. no. CAN 141. Canberra: AIHW.
- Braun, V., Clarke, V., 2006. Using thematic analysis in psychology. *Qualit. Res. Psychol.* 3, 77–101.
- Brotherton, J.M.L., Hawkes, D., Saville, M., 2022. Reasons for rejection of self-collected samples for cervical screening. *Med. J. Aust.* 216 (4), 214. <https://doi.org/10.5694/mja2.51412>.
- Castañón, A., Rebolj, M., Sasieni, P., 2019. Is a delay in the introduction of human papillomavirus-based cervical screening affordable? *J. Med. Screen.* 26 (1), 44–49. <https://doi.org/10.1177/0969141318800355>.
- Commonwealth of Australia as represented by the Department of Health 2018. Population Based Screening Framework. Publications approval number: 12300 ISBN: 978-1-76007-370-1. Available at: www.health.gov.au/sites/default/files/documents/2019/09/population-based-screening-framework_0.pdf. Last accessed 12th April 2023.
- Creagh, N.S., Zammit, C., Brotherton, J.M., Saville, M., McDermott, T., Nightingale, C., Kelaher, M., 2021. The implementation of self-collection cervical screening under the renewed National Cervical Screening Program: a qualitative insight from Victoria, Australia. *Med. J. Aust.* 215, 354–358. <https://doi.org/10.5694/mja2.51137>.
- Dillner, J., Rebolj, M., Birembaut, P., Petry, K.U., Szarewski, A., et al., 2008. Long term predictive values of cytology and human papillomavirus testing in cervical cancer screening: joint European cohort study. *BMJ* 13 (337), a1754. <https://doi.org/10.1136/bmj.a1754>.
- Fereday, J., Muir-Cochrane, E., 2006. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. *International Journal of Qualitative Methods* 5 (1), 80–92.
- Lew, J.-B., Simms, K.T., Smith, M.A., et al., 2017. Primary HPV testing versus cytology-based cervical screening in women in Australia vaccinated for HPV and unvaccinated: effectiveness and economic assessment for the National Cervical Screening Program. *Lancet Public Health.* 2, e96–e.
- Media release 8/11/2021. The Hon Greg Hunt MP. Landmark changes improving access to life saving cervical screenings. Available at: <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/landmark-changes-improving-access-to-life-saving-cervical-screenings>. Last accessed 26 November 2021.
- Media release 21/4/2022. Cancer Council Australia. Updated guidelines prepare health professionals for cervical screening ‘game-changer’. Available at: <https://www.cancer.org.au/media-releases/2022/updated-guidelines-prepare-health-professionals-for-cervical-screening-game-changer>. Last accessed 26/6/2022.
- Obermair, H.M., Bennett, K., Brotherton, J.M.L., Smith, M.A., McCaffery, K.J., Dodd, R. H., 2021. Australian national cervical screening program renewal: attitudes and experiences of general practitioners, and obstetricians and gynaecologists. *Aust. N. Z. J. Obstet. Gynaecol.* 61 (3), 416–423. <https://doi.org/10.1111/ajo.13310>.
- Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunker, A., Griffey, R., Hensley, M., 2011. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm. Policy Ment. Health* 38 (2), 65–76. <https://doi.org/10.1007/s10488-010-0319-7>.
- Ronco, G., Dillner, J., Elfström, K.M., Tunesi, S., Snijders, P.J., et al., 2014. Efficacy of HPV-based screening for prevention of invasive cervical cancer: follow-up of four European randomised controlled trials. *Lancet.* 383 (9916), 524–532. [https://doi.org/10.1016/S0140-6736\(13\)62218-7](https://doi.org/10.1016/S0140-6736(13)62218-7).
- Saville, A.M., 2016. Cervical cancer prevention in Australia: planning for the future. *Cancer Cytopathol.* 124, 235–240. <https://doi.org/10.1002/cncy.21643>.
- Smith, M., Canfell, K., 2016. Impact of the Australian National Cervical Screening Program in women of different ages. *Med J Aust.* 205 (8), 359–364. <https://doi.org/10.5694/mja16.00289>.
- Smith, M.A., Gertig, D., Hall, M., Simms, K., Lew, J.B., Malloy, M., Saville, M., Canfell, K., 2016. Transitioning from cytology-based screening to HPV-based screening at longer intervals: implications for resource use. *BMC Health Serv Res.* 26 (16), 147. <https://doi.org/10.1186/s12913-016-1375-9>.
- Smith, M., Hammond, I., Saville, M., 2019. Lessons from the renewal of the National Cervical Screening Program in Australia. *Public Health Res Pract.* 29 (2), e2921914.
- Smith, M.A., Sherrah, M., Sultana, F., Castle, P.E., Arbyn, M., Gertig, D., Caruana, M., Wrede, C.D., Saville, M., Canfell, K., 2022. National experience in the first two years of primary human papillomavirus (HPV) cervical screening in an HPV vaccinated population in Australia: observational study. *BMJ.* 30 (376), e068582.
- Sultana, F., Roeske, L., Malloy, M.J., McDermott, T.L., Saville, M., Brotherton, J.M.L., 2020. Implementation of Australia’s Renewed Cervical Screening Program: Preparedness of General Practitioners and Nurses. *PLoS ONE* 15 (1), e0228042.
- Sweeney, S.O., Cheng, Y., Botfield, J.R., Bateson, D.J., 2022. Renewal of the National Cervical Screening Program: health professionals’ knowledge about screening of specific populations in NSW, Australia. *Public Health Res Pract.* 32 (1), e31122104.
- Web page. MSAC application 1276 - National Cervical Screening Program renewal. <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1276-public>.
- Web page. The Royal College of Pathologists of Australasia. Background/History of NCSP. <https://www.rcpa.edu.au/Library/Practising-Pathology/NCSP/Background>.
- Webpage. Opportunities for improving population screening for cervical cancer. <https://www.gezondheidsraad.nl/documenten/adviezen/2021/10/19/verbetermoge-lijkheden-bevolkingsonderzoek-baarmoederhalskanke>.
- WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.
- Whop, L.J., Cunningham, J., Garvey, G., Condon, J.R., 2019. Towards global elimination of cervical cancer in all groups of women. *Lancet Oncol.* 20 (5), e238.
- World Health Organization, 2020. Global strategy to accelerate the elimination of cervical cancer as a public health problem. World Health Organization, Geneva.