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ORIGINAL RESEARCH

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Development and pilot evaluation of a decision aid for modern cervical screening

Carla Pecoraro[1], Lilantha Wedisinghe[1,2,*], Jeevan Jangam[1], Gabrielle Dore[1], Cassandra Harrison[1], Gary Chan[3], Abineash Mayooran[4]

[1]Department of Obstetrics and Gynaecology, Ipswich Hospital, 4305 Ipswich, QLD, Australia
[2]Faculty of Medicine, University of Queensland, 4006 Brisbane, QLD, Australia
[3]Faculty of Health and Behavioural Sciences, University of Queensland, 4072 Brisbane, QLD, Australia
[4]Medical Undergraduate, James Cook University, 4814 Townsville, QLD, Australia

***Correspondence**
Lilantha.Wedisinghe@health.qld.gov.au (Lilantha Wedisinghe)

Abstract

The aim of this study was to develop a cervical screening decision aid for countries which could choose between self- or clinician-collected sample for primary Human Papillomavirus (HPV) based cervical screening. A structured development process based on the International Patient Decision Aid Standards was used, including a systematic literature search for existing decision aids, a medical literature review, structured development of the decision aid which includes many iterative revisions, focus group discussions with screen eligible women, internal and external peer review by Gynaecology and non-Gynaecology experts, and finally field tested among 360 women. Most women considered the decision aid clear, helpful in decision making and would recommend it to others. This systematically developed decision aid appears to be suitable for wider use.

Keywords

Cervical screening; Decision aid; Self-collection; Cervical sampling; Clinician-collected; Human papillomavirus; Cancer of the cervix; Gynaecology; Women's health

1. Introduction

A substantial difference in cervical screening participation exists between indigenous and non-indigenous women in Australia [1]. Participation in cervical screening over a two-year period (1999–2001) in 13 rural and remote Indigenous communities compared with the rest of Queensland was 41% and 59% respectively [2]. The option of self-collection for cervical screening became available to all women in Australia from July 2022 onwards as a strategy to increase participation in screening. However, the lack of a decision aid made the screening decision more challenging. The Australian national strategy of elimination of cervical cancer [3] highlights the importance of participation in screening.

Supporting informed choice about screening requires clear, balanced information [4]. One way to facilitate informed decision-making is using patient decision aids (PDA) designed for patients or citizens facing specific decisions about treatment or screening. Helping women choose among two available options for cervical screening is important because the screening uptake rates are low in some areas of Australia. Most cervical cancers occurred in women whose screening is overdue. Women who were regularly screened prior to the diagnosis had 83% lower risk of nonlocalized cancer (Odds Ratio (OR) = 0.17, 95% Confidence Interval (95% CI): 0.12–0.24) compared to women not screened in the 5 years prior to the diagnosis [5]. The sensitivity of the primary cervical screening test which uses the polymerase chain reaction (PCR) technology is similar whether the sample was self-collected by the woman or by the clinician [6, 7].

The aim of this study was to develop a cervical screening decision aid for women in Australia to inform their decision of whether to self-collect or ask clinician to collect a sample for them.

2. Material and methods

The patient decision aid (PDA) was developed following the structured process offered by the International Patient Decision Aids Standards (IPDAS) and its' quality criteria [8].

Fig. 1 depicts the stages of this project. Phase 1 included the design of a decision aid informed by our focus group study, previous decision aid work and other relevant literature, followed by an iterative piloting and revision process involving user testing and expert feedback.

2.1 Phase 1

2.1.1 Assessing needs

Based on the IPDAS Guidelines, a four-step design process was followed. First, a literature review to synthesise evidence on: cervical screening; the efficacy and awareness of self-collected samples; and decision-making for women choosing how to get their screening, was conducted. Secondly, mixed-methods research was undertaken to determine the perspectives of women on factors that affect their decisions. A lack of awareness on self-collected samples was identified. It also identified a lack of high-quality, and easy-to-understand

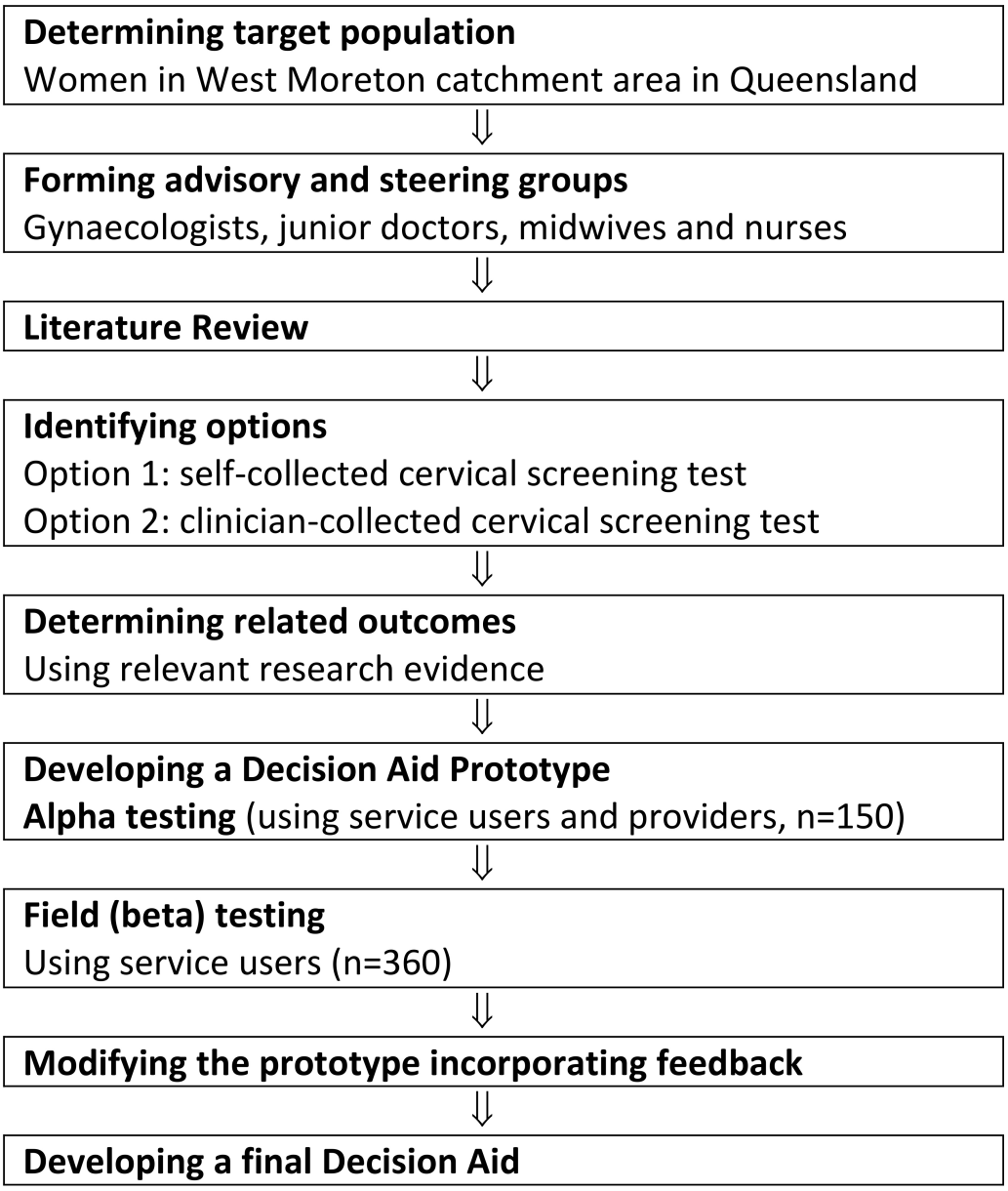

FIGURE 1. Study flowchart.

information comparing the two collection methods. Thirdly, members of the steering group provided their insights into the needs of women in making this decision and reviewed the initial prototype proposed by the study team. Finally, guided by the IPDAS guidelines and relevant evidence from the literature, the steering group moved forward with development of a patient decision aid aimed at all women.

2.1.2 Evidence based for quantitative outcome information

The evidence to inform the information included in the decision aid comes from the Australian National Cervical Screening Program and the Australian Cancer Council. Specifically, it was informed by the 2022 updates about self-collection and uptake rates. It also includes the estimates in cervical cancer mortality reduction from routine screening.

2.1.3 Advisory group

A senior advisory committee consisted of the Director of Obstetrics and Gynaecology and the Director of Midwifery and Nursing of Women's and Children's. This committee oversaw the steering group.

2.1.4 Steering group

The Principal Investigator (corresponding author) is an expert in this area who has completed a PhD in self-sampling based cervical screening and colposcopy in 2015. Decision aid design and revisions involved a multidisciplinary team with expertise in the clinical, psychosocial, and epidemiological aspects of cervical screening and experience in developing tools to support health decision-making. The team incorporated lay perspectives from a health consumer organisation representative (with similar characteristics to target audience

in age and gender) and an experienced independent citizen advocate. We worked with an experienced graphic designer to produce the PDA. The steering group participated in the interpretation of results at different phases of the study.

2.1.5 Expert review

We sought feedback on the draft decision aid from independent experts not involved in the project: lay people without medical backgrounds and clinical experts (senior gynaecologists, midwives, nurses), and an expert in English language editing. The first review emphasised the importance of visuals and revised images were created. Steps after positive cervical screening tests were summarised more clearly. Being "upfront" about the importance of following up positive results (*i.e.*, the need for repeat testing or colposcopy) was emphasised. The current requirement is that self-collected samples must be done at a clinician's office and cannot be done at home. The second review highlighted nuances in language that resulted in simplification and re-ordering of subject matter (*e.g.*, that not all tests are analysed for abnormal cell changes).

2.2 Phase 2

2.2.1 Patient decision aid prototype development (alpha testing)

The PDA prototype was developed after a literature review and information gathered from the focus groups in Phase 1. Initial decisions related to text content, layout and images were informed by the IPDAS consensus-driven research on information presentation, subject matter expertise of the research team and interpretations of the assessed needs in decision making. To reduce information overload, the PDA was limited to two A4 pages and font size kept large at 12. Each draft of the PDA was reviewed by the steering group. All study participants had experience with the collection of cervical screening tests. This process took approximately 3 months until an easy-to-read design was developed.

2.2.2 Key design features

- Offering choice: Communicating information about the similarities and differences between options using visuals makes it easy to understand across literacy levels.
- Plain language: We followed suggestions for making information easy to understand across literacy levels. A question-and-answer format is utilised to illuminate important points. Yes and no answers were conveyed and then expanded upon.
- Visuals: Colour visual aids explaining the collection process with images.

2.3 Phase 3

2.3.1 Field testing (beta testing)

The PDA was then field tested with a larger cohort of women to further instruct revisions.

Female patients were recruited from the Ipswich Hospital Gynaecology outpatient clinic waiting room. All women who attended the clinic from November 2023 and February 2024 were given a consent form, a copy of the PDA, and alpha testing clinician outcome questionnaires by the receptionist. If they chose to participate, they completed the above questionnaire which was then brought to gynaecology doctor that they have seen. At the beginning of their gynaecology appointment, they were then asked two simple questions regarding the feasibility and usability of the decision aid (1. How do you rate the information leaflet on 1–10 scale? 2. What screening test would you prefer to have next time?) and given an opportunity to provide further verbal feedback. Once again, results and feedback were discussed by the steering group and revisions to the prototype made as needed. Whilst a cervical screening test (CST) is offered to women in a specific age group, the participants were not excluded based on age, so as not to miss potential health literacy and attitudes of different ages.

Qualitative data was iteratively sought and grouped into four themes. These themes were considered when making changes to the decision aid (DA).

2.3.2 Statistical analysis

A statistician analysed the quantitative data and compared outcomes across age groups and English-speaking and non-English speaking backgrounds. Incomplete questionnaires were excluded from analysis. Each of the ten items had 4 response options (yes, no, don't know and prefer not to say). They were consolidated into 2 (yes versus no, don't know, and prefer not to say; combined) for ease of presentation. STATA (version 16.0, StataCorp, College Station, TX, USA) was used for statistical analysis.

3. Results

Over 150 people have been included in developing the PDA prototype and 373 women attended at the gynaecology outpatient clinic participated in the field testing. A total of 11 questionnaires were incomplete and 2 did not have valid consent which were excluded from the analysis.

The DEVELOPTOOLS Reporting checklist [8, 9] was designed to streamline reporting quality of PDA development process. It consists of 11 essential user-centeredness criteria and 9 additional elements. This study scores 11/11 criteria (Table 1).

According to the DEVELOPTOOLS Reporting Checklist, all eleven essential user-centeredness criteria were met with nine additional elements identified [9]. Numerous key stakeholders were involved in each step of the design, development, and refining of the decision tool. Female staff members of varying demographics were involved in the development and refining of the PDA prototype. All users involved emphasised the need for a PDA, particularly for those women who have never had screening or who are overdue for screening. They assisted to identify the need for a PDA, developed content included within the tool, and provided feedback to refine and re-design the tool within co-design workshops and focus groups. Alongside user development, an expert panel was involved. One of the researchers is an expert in cervical screening and self-sampling. Further, literature review was conducted to guide design decisions, all data was analysed by a statistician, and the final version of the PDA was edited by a professional language editor.

TABLE 1. DEVELOPTOOLS reporting checklist.

Item	UCD-11 score	Reporting Checklist and additional elements
Factor: Pre-prototype involvement		
1. Were potential users involved in any steps to help understand users?	Yes = 1.	Yes. Direct questioning (informal needs assessment and contextual inquiry form around 20 female staff members randomly) confirmed the non-existence of a PDA. All of them express the need for a PDA especially for women who have never had screening or who are overdue for screening. Yes. Around 20 staff members assisted in developing the content of the tool.
2. Were potential users involved in any steps of designing, developing, and/or refining a prototype?	Yes = 1.	Around 60 female staff members reviewed the draft design and re-designing, developing, or refining the prototype within co-design workshops.
Factor: Iterative responsiveness		
3. Were potential users involved in any steps intended to evaluate prototypes of the tool or a final version of the tool?	Yes = 1.	Yes. Evaluation of the prototype was done after each step of the process. The visuals were updated, and wording was changed.
4. Were potential users asked their opinions of prototypes of the tool or a final version of the tool in any way?	Yes = 1.	Yes. Feedback was received verbally at focus groups. After prototype was developed, potential users were given a survey and the opportunity to provide written comments. Women were able to voice their thoughts in clinic after completing the survey and with targeted questions.
5. Were potential users observed using the tool in any way?	Yes = 1.	Yes. The setting was in Gynaecology outpatient clinic where this was passively observed.
6. Did the development process have three or more iterative cycles?	Yes = 1.	Yes. 1: planning by steering committee 2: feedback on initial prototype (alpha testing) 3: 360 women in gynaecology clinic (beta testing)
7. Were changes between iterative cycles explicitly reported in any way?	Yes = 1.	Yes. Design decisions were based on a literature review. Iterative cycles were reported at each draft of the prototype.
Factor: Other expert involvement		
8. Were health professionals asked their opinion of the tool at any point?	Yes = 1.	Yes. The DA was provided to a large number of general practitioners, midwives and nurses who would be having discussions with women about cervical screening in wider context and their opinion was sought.
9. Were health professionals consulted before a first prototype was developed?	Yes = 1.	Yes. The director of Obstetrics and Gynaecology and the director of nursing in Women and Children's Health were consulted.
10. Were health professionals consulted between initial and final prototypes?	Yes = 1.	Yes. After each version of the prototype, the original steering committee reviewed the PDA. In addition to this, changes were presented to different health professionals who regularly work with women who would use the decision aid.
11. Was an expert panel involved?	Yes = 1.	Yes. A professional designer was used in development of visuals. One of the researchers is an expert in self-sampling and cervical screening. A professional language editor edited the final version of PDA. A senior statistician has analysed the data.
Additional elements in DEVELOPTOOLS Reporting Checklist		
12. Was a formal advisory panel of users involved?	Yes.	Yes. One member of the advisory committee is a user.
13. Were users, health professionals, and other relevant stakeholders involved as members of the research team?	Yes.	Yes. Users and health professionals were involved in throughout. Users were given the opportunity to provide feedback and it was subsequently incorporated into prototype revisions by the research team.

TABLE 1. Continued.

Item	UCD-11 score	Reporting Checklist and additional elements
		Beta testing was carried out in a large cohort of the patient population that it is assumed that such individuals have been included.
14. Were members of populations marginalized by social norms and policies involved?	Yes.	The decision aid was distributed to all women in the gynaecology outpatient clinic and did not collect information about their backgrounds.
15. How many users and health professionals were involved in total, and of each type?	Yes.	Steering committee was consisted of an expert in self-sampling and cervical screening, six consultant gynaecologists, 8 gynaecology trainees. Around 40 midwives, 30 nurses, 50 healthcare staff and 30 general practitioners have been involved in developing the PDA (alpha testing). Over 360 users provided feedback through the questionnaire during beta (field) testing.
16. Does the tool have a defined purpose?	Yes.	To bring awareness to cervical screening and its importance. To elucidate the two options in collecting samples and enable women to decide how it is collected (self- or clinician-collected). It could also be useful in shared decision making.
17. Is the tool intended to be used in a particular context?	Yes.	The tool is ultimately intended to be distributed to all women who require cervical screening tests. It goes directly to women and can be reinforced by clinicians.
18. Were any methods used to facilitate sharing of perspectives between groups?	Yes.	Workshops with health professionals, researchers and women considering CST collection methods were conducted for this purpose.
19. Were users involved from the outset of the project?	Yes.	Users were involved from the outset. Women were included in the steering committee and research team.
20. Were translation and cultural adaptation used to render the patient decision aid available to users across languages and cultures?	Yes.	The PDA was translated to Tamil language with careful consideration of cultural factors and needed adaptations. We aim to replicate the same into other common languages spoken in Australia.

Note: UCD: user-centeredness; PDA: patient decision aids; DA: decision aid; CST: cervical screening test.

The development process of the PDA occurred in four iterative cycles: planning by steering group; gaining feedback on the initial prototype (alpha testing); field testing within a cohort of 300 women in the Gynaecology outpatient clinic (beta testing); and continued development during writing of the paper process. Changes made between each iterative cycle were explicitly reported at each draft of the prototype. The prototype was repeatedly evaluated at each step of the process by users within focus groups, *via* a survey, as well as through targeted questioning in the outpatient clinic setting. Users were passively observed utilising the tool in the Gynaecology outpatient clinic setting. The versions were updated based on verbal and written feedback provided. This included updates to wording of the PDA and visual aids within the PDA. A professional designer was used in the development and redesign of visual aids included in the tool.

Prior to the development of the initial prototype, the Director of Obstetrics and Gynaecology and the Director of Nursing in Women and Children's Health at Ipswich hospital were consulted. After the prototype was developed, the decision aid was provided to many key stakeholders—general practitioners, midwives and nurses—who were identified as health professionals in the wider context outside of the Ipswich Hospital Gynaecology department who would be having discussions with women about cervical screening. Their opinion on the tool was sought prior to development of the initial prototype, and between versions of the prototype. The original steering group then reviewed the decision aid after each prototype version, and suggested changes were implemented.

3.1 Results of beta testing

Participant responses to questionnaire items are detailed in Table 2.

Virtually all participants (346/360 = 96%) said that the information in the decision aid leaflet is helpful for women to choose the right test for them. They did not find anything confusing or difficult to understand 94% (n = 338) or anything that needs to be changed 96% (n = 344) in the decision aid. The decision aid has improved their understanding about the self-sampling 86% (n = 310) as well as cervical screening 73% (n = 262). Consequently, they felt more confident in taking up cervical screening (285/360 = 79%). Most participants 77% (n = 276) believed that women are more likely to take up cervical screening, had they read this leaflet beforehand. A vast majority 94% (n = 338) said that it is better to send this PDA to women together with their cervical screening invitation. A slightly lower proportion of women 84% (n =

TABLE 2. Responses to questionnaire items.

	No*		Yes	
	N	%	N	%
Does this help women to choose the right test for them?	14	4	346	96
Is there anything confusing or difficult to understand?	338	94	22	6
Is there anything you'd like to change?	344	96	16	4
Is there anything that you love most?	97	75	33	25
Has your awareness about cervical screening improved after reading this?	98	27	262	73
Has your awareness about self-sampling improved after reading this?	50	14	310	86
Do you feel more confident in taking up cervical screening now?	75	21	285	79
Women are more likely to take up screening, had they read this beforehand?	84	23	276	77
Is it better to send this leaflet to women together with their CST invitation?	22	6	338	94
Do you recommend this decision aid to a friend?	59	16	301	84

No: "no" + "don't know" + "prefer not to say". CST: cervical screening test.*

301) recommended this PDA to a friend (Table 2).

English was the first language for the majority (312/360 = 87%) of participants. Only a minority (328/360 = 91%) of participants (patients attended at the gynaecology clinic) were healthcare workers. There is no significant difference in responses by the first language in all except for the item "is there anything confusing or difficult to understand?" (Table 3). A significantly higher proportion of participants from non-English language backgrounds responded "Yes" to this item ($p < 0.001$). There is no significant difference in responses by age group in all except for two item "Has your awareness about self-sampling improved after reading this?" ($p < 0.001$) and "has your awareness about cervical screening improved after reading this?" ($p = 0.005$). The significantly lower proportion of participants reported "Yes" to these two items among the older age group (60–79 years) compared to the other two age groups.

Women who completed the questionnaire then handed it over to the Gynaecology doctor that they were seen by. About 90% (328/360) of these women were interviewed by the gynaecology doctor regarding the PDA. Women highly rated this PDA, median = 9 (Inter Quartile Range (IQR) 8–10) on 1–10 scale. Half (168/328 = 51%) of participants said that they prefer to have a clinician collected sample in the next time, and 35% (n = 114) preferred self-sampling. While 12% (n = 38) did not mind having either, 2% (n = 8) said neither, which indicated that the information presented in the PAD is balanced.

3.2 Qualitative data

The qualitative data gained from field testing were grouped into four themes: positive, negative, suggestions and other comments. A total of fifty-three comments were obtained through field testing. Most comments expressed by participants was positive in relation to the PDA. Other comments opened opportunities for the clinician to further discuss patient questions or concerns about each testing method and inform about HPV.

The positive themes are represented below in Fig. 2. Overwhelmingly, positive comments were received about clear information provided, easy comparison of testing methods, and the informative diagrams. Some women reported that they felt like their fears were eased, and more aware of their own health and screening after reading the tool. Additional positive comments related specifically to the self-collect HPV testing and feeling more aware and educated on the option of self-testing. The positives of self-collected HPV testing were evidenced in additional feedback: discreet, flexible, easy, privacy and comfort, well-suited for certain demographics, and less painful. On the other hand, some women expressed positives of clinician-collect testing as giving piece of mind and maintained the option to have a doctor complete the testing. Overall, positive comments were received about the decision aid offering women the option of choice in their testing method.

There were only two comments made that were negative—both expressing that they felt that it was too long. Suggestions related to the imagery used in the graphics. One suggestion was to show the location of the swab in relation to the cervix in each testing method, with one requesting comparative zoomed in and zoomed out images of what the testing looks like. This feedback has informed both condensing of the tool and editing the graphics to be more succinct and clearer for consumer reading. A suggestion that could be adapted for patient information brochures is inclusion of step-by-step instructions with corresponding images for each testing method.

4. Discussion

The systematic development of an evidence-based patient decision aid for self-collected versus clinician-collected cervical screening testing is needed and feasible. As far as we are aware, this is the first patient decision aid targeting women of all backgrounds and has been developed following the IPDAS framework with rigorous evaluation (**Supplementary material**). The initial results of alpha testing support continuation of testing this PDA for wider distribution to all women who require cervical screening.

Participants unanimously believed that this decision aid helps women choose the right cervical screening test for them.

TABLE 3. Responses to questionnaire items by age group.

Age group (yr)	20–39		40–59		60–79		chi-square	*p*-value
	N	%	N	%	N	%		
Does this help women to choose the right test for them?								
No*	3	3	8	3	3	8	1.69	0.429
Yes	83	97	227	97	36	92		
Is there anything confusing or difficult to understand?								
No*	83	97	220	94	35	90	2.23	0.328
Yes	3	3	15	6	4	10		
Is there anything you'd like to change?								
No*	84	98	224	95	36	92	1.91	0.385
Yes	2	2	11	5	3	8		
Is there anything that you love most?								
No*	19	76	63	72	15	88	1.92	0.383
Yes	7	27	24	27	2	12		
Has your awareness about cervical screening improved after reading?								
No*	13	15	69	29	16	41	10.66	0.005
Yes	73	85	166	71	23	59		
Has your awareness about self-sampling improved after reading?								
No*	6	7	30	13	14	36	19.48	<0.001
Yes	80	93	205	87	25	64		
Do you feel more confident in taking up cervical screening now?								
No*	14	16	48	20	13	33	4.80	0.091
Yes	72	84	187	80	26	67		
Women are more likely to take up screening, had they read this?								
No*	20	23	55	23	9	23	0.00	0.999
Yes	66	77	180	77	30	77		
Is it better to send this leaflet together with the screening invitation?								
No*	3	3	16	7	3	8	1.40	0.497
Yes	83	97	219	93	36	92		
Do you recommend this decision aid to a friend?								
No*	12	14	41	17	6	15	0.59	0.743
Yes	74	86	194	83	33	85		

No: "no" + "don't know" + "prefer not to say".*

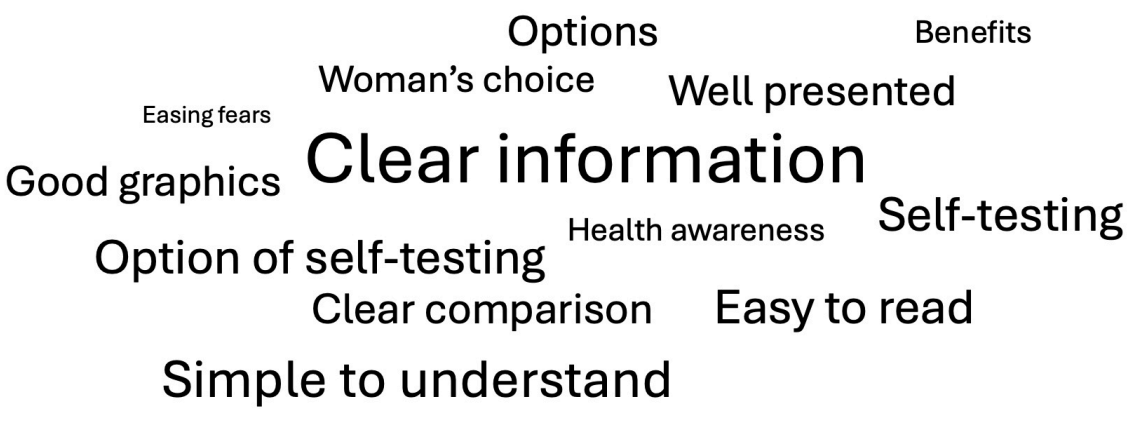

FIGURE 2. Comments written on questionnaires regarding the PDA (word cloud).

They found it simple to understand. It appears that the decision aid is not biased towards self-collection, as many participants still preferred the clinician collection to self-collection. The PDA probably motivated women to take up cervical screening which is a positive sign.

There are several potential implications of this tool. Our PDA has the potential to capture an audience that is not aware of the newer option of self-collected cervical screening test. It also fills an important gap in the decisional needs and barriers [10] related to uptake of the test [11], such as anxiety [12] about the process of collection. The literature supports that there is an urgent need to increase awareness for women. Additionally, this tool can be adapted for use more broadly across Australia and in other countries (*i.e.*, translation into other languages with careful consideration of cultural factors and needed adaptations) or on an interactive digital platform [13].

There are limitations to our patient decision aid. While cervical screening is recommended for all women aged 25–74, our field testing extended only to women who were referred to our Gynaecology Outpatient Clinic, meaning they were engaged with a clinician in the community and more likely to get a cervical screening test before answering the questionnaire. Consequently, we recommend extending this study to the general population. In addition, some of these women had abnormal results in the past and thus may have higher health literacy on the topic. Similarly, we are unable to report on the diversity of the sample used in field testing, except for age.

The strengths of the PDA are its foundation in evidence-based research on cervical screening [14–16] and up-to-date information corroborated with the Australian National Cervical Screening Program. The decision aid can be easily updated to reflect changes in recommendations as scope of knowledge evolves. The decision aid can be easily dispersed and advertised to target the intended audience. It can be accessed with discretion for those wanting privacy in decision making and not wanting to discuss with others.

5. Conclusions

In conclusion, this tool is an easily scalable intervention that can be disseminated more widely to encourage and inform women about the importance of cervical screening and the options of self-collected and clinician-collected samples. This thereby enhances patient experience and expedites appropriate care for women who have abnormal results. The information is presented in the PDA is simple, balanced and was highly rated by the participants. This study strongly supported the need to making this leaflet accessible to women prior to their cervical screening test which will engage them in screening.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

LW—designed the research. LW, CP, GD and JJ—performed the research. GC—analysed the data. LW, CP, GD, AM and CH—wrote the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This prospective study received ethical approval from Clinical Research Ethics Committee (approval number: 2023/QWMS/101062). Written permission has also been granted from the institutions where the research was conducted, and informed consent has been obtained from the patients. The study was conducted in accordance with the Principles of the Declaration of Helsinki.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.ejgo.net/files/article/1867410758706315264/attachment/Supplementary%20material.pdf.

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