PEC Innovation 5 (2024) 100347

Contents lists available at ScienceDirect

PEC Innovation

journal homepage: www.elsevier.com/locate/pecinn

# Development and pilot testing of the Population And ContExt adaption of decision aids (PACE) framework

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ARTICLE INFO

*Keywords:*
Shared decision-making
Patient decision aid
Contraception
Cultural adaptation

ABSTRACT

*Objective:* This study aimed to develop and pilot test a new framework for the adaptation of patient decision aids (PtDAs) using a specific case example of contraceptive method PtDAs for Chinese-speaking migrant women.
*Methods:* We developed a novel approach for adaptation – the PACE (Population And ContExt adaption of decision aids) framework – that incorporated both existing models and frameworks and innovative elements. It involves six stages: selection and appraisal; review by content experts; content validity and usability pre-testing; translation; decisional needs assessment; and perceived acceptability, usability and feasibility testing. We then followed the framework to pilot and adapt a suite of PtDAs on contraceptive methods for Chinese-speaking migrant women in Australia. Twenty healthcare providers and 22 Chinese migrant women participated during the stages five and six.
*Results:* The pilot resulted in adapted PtDAs that were acceptable to end users. For future research, we proposed further recommendations and considerations based on lessons learnt, which include flexibility in applying the framework and considering an additional real-world evaluation step.
*Conclusion:* Adaptation of PtDAs required a multi-stage and multidisciplinary team-based and pragmatic approach as exemplified in the application of the PACE framework.
*Innovation:* The PACE framework developed and piloted in this study fills a crucial gap in knowledge about how to adapt PtDAs for new populations and contexts and provides an innovative and systemic approach to guide the adaptation process.

## 1. Introduction

Shared decision-making (SDM) and the use of patient decision aids (PtDAs) are gathering momentum in policy and the health service research agendas globally. While there are several existing guidance papers and resources on developing new PtDAs [1-3], the literature on adapting PtDAs for new languages, cultures and health systems is limited. Adaptations can help optimise implementation of population and context-dependent interventions which could include communication or shared decision-making tools [4]. Many of the existing international and local guidelines for health material adaptation predominately focus on the adaptation of clinical guidelines, questionnaires, measurement scales, health education or health promotion materials [5-7], which may not be optimally suited for PtDA adaptation efforts. Adaptation of existing PtDAs which are based on evidence review, and/or field tested in other populations or settings, could potentially be a resource-saving and time-efficient approach for new populations, especially those that are socioeconomically disadvantaged and underserved [8-10].

This study was set against the backdrop of the increasing need for exploring the opportunities and challenges to adapt or develop PtDAs for culturally and linguistically diverse groups or new health contexts. It

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https://doi.org/10.1016/j.pecinn.2024.100347
Received 7 November 2023; Received in revised form 18 September 2024; Accepted 27 September 2024
Available online 30 September 2024

developed and piloted a framework that could have broader implications and potential to be further applied to future efforts to expand the adaptation of PtDAs among new populations and contexts in Australia and globally. The Chinese-speaking population group in Australia was chosen as a target population for this pilot and case study as people from China are one of the largest overseas-born groups (8.3 %), and the Chinese language including Mandarin and Cantonese is one of the most spoken languages at home (3.7 %) other than English [11]. This pilot study adapted an existing contraceptive-choice PtDA for use with Chinese migrant women living in Australia. This article aims to provide a brief overview of the framework used in this project, to demonstrate the methodological stages that were taken, and to provide practical suggestions for future research and practice.

## 2. Methods

### 2.1. The PACE framework for adaptation overview

This project developed a six-stage framework for adapting PtDAs and then followed it to adapt an existing contraceptive method-choice PtDA for Chinese-speaking migrant women. The initial development of the framework was based on a review of key literature on the development of PtDAs and adaptation of health materials and interventions, as well as the authors' collective knowledge and team deliberations. This framework is referred to as the PACE (**P**opulation **A**nd **C**onte**X**t adaption of decision aids) framework hereafter. The PACE framework incorporated both existing models and frameworks and innovative elements in executing each stage. The overview of the adaptation process is provided in Fig. 1 and examples of its application to adapt contraceptive method-choice PtDA are provided in Table 1. The rationale and justification for each stage is provided below.

#### 2.1.1. Stage 1: selection and appraisal

This stage was primarily informed by the International Patient Decision Aid Standards (IPDAS) criteria [17] and 'Translation is not enough - Cultural adaptation of health communication materials: A five-step guide' that was developed by the European Centre for Disease Prevention and Control (ECDC) [7]. The IPDAS criteria are maintained and regularly updated by the IPDAS collaboration and is an internationally recognised standard for guiding the development, quality evaluation and certification of PtDAs [17,18]. The ECDC cultural adaptation guide was specifically developed for adapting health communication materials, as opposed to questionnaires and measurement instruments, and has a strong focus on involving key stakeholders and end-users during the adaptation process [7]. It provides step-by-step guidance, checklists, a case-study demonstration, practical tips, and example templates for applying this framework to adaptation works [7].

The criteria provided in Box 1, many of which were derived or adapted from the IPDAS [19] qualifying criteria and ECDC guide [7], may be useful for assessing the eligibility of the existing source materials.

#### 2.1.2. Stage 2: review by content experts

This stage follows the guidance and recommendations from the ECDC guide [7], which is 'early review by content and linguistic experts.' This stage aims to make sure the content of the communication material to be adapted is locally and culturally relevant and appropriate [7]. The ECDC guide recommends that existing local and national guidelines, research studies, data and websites should be referenced and incorporated into the adapted material to enhance relevance and consistency [7]. The ECDC also recommends the source material be reviewed by content experts who have certain required characteristics [7]. For example, it recommends that the content expert is a well-known professional in the content area, is able to identify locally relevant policy and practice resources and commit to reviewing the source material [7]. Documenting the credentials of the content experts, review process and decisions is recommended for this stage for transparency reasons. An example content grid which was adapted from the ECDC guide is provided in Appendix A.

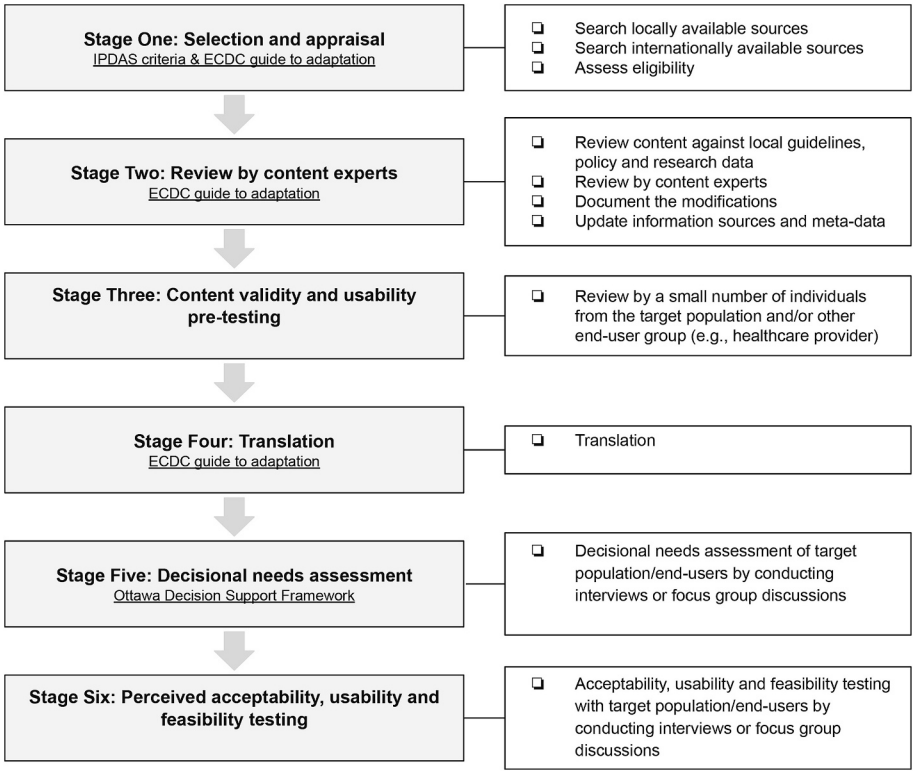


**Fig. 1.** Overview of the PACE framework.

**Table 1**
Stages and methods involved in adapting contraceptive method-choice PtDA.

| Stages | Methods |
|---|---|
| Stage 1 | – English-language contraception-related materials were identified via Google keyword searches and targeted searches of the major Australian and international family planning and health promotion organizations' websites.<br>– The Decision Aid Library Inventory (DALI) [12] hosted by the Patient Decision Aids Research Group was manually searched<br>– A systematic review of PtDAs on contraceptive methods [13] and PtDAs that were known to the research team were reviewed.<br>– Available sources were appraised for eligibility against the criteria for selecting source PtDA (see Box 1). |
| Stage 2 | – Process coordinator checked the selected PtDAs's content against the Australian contraception clinical practice handbook [14].<br>– A multidisciplinary team of content experts were invited to review the document for its clinical content and the language (i.e., linguistic modifications to ensure the English language and terminologies are suitable for the Australian context).<br>– All changes that were made to the original PtDAs were documented in a content review grid that was adapted from the ECDC template (see Appendix A) [7].<br>– The supporting document for the PtDAs, including version description, authors, funding source, publication data, terms of use, notes and information sources, was updated in consultation with the original developers. |
| Stage 3 | – Three group discussions with general practitioners (GPs) ($n = 16$) were conducted. GPs were prompted to comment on the content, format and structure of the PtDAs as well as their perceptions of usability and feasibility. |
| Stage 4 | – Process coordinator, who is fluent in both the Chinese and English languages and medically trained, conducted the initial translation of the PtDAs.<br>– A bilingual content expert checked the quality of the translation. |
| Stage 5 | – In-depth semi-structured interviews with healthcare providers were conducted to explore their perceptions of challenges and opportunities to provide decision-support for Chinese migrant women during contraceptive counselling [15].<br>– In-depth semi-structured interviews with migrant Chinese women were conducted to explore factors influencing Chinese women's contraceptive method choice and experiences and investigate their decisional needs [16].<br>– Note: Each interview was divided into two parts. During the first part of each interview, the experienced or perceived decisional needs were explored. The second part addressed the research objectives of stage six. |
| Stage 6 | – Healthcare providers and the women participants were shown the adapted PtDAs and were prompted to provide feedback on their format, design, content, perceived acceptability, feasibility and usability. |

#### 2.1.3. Stage 3: Content validity and usability pre-testing

This stage aims to: (1) explore if the content of the PtDA is relevant, accurate and understandable; (2) optimise the PtDA content adaptation before proceeding with translation; (3) observe and gather preliminary information on potential usability and feasibility issues of the PtDA; and (4) test and refine data collection methods for stage five and six. This pre-testing stage can be on a small scale, and ethics approval may or may not be required depending on local requirements. If possible, this stage can utilise existing networks of professionals with experience in providing care in the subject topic area and/or individuals who have similar characteristics to the target population. Formal data collection and analysis, i.e., audio recording, transcription, and coding, is usually not required. The PtDA can be presented to them to think aloud while reviewing. Prompt questions that can be used are presented in Box 2.

#### 2.1.4. Stage 4: translation

This stage is partly informed by the ECDC guide to health communication material adaptation. [7] The ECDC guide recommends that a native speaker of the target language who is familiar with the subject area to undertake the translation task [7]. The use of professional translators is not required at this stage as it can be highly resource-intensive and costly unless it is required by institutions for quality control reasons or is the only available option. Forwards and backwards translations are also not required. The justification for such an approach to translation is as follows. First, this stage closely follows the recommendations made by the ECDC guide, which suggests one translator who is not necessarily a professional translator but possesses the above-mentioned characteristics to translate the material [7]. The ECDC guide specifically suggests not using multiple translators as this may result in inconsistency in translation and require extra efforts in harmonising versions of translation [7]. Instead, the ECDC guide recommends a quality check and review by another person who is proficient in both the target language and the content area [7]. Second, the source PtDA should usually be written in simple English and at readability levels tailored to people with average to low health literacy, making translation relatively easy and straightforward. Third, it is imperative for someone familiar with medical terms, linguistic variations and contextual background information in both source and target language to chair the translation. Fourth, it is anticipated that the PtDA will undergo further refinements and changes during the later stages of the adaptation as part of an iterative process.

#### 2.1.5. Stage 5: decisional needs assessment

This stage is informed by the Ottawa Decision Support Framework (ODSF) [20]. The ODSF is a theoretical framework that had been designed to guide the process of developing and implementing shared decision-making interventions targeted at either the patients or the providers [20,21]. The ODSF asserts that providing tailored decision support for patients and healthcare providers based on their decisional-needs is likely to improve decision outcomes, including decisions that are based on evidence-based information and personal values, behavioural actions and satisfaction. [20] Decisional needs could include decisional conflict (uncertainty); insufficient knowledge or unrealistic expectations; lack of support from others; inadequate access to services and resources; unclear values as to what is important; and limited confidence or skills in making informed decisions [22].

The aim of this stage is to identify priority content areas for subsequent iterations of the adapted PtDA; and to identify broader contextual factors that need to be addressed in order to successfully implement the PtDA among the target population group; or complement efforts to

**Box 1**
Criteria for selecting source PtDA.

1. Presents information on all relevant options for addressing the index health issue, not a subset of the options
2. Meets the six qualification and ten certification criteria in the IPDAS Minimum Standards (i.e., IPDASi v4) [17]
3. Is evidence-based (i.e., based on best available scientific research evidence) [7]
4. Uses easy or plain language [7]
5. Developed with end-user involvement [7]
6. Was field tested among end-users (optional)
7. Has been shown to be effective for the purpose desired (optional)
8. Is in the public domain, copyright free, or possible to obtain permission to adapt [7]

**Box 2**
Example questions for content validity and usability pre-testing.

1. Looking at the decision aid, can you please describe your initial reaction and thoughts?
2. What do you think of the content of the decision aid? Any thoughts on coverage, accuracy, and relevance?
3. What could be changed or improved?
4. Could you please comment on the usefulness of this decision aid to you?
5. Do you have any other comments or anything that you would like to share?

improve care quality outcomes as a whole. This stage could be in the form of individual interviews or focus groups with end users. Example methods and questions are published elsewhere [15,16]. For Stages 5 and 6, data collection can be undertaken in a single session to save time and resources.

#### *2.1.6. Stage 6: acceptability, usability and perceived feasibility testing*

This stage aims to explore the target populations' perceptions of the design, information presentation, usefulness and feasibility of the adapted PtDA and to collect their feedback about potential improvements. This stage is partly informed by 'a systematic development process for patient decision aids' proposed by Coulter and co-authors [1]. Their model is intended for the creation of new PtDAs, and therefore, describes a multi-stage process for prototype development and alpha and beta testing of the prototypes before finalising the PtDA design [1]. In the model proposed by Coulter et al., alpha testing refers to the comprehensibility, usability and acceptability testing of the PtDA by key stakeholders and typical end-users. Beta testing refers to the feasibility testing in 'real life' settings [1]. This stage in the current PACE framework combines elements of both alpha and beta testing of the PtDA. Individual interviews with end users and sample questions are published elsewhere [23].

## 3. Application of the PACE framework to adaptation of contraceptive method-choice PtDA for Chinese-speaking migrant women and results

### *3.1. Stage 1: selection and appraisal*

As a first step, we searched for both the local and international sources for suitable existing PtDAs. At the time of searching (early 2017), we were not able to find a contraceptive method resource in Australia that met our selection criteria (see Box 1). A search of the Decision Aid Library Inventory (DALI) [12] returned one English-language PtDA that was developed by the Mayo Clinic in the USA [24]. Although this PtDA met the IPDAS qualification and certification criteria, documentation about its development process and evaluation among end-users were lacking. A systematic review on women's values in contraceptive choice published in 2014 identified 17 PtDAs on contraceptives and their associated interventional or evaluative studies [13]. We reviewed those PtDAs and found that the majority ($n = 12$) did not meet our selection criteria. Five studies included in this systematic review evaluated the World Health Organisation (WHO) family planning Decision Making Tool [13,25]. The tool was assessed against the eligibility criteria (see Box 1) and was excluded on the basis of not meeting some IPDAS minimum standards; and also due to the entire package containing 244 pages which could have posed significant time and resource constraints to adaptation. After excluding PtDAs found through the above channels, we chose to adapt a suite of contraceptive method PtDAs that were developed and evaluated in the Right For Me study in the United States [26], which became known to us via our professional networks.

The Right for Me study was a large-scale cluster randomised trial examining the effects of two strategies (patient-targeted versus provider-targeted) in facilitating SDM during contraceptive care [26,27]. The Right for Me PtDAs (seven one-page PtDAs in total), along with a training video, were part of the provider-targeted intervention [26]. They were developed based on the latest clinical evidence and the US national guidelines and with the involvement from key stakeholders and patient representatives [26]. They were classified as encounter PtDAs which were similar to the Option Grid™ (key attributes of options are presented in a tabular format allowing for easy comparison) [26,28] and were specifically developed in primary and reproductive healthcare settings [26,27]. Permission to adapt the PtDAs was obtained.

### *3.2. Stage 2: review by content experts*

The content review process began with cross-checking the source PtDA content against local contraceptive guidelines and research data. A group of multidisciplinary content experts contributed to cross-checking. Through content review, five types of changes or modifications were made to the original seven-page PtDA. A detailed summary of the changes/modifications is shown in Table 2.

During the content review process, some of the verbal probability terms of 'possible', which were used to describe the possibility of side effects, were replaced with numerical formats, such as frequency. The need for a visual aid was prompted when extra explanations on how methods work, and the mechanism of action for each method were added to the PtDA. Female reproductive system anatomical terms were frequently mentioned in the PtDA and the need for a pictogram was flagged. To improve the overall design of the PtDAs, the process coordinator developed the illustrations for a female reproductive system pictogram using royalty-free images. A paragraph on key facts and myths about contraception and less effective contraceptive methods/approaches, which were reproduced with permission from a family planning organisation webpage, was added under the pictogram (see Appendix B for full set of final PtDAs).

### *3.3. Stage 3: content validity and usability pre-testing*

For this stage, we leveraged the existing three GP groups who met monthly to discuss emerging clinical evidence as part of the larger Ask Share Know project. We presented the PtDAs at their meetings with consent and conducted observations in the form of focus group discussions. During the discussions, GPs were prompted to comment on the content, format and structure of the PtDAs as well as their perceptions of usability and feasibility. A training video about the intended use of the source PtDA was shown to two groups of GPs at the beginning of their discussions. The process coordinator took detailed notes during the meetings and summarised the findings by reviewing the field notes.

Overall, the adapted English language PtDAs were well received by the GPs in terms of content, usefulness and feasibility, especially by GPs who were exposed to the training video at the start of their group discussions. No major changes to the content were made after the GP discussions.

**Table 2**
Summary of modifications made during the content review process.

| Change/modification category | Sub-category | No of changes | Examples (USA-Australia) |
|---|---|---|---|
| Linguistic contextualisation | Spelling | 3 | health care-healthcare<br>sterilization-sterilisation<br>estrogen-oestrogen |
| | Change of description/local contextualisation of language | 40 | birth control- contraception<br>non-temporary bleeding changes-long-term bleeding changes<br>Condom: A thin latex or *polyurethane sleeve* is put on the erect penis before sex - A thin latex or *non-latex sheath* is put on the erect penis before sex |
| Available methods | Method type | 7 | Deletion: patch; spermicide; sponge; cervical cap; TwoDay method; female sterilisation by hysteroscopy; emergency-combined pill |
| | Method name/description/ terminology | 7 | progestin- progestogen<br>progestin pill-progestogen only pill<br>ring-vaginal ring<br>natural method- family awareness and traditional<br>ovulation method-billings/ovulation method<br>ulipristal pill-ulipristal acetate pill<br>progestin emergency pill-levonorgestrel emergency contraceptive pill |
| | Method classification | 1 | short-acting-shorter acting<br>Note: At the time of adaptation, contraceptive injection (depot medroxyprogesterone acetate) was categorised as a long-acting contraceptive method in Australia whereas it was grouped under short-acting in the source PtDAs. Therefore, the 'short-acting' group name was changed to 'shorter-acting' to reflect the relatively shorter acting nature of injection compared to other long-acting methods. |
| | Method use (duration/frequency for use) | 3 | Injection: how often: every 13 weeks-every 12 weeks<br>Hormonal IUD: how often: every 3 to 5 years-every 5 years<br>Copper IUD: how often: every 10 years-every 5 or 10 years depending on the type |
| | Method efficacy data or its explanation | 6 | Diaphragm: Not always following the instructions: 12 in 100 people-18 in 100 people<br>Note: While the primary source for method efficacy data [29] remained the same in both countries, some critical modifications were made due to some method use differences between the two countries. |
| Additional information | Return to fertility | 7 | Shorter acting and long-acting PtDA: add row on 'how long does it take to return to normal fertility after stopping?' |
| | Anaesthetic requirement | 3 | Permanent PtDA: add row on' what type of anaesthetic is required?' |
| | Reversal | 3 | Permanent PtDA: add row on 'can it be reversed?' |
| | Side effect | 4 | Shorter-acting PtDA: add row on 'chance of developing blood clot?'<br>Shorter-acting and long-acting PtDA: add row on mood change and weight gain |
| | Side effect probability information in frequency format | 13 | Combined pill-chance of developing blood clot-add 'around 9–10 in 1000 women in a year (4–5 in non-users)' |
| | Limitations | 2 | Fertility awareness and traditional: add row on limitation |
| Removal of information | | 4 | Shorter acting PtDA: remove row on 'Skin irritation' (patch not available in Australia)<br>Shorter acting PtDA: remove row on 'vaginal irritation' (to make room for other side effect information) |
| *Re*-ordering the sequence | | 3 | |

### 3.4. Stage 4: translation

We purposefully avoided using professional translators as per our earlier justification. "Chinese" is not a single homogenous language, but a language family with regional variations in both spoken dialects and writing systems. The first author (HD), who is fluent in both the Chinese and English languages and had obtained a medical degree from a Chinese institution, conducted the initial translation of the PtDAs. A bilingual content expert (ML) checked the quality of the translation. The PtDAs were initially translated into a simplified Chinese format, which is widely used in Mainland China.

### 3.5. Stage 5: decisional needs assessment

A total of 22 Chinese migrant women and 20 healthcare providers, including GPs and nurses, were individually interviewed for this stage. Detailed description of recruitment, data collection and analysis methods are described elsewhere [16]. In the decisional needs assessment of Chinese migrant women, we found a high level of aversion towards hormonal contraceptive methods and preference for male condoms, withdrawal, and fertility-awareness-based methods. We also found that most women had no experience of visiting healthcare providers for contraception-related reasons, nor did they perceive it as necessary. Many women turned to language sources from China for information. This finding implied that only focusing on providing decision support for Chinese women during clinical encounters through shared decision-making with healthcare providers may not be adequate or far-reaching [16]. Extra support outside the clinical encounter settings and in the community or online, using proactive, and linguistically and culturally appropriate methods such as health promotion or education, might be needed in addition to the use of PtDAs [16].

We found that healthcare providers often asked Chinese migrant women about their contraceptive needs opportunistically [15]. The common challenges they faced in engaging Chinese migrant women in contraceptive discussions were language barriers, women's discomfort towards discussing sex-related topics, and women's lack of knowledge and awareness of general sexual and reproductive health and contraceptive methods [15]. The findings implied that healthcare providers need an enabling environment to implement shared decision-making with Chinese migrant women [15]. Such enabling environmental factors included women's adequate sexual and reproductive health literacy, availability of professional interpreting and translation services, and healthcare providers' preparedness and communication skills in engaging Chinese migrant women in contraceptive discussions [15].

### 3.6. Stage 6: acceptability, usability and perceived feasibility testing of PtDAs with Chinese migrant women and healthcare providers

A detailed description of the results for this stage is described elsewhere [23]. Overall, adapted PtDAs were perceived by both the women and healthcare providers to be informative, comprehensive, and useful in supporting informed decisions. While no major changes were made to the PtDAs after the interviews, in response to some concerns around a lack of pictures and too much text, a supplementary animated video on contraceptive options and decision-making with both the English and Chinese subtitles was created. Based on findings that healthcare providers' concerns around length and information load in the PtDAs were eased with the explanation of how to use them, an animated training video for healthcare providers was also created.

## 4. Discussion and conclusion

### 4.1. Discussion

Here we have described the development and application of the PACE framework, a six-stage approach to adapt an existing contraceptive method-choice PtDA for use in the Australian context with Chinese migrant women. The adapted PtDA was perceived by both Chinese women and healthcare providers to be comprehensive and useful in supporting informed decisions. The PACE framework can guide future efforts to adapt PtDAs for new populations including culturally and linguistically diverse migrant groups, and for different country settings or contexts.

During the pilot-testing of the PACE framework, some key lessons were observed in each stage. Stage one lays out key considerations for selecting source PtDA, and we found selecting a source PtDAs that was not only evidence-based but also simple in language and design, can help to reduce resource intensity in later stages. Content review in stage two resulted in a considerable number of changes to the source PtDA as shown in our example. Even though this stage did not involve linguistic translation, the contextualisation and localisation of the content itself was found to be of significant importance. Australia and USA are both English-speaking countries and economically developed with many commonly available contraceptive methods. Adaptation to other contexts may require additional changes to options. The results from this stage highlighted the importance of clinical and contextual content adaptation before using existing PtDAs that were developed in a different country or cultural context, even when the source language is the same as the target language. Without the detailed contextualisation and content review process, information presented in those materials can be inaccurate or misleading when used directly. Pre-testing of the PtDAs in stage three helped to further validate the content accuracy and relevance and refine data collection methods for the later stages. The translation approach described in stage four was pragmatic and helped to overcome funding constraints. Decisional needs assessment in stage five allowed for in-depth exploration of broader contextual and personal (knowledge, beliefs and attitudes) factors influencing target populations' decision-making on the subject topic. And lastly, stage six of acceptability and feasibility testing helped to further refine the PtDAs content and design, develop new supplementary resources and explore potential implementation methods.

In our example, adapted PtDA did not require much cultural adaptation of content and design (apart from language translation) to the target population. Rather, the adaptation mostly reflected the contextual and clinical content adaptation to the wider Australian context. For example, through contextualisation, the PtDAs provided information on the complete range of contraceptive options available in Australia to support Chinese migrant women's informed choice. While the Chinese migrant women may culturally have a limited range of 'suitable options' as reflected during decisional needs assessment, these PtDAs purposefully, based on community and healthcare provider feedback, offered information and choice of all methods. Previously, Alden and his colleagues proposed a model for adapting PtDAs for different cultural mindsets to increase their effectiveness [30]. According to that model, PtDAs can be culturally targeted for a cultural group with culturally specific elements such as colours, images, linguistics, socio-cultural values, and group-specific information or data [30]. In our example in the source PtDAs 'Right for Me', the colours used on each page indicated different categories of contraceptives (categories based on modes of action and duration of protection), and therefore the colours did not have inherent cultural meaning. There were no images, apart from the research group logo, on the PtDA pages. As with the principles of cultural targeting [30], the key questions about contraceptive methods could have incorporated what mattered most to the specific cultural groups. This was explored in stage five decisional needs assessment, and we found that Chinese migrant women tended to care most about the impact of contraceptives on menstrual bleeding patterns, future fertility and other side-effects such as pelvic pain, weight gain, and skin changes. However, these key attributes about contraceptive methods were already presented in the PtDAs prior to the interviews and therefore, no further additions or changes were required. Using an encounter PtDA in a simple table format with mostly factual information alleviated the need for full-scale cultural adaptation. This highlights the importance of careful selection of source PtDAs, and considerations of simplicity in both language use and design; and resource intensity required. Prior research evidence from an RCT study showed that culturally targeted PDAs may not necessarily result in significant changes in patient's level of knowledge, empowerment, and decisional conflict compared to not-targeted PDAs [31]. In this study, although the decision outcomes were not evaluated, the findings from stage six of acceptability and feasibility testing were mostly positive [23].

In the PACE model, the decisional needs assessment was placed as a fifth stage after the stages of potential PtDA selection, content review, pre-testing and translation. Whereas in developing new PtDAs, decisional needs assessment is often placed before prototyping and designing [1]. The rationale for this arrangement in the PACE model is as follows. First, the PACE model aims to be pragmatic and rapid, with a particular focus on adapting existing PtDAs for new populations or contexts. Conducting a decisional needs assessment as a first step could have added additional complexities or uncertainties, especially when the needs identified are broader than what PtDA as a single intervention could address. This could especially be the case for underserved populations. In our case, having the decisional needs assessment in the later stages helped us to understand the broader contextual issues such as the need for improved sexual and reproductive health literacy that need to be addressed in addition to the use of the PtDAs and has provided important future directions for the implementation of the adapted PtDA. Second, stage five (decisional needs assessment) and stage six (acceptability and feasibility assessment) were undertaken during a single interview session with the participants. This saved time and resources for both the research team and the participants and avoided having to recruit and interview participants separately for each of the stages. The IPDAS Collaborative model of developing PtDAs also acknowledges the challenges in conducting formal needs assessment among disadvantaged groups [2]. As exemplified in the recent developments in rapidly developing PtDAs during the COVID-19 pandemic [32], a balanced approach to rigour, rapidity and practicality may help to improve efficiency in the development or adaptation of PtDAs. Our project reflects the principle that 'perfect may be the enemy of the good'. [33] A pragmatic approach such as PACE, which focuses on the adaptation of PtDAs within a short timeframe with limited resources, can potentially help to overcome resource barriers that researchers face when attempting to adapt SDM tools for new cultural, linguistic or health system contexts. However, flexibility in applying the PACE framework is recommended. If resources allow, the decisional needs assessment could be moved up to stage one to inform a broader intervention. If resources are constrained, the decisional needs assessment could be conducted

using secondary data sources or skipped altogether. For example, during the COVID-19 pandemic, the rapid development of PtDAs was based on public comments to media posts to identify decisional needs [32].

The six-stage PACE framework undertaken during this study synthesised and expanded on disparate models and approaches in a single comprehensive framework. It also shares many similar steps with other frameworks identified in a scoping review of cultural adaptation and validation of PtDAs [34]. Common steps between our framework and the scoping review finding include: appraisal of original PtDAs; translation; linguistic adaptation; and usability, acceptability, and content validity testing. Additionally, our six-step framework provides a detailed description and an of example how to execute each step. Our framework also shares some similarities to the ADAPT guidance to adapt interventions to new contexts [4]. For example, both frameworks recommend forming adaptation team/ content expert teams and assessing the evidence base and context-fit of the intervention/document before proceeding with the adaptation [4]. However, our framework is more specific to PtDAs while the ADAPT guide is more general and applicable to a wide range of interventions. ADAPT guidance however could be used as a complementary tool for assessing the rationale for adaptation and the need for a PtDA among the target population before commencing the adaption process. Similarly, other frameworks or tools for adapting health interventions or clinical guidelines can be referred to alongside our framework to ensure all relevant population and contextual elements are taken into consideration along the adaptation journey [5,35,36].

It is worth noting that adaptation of the PtDAs may not always be the best viable option as opposed to developing a new one. For example, in some instances, there might not be an existing PtDA available for adaptation on the intended topic or those available may not meet the assessment criteria as suggested in Step 1. In these instances, developing a new one using established frameworks or models such as the one proposed by the IPDAS collaboration [2] or the Ottawa Decision Support Framework [3] could be an option. There could also be some disadvantages or uncertainties to adapting health materials. Evidence from adapting clinical guidelines has shown that adaptation can still be a lengthy and resource-intensive process despite the original purpose being to increase efficiency [37,38]. The adaptation would also require methodological expertise which may not be readily available for some groups, especially for those from low-resource settings [37]. For PtDAs, there is a gap in knowledge about the efficiency and effectiveness of adaptation versus de novo development.

One limitation of our framework is that it lacks an evaluation stage in real-world settings for PtDAs effects on communication and implementation outcomes. Therefore, we recommend that an evaluation stage be considered as an add-on final stage in the PACE framework. We also did not involve Chinese migrant women in stage three of pre-testing. We acknowledge this as a key limitation and recommend representatives from the target population group to be involved in the adaptation process from the early stages of adaptation when possible.

### 4.2. Innovation

The PACE framework developed and piloted in this study fills a crucial gap in knowledge about how to adapt PtDAs for new populations and contexts and provides an innovative and systemic approach to guide the adaptation process. To our knowledge, this is the first study in Australia to use a systemic approach to adapt a PtDA not only to the Australian context, but also to a population group that is culturally and linguistically diverse. The steps described in PACE not only leverage on existing framework, but also incorporate innovative elements such as assessment criteria tailored specifically for PtDAs with considerations for technical and practical aspects of the adaptation process; and detailed collection, documentation, and analysis guide for data generated to inform adaptations to be made.

Shared decision-making, which is considered a 'pinnacle of patient-centred care' [39] continues to evolve both theoretically and in practice; and innovative approaches to facilitate it continue to be experimented and implemented across many of the medical fields and in many parts of the world. PtDAs can be effective tools to facilitate shared decision making yet developing new one can be highly resource-intensive which can be a limiting factor in extending the reach of those tools to new populations and contexts especially those that are underserved. The PACE framework has the potential to help overcome such barriers by providing novel, pragmatic and step-by-step guidance for adaptation which is accompanied by an example of real-world application with promising results.

### 4.3. Conclusion

This study highlights the complexity and necessity of a multi-stage and team-based approach to adaptation of PtDAs. The PACE framework and lessons learnt can provide guidance for future efforts to adapt PtDAs to new populations and contexts both in Australia and internationally.

## Ethical approval and consent to participate

Ethical approvals were obtained from the University of Sydney human research ethics committee [ref: 2018/159] and Family Planning NSW Project Ethical Risk Team (PERT) [ref: PERT 25]. All participants read the participant information statement and consented to participate.

## Consent for publication

Participants were informed within the participant information sheet that the data collected during the interviews would be published. They then signed a consent form indicating their consent for publication.

## Funding

HD's doctorate study is supported by Australian National Health and Medical Research Council (NHMRC)/Centres of Research Excellence project: Testing, Translation and Uptake of Evidence in General Practice: A systems approach to rapid translation. The funding agreements ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report.

## Authors' contributions

HD, LT, ML and DB developed the study concept. HD, LT, ML, DB, CT and CB contributed to developing research questions, sampling and recruitment methods and overall design of the study. HD carried out the data collection. HD, LT, ML, DB, CT, CB, and RT contributed to data analysis and interpretation of data. HD drafted the initial manuscript. LT, ML, DB, RT, CT and CB read and critically reviewed the manuscript.

## CRediT authorship contribution statement

**Hankiz Dolan:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Deborah Bateson:** Writing – review & editing, Supervision, Methodology, Investigation, Formal analysis, Conceptualization. **Mu Li:** Writing – review & editing, Supervision, Methodology, Investigation, Formal analysis, Conceptualization. **Rachel Thompson:** Writing – review & editing, Supervision, Methodology, Investigation, Formal analysis. **Chun Wah Michael Tam:** Writing – review & editing, Methodology, Investigation, Formal analysis. **Carissa Bonner:** Writing – review & editing, Methodology, Investigation, Formal analysis. **Lyndal Trevena:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

## Declaration of competing interest

Deborah Bateson had been supported to attend educational events by Bayer Healthcare and Mayne Pharma, both are manufacturers of contraceptives, and had attended advisory committees Organon, Besins and Mayne Pharma as part of her role at Family Planning New South Wales and The University of Sydney. Rachel Thompson has received research funding from government and non-profit organizations to study shared decision-making and shared decision-making interventions, including contraceptive care; she receives royalties from Oxford University Press from the sale of a book on shared decision-making and owns copyright in several decision aids, including a decision aid on contraception. Carissa Bonner received government and non-profit funding not related to this topic. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Availability of data and materials

The data generated during the current study will be available from the corresponding author on reasonable request and in accordance with the consent and ethical approval.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pecinn.2024.100347.

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