



Patient and healthcare professional perspectives on implementing patient-reported outcome measures in gender-affirming care: a qualitative study

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ABSTRACT

Objectives Patient and healthcare professional perspectives are needed to develop a gender-affirming care patient-reported outcome measure (PROM) implementation plan. We aimed to identify top considerations relevant to gender-affirming care PROM implementation from patient and healthcare professional perspectives.

Design, settings and participants This qualitative study conducted in the UK between January and April 2023 includes focus groups with a patient sample diverse in age and gender identity, and a healthcare professional sample diverse in age and role. Established methods in implementation science and the Consolidated Framework for Implementation Research were used to create interview guides, and analyse data. Focus groups were audio recorded, transcribed verbatim and analysed by two independent researchers. Patient and healthcare professional focus groups were conducted separately.

Primary outcome measures Patient and healthcare professional perspectives on PROM implementation were explored through focus groups and until data saturation.

Results A total of 7 virtual focus groups were conducted with 24 participants (14 patients, mean (SD) age, 43 (14.5); 10 healthcare professionals, mean (SD) age, 46 (11.3)). From patient perspectives, key barriers to PROM implementation were mistrust with PROMs, lack of accessibility, burden, and lack of communication on why PROMs are important and how they will help care. From healthcare professional perspectives, key barriers to PROM implementation were lack of accessibility, burden with PROM administration and scoring, costs of implementation (financial and time), and lack of communication on what PROMs are and how they benefit service provision.

Conclusion Gender-affirming care PROM implementation must address: patient mistrust with PROMs, accessibility, communication on what PROMs are and how they can be used, reducing burden, and hybridised implementation. These factors may also be applicable to other clinical areas interested in implementing PROMs.

INTRODUCTION

Gender-affirming care includes psychosocial, hormonal and surgical care to help with gender transition.¹ International standards emphasise that individual patient needs must

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Several international calls have been made for evidence-based patient-reported outcome measure (PROM) implementation to improve gender-affirming care. A recent systematic review identifies that there is no literature on the patient perspective to implementing PROMs for gender-affirming care, representing a key barrier to PROM implementation for this area.

WHAT THIS STUDY ADDS

⇒ This is the first study to investigate patient and healthcare professional perspectives on gender-affirming care PROM implementation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Gender-affirming care PROM implementation must address: patient mistrust with PROMs, PROM accessibility, communication on what PROMs are and how they can be used, reducing PROM burden, and hybridised implementation. These findings can be used by clinicians, commissioners and policy-makers interested in leading PROM implementation initiatives for gender-affirming care with potential generalisability to other clinical areas.

be comprehensively understood to offer high-quality gender-affirming care.¹ Patient-reported outcome measures (PROMs) are self-report instruments helping align care with patient needs.² Gender-affirming care could benefit from widespread, systematic and patient-centred PROM implementation. However, research demonstrates PROM implementation for gender-affirming care is inconsistent, does not follow established methods in implementation science and lacks patient centredness.³

The existing literature on PROM implementation for gender-affirming care has identified over 200 PROMs used for gender-affirming care.³ However, the benefit of these PROMs is limited due to unaddressed

Table 1 CFIR domains and definitions from Damschroder *et al*¹⁰

CFIR domain ¹⁰	Definition
Innovation ¹⁰	The 'thing' that is being implemented, for example, PROMs. ¹⁰
Outer setting ¹⁰	The context in which the Inner Setting exists, for example, healthcare system, country. ¹⁰
Inner setting ¹⁰	Where the innovation is being implemented, for example, gender clinics. ¹⁰
Individuals ¹⁰	Roles and characteristics of people, for example, implementation team members, innovation deliverers (ie, healthcare professionals), innovation recipients (ie, patients). ¹⁰
Implementation process ¹⁰	Sequential steps and strategies to implement the innovation. ¹⁰

implementation challenges.³ Rather than develop new PROMs which may contribute to research waste, implementing existing PROMs more effectively to meet current needs is reported to be a more efficient use of healthcare funding and resources.^{4 5} Past literature emphasises the potential for PROMs to improve gender-affirming care quality, if implemented effectively.⁶

Patient and healthcare professional perspectives on implementation barriers and enablers must be understood to create a PROM implementation plan.⁷⁻⁹ The Consolidated Framework for Implementation Research (CFIR) is an implementation science 'meta framework', combining key implementation science concepts in one framework. The CFIR can guide design and analysis of qualitative implementation studies and comprises of five domains (table 1).¹⁰⁻¹² The CFIR has been successfully applied to PROM implementation initiatives and includes guidance for developing interview guides, and categorising implementation barriers and enablers.^{8 13}

We aimed to understand patient and healthcare professional perspectives on PROM implementation for gender-affirming care through focus groups. Results can be used to implement PROMs for gender-affirming care.

METHODS

Reporting

Reporting follows Consolidated criteria for Reporting Qualitative research.¹⁴

Patient and public involvement

Six patient and public partners representing members of the transgender and non-binary community, recruited through representatives from national transgender charity organisations and community support groups, were involved in designing and conducting this study. Patient and public partners confirmed the relevance and importance of the research question, were involved with

reviewing and pilot-testing focus group interview guides, and confirmed applicability and relevance of findings.

Research team, reflexivity

Focus groups were conducted by a cisgender male and doctoral candidate at the University of Oxford (RK) with qualitative research training. The researcher is also an MD candidate, with a clinical background. To aid reflexivity, memos and notes were drafted following each focus group to build awareness of positionality and discuss potential challenges and issues that arose from the focus groups. This was a continual process.

Relationship with participants

A relationship was not established prior to study commencement with participants. Participants knew the researcher identity and research goals. The researcher introduced themselves, reasons for the focus group and data security during focus groups. Participants were provided with contact information if they had additional questions or concerns.

Methodological orientation

We followed established qualitative implementation science methods from the CFIR.^{10 12 15 16}

Participant selection

Recruitment occurred through an intermediary at the gender clinic (AL) who sent a recruitment email to patients and healthcare professionals on email lists. The email explained the study, time commitment and data security. Patients were purposively selected to maximise diversity in gender identity and age. Healthcare professionals were sampled purposively to maximise diversity in role. Participants received a £40 voucher in line with the National Institute for Health and Care Research guidance for participant reimbursement.

Setting

Data were collected through virtual focus groups on Microsoft Teams. Only participants and researcher were present.

Data collection

A focus group interview guide (online supplemental appendix 1) was developed covering gaps from a past systematic review³ and key CFIR concepts.¹⁰ This was pilot tested with a patient and public involvement group (six members from the transgender and non-binary community representing national transgender organisations and support groups) and a healthcare professional (AL). Patient focus groups were conducted separately from healthcare professional focus groups. Focus groups were 1.5 hours and audio recorded. Focus groups continued until data saturation, were not repeated and were transcribed verbatim (RK). Findings were returned to participants for checking, with quotes anonymised with a participant ID, organised according to CFIR domains.

Table 2 Examples of CFIR categorisation

Text	CFIR domain ¹⁰	CFIR construct ¹⁰	CFIR subconstruct ¹⁰
'But also some people don't have the money or the access to technology or the Internet, so therefore paper might be a lot easier for PROMs.'—P011	Inner setting ¹⁰	Structural characteristics ¹⁰	Information technology infrastructure ¹⁰
'I was thinking about whether some people might feel reluctant to engage if they didn't really understand why it [PROM implementation] was being done or...what the purpose of it was...'—S006	Implementation process ¹⁰	Engaging ¹⁰	Innovation recipients ¹⁰
CFIR, Consolidated Framework for Implementation Research.			

Data analysis

Two researchers (RK and LJ) independently analysed transcripts according to the CFIR (examples displayed in [table 2](#)) on Microsoft Word (V.16.69) with disagreements resolved through discussion. Data analysis occurred on Microsoft Excel (V.16.69). Rigour was achieved through ongoing deliberation and application of researcher reflexivity, debriefing meetings between researchers (RK and LJ) to cover analysis progress and identifying key concepts from analysis.

RESULTS

A total of 7 focus groups (3 patients, 4 healthcare professionals) with 24 participants (14 patients, 10 healthcare professionals) ([table 3](#)) were conducted in January–April 2023.

Patient perspectives on gender-affirming care PROM implementation organised by CFIR domain Innovation

Top considerations to PROM implementation from the patient perspective under the innovation domain were mistrust with PROM administration and scoring, in particular, how PROMs could address wider systemic issues for gender diverse people. In general, patients widely felt unsettled with how PROM scoring may impact care quality and access. Only one participant mentioned not feeling mistrust with PROMs as completing forms is an 'automatic' process for them.

I don't have any trust that PROMs are feeding in to change the system or change the approach of everything. It...feels like a paperwork exercise.—P013

A score would unsettle me.... It would also skew my responses if I knew I was being marked... What do I need to say to get treatment? Is this gonna be if I get a 26, 'Ohh you didn't get 30, you're not getting any treatment because we don't think you qualify.'—P003

I am on the opposite side... I have filled so many... forms out...that it has become an automatic process for me...From what I have heard, this is a very unique perspective.—P006

Participants were concerned about lack of PROM accessibility. Specifically, PROMs being inaccessible to people with neurodivergence, and the need for large print, simplified language, multiple languages and high contrast versions of PROMs. PROM burden (PROM length, time needed to complete and repetitive questions) concerned some participants.

Accessibility is always the biggest thing. So, if English isn't the first language, dyslexia, if they've got difficulties reading..., if they've got sight issues.—P011

I did notice...an awful lot of repetition... I think I would find it difficult not to put a line through it (PROM) and throw it away.—P005

Outer setting

A widespread perspective on enabling PROM implementation under the outer setting domain was positioning PROMs as a way to hold the National Health Service (NHS) accountable for providing high-quality care. Patients mentioned increased motivation to complete PROMs if they would improve their care.

The idea that the clinician, the clinic, the NHS is being held...accountable through the PROMs... would make people want to fill them in...—P012

Some patients were concerned about who PROM data is shared with. Specifically, patients with negative general practitioner (GP) interactions worried PROM completion would negatively impact care. Patients with positive GP interactions were also concerned that sharing PROM data with GPs would limit interim care received by their GP.

I would definitely not fill a PROM in before or after a clinic meeting. Not a hope. To know this would go back to my wait time, primary GP surgery horrifies me, after the damage they have done to me.—P004

It's difficult to access interim care through a GP whilst you're waiting for...support from a gender clinic. It's...seen as they've handed the job on, and I think if the information is being shared directly with some GP's... it might be seen that you're already engaging with the process. Therefore, they don't

Table 3 Demographic information of focus group sample

Patient characteristics	Frequency (%)
Demographic information	
Age (mean, SD)	43 (14.5)
Gender*	
Male	1 (7%)
Female	9 (64%)
Trans female	1 (7%)
Agender	1 (7%)
Non-binary/genderqueer	1 (7%)
Non-binary	1 (7%)
Sex assigned at birth	
Male	10 (71%)
Female	3 (21%)
Intersex	1 (7%)
Race	
White	13 (93%)
Mixed white/Asian	1 (7%)
Ethnicity	
British	9 (64%)
Scottish	1 (7%)
Mixed British/European/Middle-Eastern	1 (7%)
Mixed British/Irish	2 (14%)
Mixed Russian/Jewish	1 (7%)
Healthcare professional characteristics	
Demographic information	Frequency (%)
Age (mean, SD)	46 (11.3)
Gender	
Female	9 (90%)
Male	1 (10%)
Sex assigned at birth	
Female	9 (90%)
Prefer not to answer	1 (10%)
Race	
White	8 (80%)
Asian	1 (10%)
Mixed white/Asian/black	1 (10%)
Ethnicity	
British	7 (70%)
Scottish	1 (10%)
Chinese	1 (10%)
Mixed	1 (10%)
Healthcare professional role	
Nurse	3 (30%)
Speech and language therapist	1 (10%)
Peer support worker	2 (20%)

Continued

Table 3 Continued

Patient characteristics	Frequency (%)
Physician	3 (30%)
Assistant psychologist	1 (10%)
*Participants were asked about gender and sex assigned at birth using the two-step method, where participants were first asked their gender and then their sex assigned at birth through an open-ended response	

need to do anything...So I think the audience for the information is really important that we [patients] get a choice about...—P005

Patients also reported mistrust with PROMs were related to the negative political environment around gender-affirming care. Patients felt it was important PROM implementation did not add to waiting times. Some participants reported completing PROMs was a dehumanising experience.

What it comes down to...is [completing PROMs] dehumanizes the person that you're asking to fill in the form.—P009

Inner setting

The most widely encountered consideration under the inner setting domain was lack of communication on information about PROMs. Key questions patients wanted answered were: why PROMs are being administered, how PROM responses impact care, and how PROMs benefit patients. Lack of communication on PROMs contributed to mistrust with PROMs. Hybridised PROM implementation (ability to complete online or in-person) was also supported.

And there's...no information... Whenever I've got PROMs, it's...like this is a form - fill it out and give it back to us now...that's it.—P013

People are more likely to want to help their own care. I think it's...an explanation at the top, which...it's a lot of information...but...necessary. Either having a paragraph or a QR code to a video and explaining this is what a PROM is, this is why we're collecting... information, this is the confidentiality, this is the data breach... And I think there should definitely be a mix of both [online and in-person administration] because some people wouldn't want to do it sat in the clinic with the time pressure. But also, some people don't have the money or...access to...the Internet...—P011

Patients felt PROM implementation should be tailored to the needs of patients. For example, incorporating patient preferences on how they would like to be communicated with. Patients also widely reported PROM implementation would be enabled with adequate space and time to complete the PROM.

It is a difficult one with PROMs because they are going for personal questions. It needs to be an environment where you can ask for help...but if you want that privacy, the helper leaves the room...—P003

Individuals

Under the individuals' domain, patients felt having peer support staff at the gender clinic available if PROM completion was distressing was an important safeguard. This concept was important to patients as it was a widespread belief that PROMs asked sensitive questions. A strategy to enhance PROM accessibility was having clinics partner with local organisations. One participant mentioned they use an organisation to help them with completing forms. Other participants agreed that partnering with local organisations may enable PROM implementation.

Just letting them [patients] know that if any gender service has a peer support network...that's available if anything on the PROM is more distressing to them...—P011

I'm autistic and have ADHD, and I personally sometimes struggle to fill in forms. Pointing people to some organizations that could be of help might be useful. So, Citizens Advice is the most neutral one, but there could also be some like LGBT specific ones...—P014

Implementation process

A widespread consideration held by patients under the implementation process domain was assessing how often they would like to complete PROMs. Patients emphasised PROM implementation should reinforce that patients matter over the PROM itself. One way to communicate this is through thinking about the person behind the PROM and assessing their needs.

You have to...take the PROM and say...I'm not asking the computer to fill this in - I'm asking a person to fill this in. So 'what does that individual person need?' Not 'what does the PROM need?' Because the PROM shouldn't be the thing that we're worried about, it should be the person that's filling it in.—P009

In addition, some patients mentioned the importance of PROM administration timing. Specifically, some patients mentioned lower motivation to complete PROMs immediately following a distressing appointment. Some patients also mentioned that PROM implementation could be enabled if clinicians helped to explain the PROM as part of the implementation process.

Immediately after...you just had your appointment, 'Here's a PROM' wouldn't work because for quite a lot of people, the sessions that they go to are quite distressing and emotional, and that's not something you want to immediately put yourself into doing is filling in a PROM.—P011

Online supplemental appendix 2 provides additional quotes organised by three major themes; online supplemental appendix 4 provides additional quotes organised by all CFIR constructs represented.

Healthcare professional perspectives on gender-affirming care PROM implementation organised by CFIR domain Innovation

In general, healthcare professionals reported PROM complexity was a key barrier to implementing PROMs. Participants were concerned about PROM length, uncertainty about when and how often to administer PROMs, and PROM administration and scoring burden. Automation of scoring with graphical display of results was widely mentioned as an implementation enabler. In additional healthcare professionals felt adapting PROMs to patient accessibility needs was important.

It does add to the complexity and the burden of the consultation for the patient and for us [clinicians] as well because it's another thing to talk about and it's already quite a complicated consultation to start with...And I think that's OK, if there's some really clear usefulness of it...Also if scoring is done as something that we could click on and see the whole of the graph and how it's working out, that'd be fantastic. If it was another thing that we had to hunt through billions of documents to find and understand the process before we started the work, that would just be a burden.—S010

Making PROMs accessible to all groups, including people with intellectual disabilities or lower literacy skills, or making easy read versions is important.—S005

Healthcare professionals were also concerned about implementation costs. A few participants were concerned about the cost to the clinic's reputation if implementation was unsuccessful.

It's...these things that are unseen and people don't...think about the doctor's time, the clinical time it costs for the person to sit and explain it to them, the cost...to send out any surveys. And the cost of the paper, the cost of the letter, the cost of postage returned, the time too, and if it is going to be taken from one system to another, if it has to be done manually, then that's another person's time.—S002

Outer setting

Under the outer setting domain, healthcare professionals generally felt that the political environment of gender-affirming care may pose barriers to PROM implementation. Specifically, there were widespread beliefs that engaging patients to complete PROMs might be difficult due to feelings of mistrust with clinicians stemming from the current political environment.

There is always paranoia with what you are going to do with this really personal information of mine. I

see that's increased over recent times and I think it's because of the stuff that happens within politics and the media at the moment. People...are much more on hyper alert for that.—S005

Some healthcare professionals felt a barrier to PROM implementation was uncertainty of how to handle responses if patients scored high in PROM sections. For example, if a patient was sent a PROM remotely and scored high on a scale measuring psychological distress. Some participants mentioned the benefits of having an open text box to capture patient comments at the end of a PROM. However, other healthcare professionals felt this would contribute to the uncertainty of how to handle critical PROM responses.

If a PROM is sent out beforehand, somebody completes it, sends it back to admin and then it looks very challenging if lots of things are scored highly on - then it has to be from a risk perspective, and a duty of care, would then be having to end up dealing with it before the patients actually arrive for the consultation.—S008

The problem with [open text box for comments at the end of PROM] is if the patient writes, 'I'm going to kill myself'. You know what? We're gonna pick that up and what are we gonna do with that?—S010

Inner setting

Under the inner setting, it was important for healthcare professionals to have communication on what PROMs are, how they can be used to guide clinical care and the benefits PROM implementation brings to care provision. Participants mentioned failing to communicate these key concepts pose barriers to PROM implementation. It was also widely believed that hybridised PROM implementation would be important for implementation success.

Making it clear how PROMs are going to benefit and help and why we're collecting this data and making it clear like we're not just collecting it for fun, what we're trying to achieve from it, I think will really help.—S004

Having electronic and hard copy available is important, because not everyone has an e-mail or wants to use the computer or can afford Internet.—S007

A few healthcare professionals mentioned issues around PROM data security. Specifically, PROMs being sent to unintended recipients. PROMs taking away clinic time was also an important consideration to PROM implementation mentioned by most participants.

You have to be really careful not to out a patient. So, if you sent it to an old address and they and they opened it, then they might say, 'Oh my goodness, I didn't realise they went to a gender clinic'.—S010

It is looking at appropriate use of time and it's [PROMs] going to take time away from...face-to-face contact with clients.—S004

Individuals

Under the individuals' domain, healthcare professionals mentioned the need for staff to facilitate PROM implementation. Some participants mentioned that assistant psychologists and administrative staff could form part of the PROM implementation team. An assistant psychologist felt PROM implementation could form a part of their responsibilities.

There does need to be human behind PROMs, so it doesn't feel like we're just cold robots asking for your data. This [PROM implementation] kind of aligns with the assistant psychologist job.—S004

It was also mentioned by some participants that senior management buy-in may facilitate implementation.

You need to get to senior management buy into this. So, it's not just seen as something that our that little Gender Clinic's gone off on a tangent again and done something a bit different.—S002

Implementation process

Under the implementation process domain, participants emphasised the importance of patient engagement. It was mentioned by some that communicating with patients benefits of PROMs and why they are being implemented could facilitate higher engagement. Some healthcare professionals mentioned a strategy to increase patient engagement is confirming patient accessibility needs and ensuring PROMs were accessible.

Some people might feel reluctant to engage if they didn't really understand why it [PROM implementation] was being done or...what the purpose of it was...there would need to be some explanation...for people.—S006

It would be worth having...a question say, 'Do you have any specific needs? Do you need the PROM adapted into specific formats? Please let us know what you would like and then we can change the text, send different text size, different colour.'...so asking the person first.—S003

Some healthcare professionals felt PROM implementation is a continuous, iterative process and emphasised importance of regular feedback from patients on PROM implementation.

It would be good to have a regular focus group with patients, like, every six months...just to see what they think. Because with something like this, it's not ever gonna be just one solution or one like a one-time thing. It needs to be sort of a continuous evolution.—S004

Online supplemental appendix 3 provides additional quotes organised by three major themes; online supplemental appendix 5 provides additional quotes organised by all CFIR constructs represented.

DISCUSSION

This study identifies considerations relevant to PROM implementation for gender-affirming care from patient and healthcare professional perspectives. A recent systematic review identified a lack of literature on patient and healthcare perspectives on PROM implementation and our study fills this gap.³

Patient and healthcare professional perspectives on PROM implementation demonstrated overlap. Both groups emphasised addressing the following for PROM implementation: PROM accessibility (accessible to people with neurodivergence; multiple languages, large print and high contrast versions); communication on what PROMs are, their importance and how they can be used to improve care; hybridising implementation; and reducing burden. These key considerations may not be gender-affirming care specific and could also apply to other clinical areas interested in implementing PROMs.

Our results are in line with past literature reporting on healthcare professional knowledge about PROMs as important for PROM implementation,¹⁷ PROM implementation being a continuous process¹⁸ and reducing PROM burden to facilitate implementation.¹⁹ Using computerised adaptive testing has reduced PROM the implementation burden in other clinical areas.^{20 21} However, no PROM implementation studies currently exist in for gender-affirming care and our study fills this gap. The findings from our study can be used to help guide implementation of PROMs for gender-affirming care. Over 200 PROMs have been identified for gender-affirming care³ and the findings from this study can help to maximise their uptake, helping to ensure the optimal potential for PROMs are reached, and efficient use of healthcare funding and resources.⁴⁵ The results from our study can also help to maximise the potential benefit of PROMs for gender-affirming care.⁶

Several considerations specific to gender-affirming care PROM implementation were covered in this study. First, communicating with patients and healthcare professionals about why PROMs are being administered and how scoring works prior to PROM administration. This was related to a key theme regarding trust with this population. Second, confirming patient accessibility needs prior to PROM administration. Partnering with local and LGBTQ+ organisations was mentioned as strategies to increase PROM accessibility. Third, it is important to confirm with patients who they consent to have their PROM data and results shared with. A practical consideration to reduce the risk of PROMs sent to unintended recipients is implementing multifactor authentication for remote PROM completion—this would be important given the theme of trust and fears regarding data privacy. This consideration has been used in other settings with remote patient monitoring.²²

Strengths of this study include: a patient sample diverse in age and gender identity, a healthcare professional sample diverse across interdisciplinary roles and application of established methods in implementation

science.^{10 15} Using CFIR to structure the study lends to developing real-world implementable strategy solutions.

Limitations include lack of racial and ethnic diversity in the sample. Future research should aim to seek perspectives from groups not represented in this study (ethnic minority trans patients and those experiencing multiple marginalisation's within healthcare). Survey studies using open-ended responses may provide methods to capture perspectives in larger samples of people.²³

This study provides practical recommendations for PROM implementation for gender-affirming care. These include: improved communication on PROMs and rationale for implementation, ensuring PROMs are accessible to patient needs, and ensuring PROM results are only shared with individuals patients consent to have PROM results sent to. Further, hybridising PROM implementation and identifying staff who can help facilitate implementation (ie, administrative, assistant psychologists) may maximise PROM implementation. Further studies may seek to qualitatively explore the most acceptable PROM to use for different gender-affirming care clinical settings.^{3 24}

CONCLUSION

PROM implementation for gender-affirming care must be patientcentred and address key concepts important to healthcare professionals for successful and sustained PROM implementation. The main considerations for PROM implementation include: patient mistrust with PROMs, PROM accessibility, communication on what PROMs are and how they can be used, reducing PROM burden, and hybridised implementation. These considerations can be used to help guide implementation of one of the over 200 PROMs identified for gender-affirming care, ensuring efficient use of healthcare resources and improved quality of gender-affirming care delivery.

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Contributors RK, AL, CH, JR and MS were involved with conceptualising the study. RK and AL were involved with recruiting participants. RK conducted focus groups. RK, LJ, AL, CH, AJ, JR and MS were involved with data analysis and interpretation. RK led the writing of the manuscript. RK, LJ, AL, CH, AJ, JR and MS were involved with critical revision of the manuscript. All coauthors approve of the submission. RK takes overall responsibility for content and acts as the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants but Clinical Trials and Research Governance Department, University of Oxford exempted this study. Participants gave informed consent to participate in the study before taking part. This study was independently reviewed by, and registered with, the Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust: SER-22-027.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as online supplemental information. RK had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Appendix 1. Focus Group Interview Guide

Patient Focus Group Questions*

1. What do you think about using a PROM in clinic?
2. Thinking about the PROM, would you want to complete something like this at your appointment at a gender clinic?
 - a) Why/why not?
 - b) If not, do you have suggested changes to the form that would change your answer?

Barriers and enablers to PROM completion

3. You might be asked to complete a PROM before coming to clinic, in clinic (e.g., in the waiting area), or after a clinic appointment while on the waiting list for treatment. Taking each of these in turn, what do you think would make it easier for you to complete the form? For example, having your clinician ask you to explain the PROM, having your clinician explain how results will be used, information on how your form responses will be confidential...
 - a) Probe for reasons why: i.e., feeling safe to complete the PROM
 - b) Is this a view shared by others here? Do you feel the same or differently about this?
4. Thinking again of the situation where you might be asked to complete a PROM like this for your gender clinic appointment, what what might stop you completing the PROM? For example, feeling unsafe to complete the PROM, not having a private location to complete the PROM, feeling like the PROM will be a waste of time...
 - a) Probe for reasons why: i.e., accessibility, people feeling like their results won't be used

- b) Is this a view shared by others here? Do you feel the same or differently about this?

Suggested adaptations to the PROM

- 5. Is there anything we can change about PROMs so that so that it is easier for you to complete? For example, a message about how your PROM information will be kept secure, or ways to administer the PROM online?
- 6. Is there anything we can change which would encourage or help you to answer all of the questions in a PROM?

Suggestions on PROM implementation – logistics of completion

- 7. When would you like to complete the PROM (for example: before and after every gender clinic appointment, only for some appointments, etc.)?
 - a) Prompt for: burden on frequency of completion, when patients view it is most critical to measure outcomes, certain times when it may not be a good idea to complete the PROM
- 8. Where would you like to complete the PROM (i.e., at home, or in clinic or other location)?
 - a) Prompt for: reasons why participants have a preference for a certain location, if they would need any supports to complete the PROM at these locations, why it would be easier/more difficult in certain locations

Suggestions on PROM implementation – burden and form administration

- 9. How long would you be willing to spend to complete the PROM (i.e., 5-10 minutes, 10-20 minutes)?

10. How would you like to complete the PROM (i.e., pen and paper, iPad, on own device, a device from clinic)?

Thoughts on score communication

11. After completing the PROM, the results can be used to show a score. Would you be interested in seeing your scores? If we sent you the scores, how would like us to do this?

Thoughts on supports needed

12. If you could have support filling out this PROM, what would you like (i.e., online resources, specific instructions, contact information for mental health support)?

Final thoughts/comments

13. Do you have any final thoughts or comments to add?

*PROM used as an example for focus group discussions was the Gender Congruence and Life Satisfaction Scale (GCLS), used with permission from developers and available at: Jones BA, Bouman WP, Haycraft E, Arcelus J. The Gender Congruence and Life Satisfaction Scale (GCLS): Development and validation of a scale to measure outcomes from transgender health services. *Int J Transgend*. 2018 Apr 26;20(1):63-80. doi: 10.1080/15532739.2018.1453425. PMID: 32999594; PMCID: PMC6831013.

Healthcare Professional Focus Group Questions**Barriers and enablers to PROM implementation*

1. What are your initial thoughts about implementing PROMs at your clinic?
2. One way that clinics implement PROMs is through setting up an electronic system. The electronic system can contact patients once they are referred to a clinic but before they come in. Patients can then complete the PROM and have their responses scored. What are your thoughts on having a system like this for your clinic?
 - a) Prompt for: what barriers might you encounter implementing this in your clinic?
 - b) Would limited resources or culture issues make implementing this system a challenge?
3. If your team wanted to use PROMs regularly with patients in clinic, what are the barriers or likely issues you anticipate? For example: disruption to clinic flow, burden on clinicians to administer and score the PROM, lack of information on how to use PROM responses to improve care.
4. Sometimes it can help motivate patients to complete PROMs. For example, if clinicians encourage patients to complete the PROM or patients see their results being used to guide or improve care.
 - a) What might be the barriers to encourage patients to complete PROMs in your clinic?
 - b) What would help to make this easier to do?
5. Another helpful strategy can be having patients see how their PROM results are being used to guide or improve care.

- a) What might be the barriers to showing patients how their PROM results are being used for their care?
- b) What would help to make this easier to do?

6. What would make it easier for you and your clinic to implement PROMs for day-day use?

Suggestions on PROM Implementation – logistics of completion

7. PROMs can be administered electronically to patients, or by pen-and-paper, for example by having a receptionist hand the PROM to patients when they arrive, and collecting the PROM before going into their appointment. Can you describe how you think PROMs should be implemented into your clinic?

- a) How will it interact or conflict with current programs or processes?

8. When do you think PROMs should be completed (for example: before and after every gender clinic appointment, only some appointments, etc.)?

- a) Probe for reasons why: clinician or patient burden in administering the PROM, data handling (i.e., more data to integrate with increased frequency of completion), the most important clinical timepoints which would be useful to measure PROMs?

Thoughts on how PROMs will be used

9. How do you envisage your clinic using PROMs data?

a) Probe: using PROM responses to improve care?

10. How will your clinic keep PROM responses confidential so that patients do not worry about critical responses having a potential impact on their care?

Ability to integrate PROM into current workflow

11. How might PROMs fit with your existing work processes and practices in your setting?

12. What kinds of changes or alterations do you think need to be made to PROMs so it will work effectively in your setting?

a) Do you think you will be able to make these changes? Why or why not?

Costs of implementation

13. What costs do you think should be considered when deciding to implement the PROM?

Impact of clinic infrastructure and culture on PROM implementation

14. How do you think the infrastructure of your clinic (composition of staff, age, maturity, size, or physical layout) facilitate or hinder the implementation of PROMs?

a) What are ways you think these structural challenges can be overcome?

b) What kind of approvals will be needed? Who will need to be involved?

- c) Can you describe the process that will be needed to make these changes?

15. How do you think your clinic's culture (general beliefs, values, assumptions that people embrace) will affect the implementation of PROMs?

Resources for PROM implementation

16. Do you expect to have sufficient resources to implement and administer PROMs?

- a) What resources are you counting on? Are there any other resources that you received, or would have liked to receive? What resources will be easy to procure?

Self-efficacy for PROM implementation

17. How confident are you that you will be able to successfully implement PROMs? What gives you that level of confidence (or lack of confidence)?

Final thoughts/comments

18. Do you have any final thoughts or comments to add?

*PROM used as an example for focus group discussions was the Gender Congruence and Life Satisfaction Scale (GCLS), used with permission from developers and available at: Jones BA, Bouman WP, Haycraft E, Arcelus J. The Gender Congruence and Life Satisfaction Scale (GCLS): Development and validation of a scale to measure outcomes from transgender health services. *Int J Transgend*. 2018 Apr 26;20(1):63-80. doi: 10.1080/15532739.2018.1453425. PMID: 32999594; PMCID: PMC6831013.

Appendix 2. 3 Major Themes and Supportive Quotes from Patient Focus Groups

Major Theme	Supporting Quotes
Innovation (PROM): Source, Design, Accessibility, Complexity	Of the amount of trust we're placing in the information we give and how it's to be used, it's so important to moving forward because I feel a lot of people will just walk away from it. Just say, 'No thank you' and put a line through it. And it's rightly said. This is what's got to be addressed. You've got to have trust with PROMs. And as I say, and I absolutely agree, trust permeates to us. But unless you can build that trust up, and it really does need building up, then it's just not going to be there. - P004
	I think scoring would skew things heavily towards exaggeration, lying and manipulation of the PROM. If you're giving me a score, what's that for? And if it's not for assessment, why are you giving me this? Because now I feel like it's an assessment. And it does become very - I'm playing a game now. I'm not answering the questions. But that's how it feels to me, it's I need to win. Because I know I need to get this form filled in, so you give me the 30 or whatever the threshold is. And that's how I would see it if you said that I was getting a score at the end. - P011
	I think that there's a lot of work showing differences in the way neurodivergent people respond to questionnaires and also specific difficulties with ambiguous wording that most neurotypicals resolve to the same meaning and neurodivergent people tend to sit and worry which meaning they should respond based on that. So, I guess that really that's really about the accessibility of the questions themselves. Have they been written in a way that takes account of those kinds of differences? – P012
	One of the things that I did notice is an awful lot of repetition. And I know that you ask a question in several different ways to try and get to the root of an answer, but I did notice that I think I would find it difficult not to put a line through it and throw it away. - P005
Outer Setting: Local Attitudes and Inner Setting: Communication	Definitely trust and transparency from the NHS and wider government is at an all-time low for trans people. - P003
	I just want to recall that it's become obvious that there is a very big need for transparency, especially around why PROMs are needed. - P006
Individuals: Implementation Team Members and Implementation Process: Assessing Needs	Just letting them [patients] know that if any kind of gender service has a peer support network, letting them know that that's available if anything on the PROM is more distressing to them, there's people that they can talk to. - P011
	It is about person-centred care. I mean, I understand the need to have robust clinical tools that can be applied across and that can actually show differences between

	people pre- and post-interventions, but it's about person-centred care, it's always gonna boil down to that. Essentially that people will have different needs, different accessibility needs that kind of thing and they will need to be asked what they are. - P008
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Appendix 3. 3 Major Themes and Supportive Quotes from Healthcare Professional Focus Groups

Major Theme	Supporting Quotes
Innovation: Scoring and Complexity and Outer Setting: Critical Responses	I will say that a PROM needs to be easy to add up and calculate. I've done some of the psychological measures before, where, like, oh, my God, you need a PhD in maths to try and figure out what the score is. I would like a PROM to be very straightforward and easy to score. I also used one and you had to go online and score it. It was honestly a nightmare. – S008
	Making PROMs accessible to all groups, including people with intellectual disabilities or lower literacy skills, or making easy read versions is important. – S005
	The problem with [open text box for comments at the end of PROM] is if the patient writes, 'I'm going to kill myself'. You know what? We're gonna pick that up and what are we gonna do with that? – S010
Inner Setting: Communications, Available Resources	I think basically every single possible way that you can communicate on what PROMs are and what they are used for, you need to communicate it because people learn and take in information in very different ways and so I think you need to reinforce that message in every possible way that you can at every opportunity that you get. So, if you're sending out written information, it needs to be a paragraph. If you need more information, click on this link and you can watch a video. If you'd like to talk to someone about this, then please call. If you have any face-to-face meetings then it needs to be the first thing that you say is just to reiterate, make sure that everybody is aware that this is what this is, what it's for. This is why we're doing it, and if you have any issues with that then please you know. Communicate with us about it and let us help you. So every possible way that you can.-S002
	Unfortunately, I think a lot of the time, the system doesn't support it, and it's not 5 minutes, it's 10 minutes. It's 15 minutes. And then if the system is down for any length of time, that means going back after your next appointment trying to remember what was said at the first appointment, so you review the PROM and that means your day is extended by half an hour, an hour, whatever. If you don't do it that same day, then it gets taken over to the next day. If you only work part time, it gets taken over to the next week and then suddenly you get this snowball where you know I can see that that would be a concern. – S002
Individuals: Implementation Facilitators and Implementation Process: Engaging	Or I don't know if admin could support with this. I think if we are going to send out paper copies, there will need to be admin support to send those out at the appropriate points and depending on how often we decide for these to be done-S003

	Having patients feel as though they're part of it. They'll benefit from it. And if they are gonna gain from this, then they will feel more engaged to do it and take part in the PROM, where the thing it's just us doing it for the sake of it, for the number crunch and it will be very hard for them. – S003
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Appendix 3. Additional Patient Supportive Quotes on Gender-Affirming Care PROM Implementation

CFIR Domain	CFIR Construct	Sub-Construct	Supporting Quote(s)
Innovation	Innovation Source	PROM	I don't have any trust that PROMs are feeding in to change the system or change the approach of everything. It just feels like a paperwork exercise. Don't trust that it's going to feed in and improve the system for trans people at all. – P013
			I think it is [PROM implementation] kind of a step back. Personally, I am quite suspicious of the consumers of this kind of information, on what the motives are for using them. - P005
			Of the amount of trust we're placing in the information we give and how it's to be used, it's so important to moving forward because I feel a lot of people will just walk away from it. Just say, 'No thank you' and put a line through it. And it's rightly said. This is what's got to be addressed. You've got to have trust with PROMs. And as I say, and I absolutely agree, trust permeates to us. But unless you can build that trust up, and it really does need building up, then it's just not going to be there. - P004
		Score	Yes, a score would unsettle me a little bit. It would also skew my responses if I knew I was being marked at the end of it. I would be seeing this more as, 'What do I need to say to get treatment?' Is this gonna be if I get a 26, 'Ohh you didn't get 30, you're not getting any treatment because we don't think you qualify'. - P003
			I think scoring would skew things heavily towards exaggeration, lying and manipulation of the PROM. If you're giving me a score, what's that for? And if it's not for assessment, why are you giving me this? Because now I feel like it's an assessment. And it does become very - I'm playing a game now. I'm not answering the questions. But that's how it feels to me, it's I need to win. Because I know I need to get this form filled in, so you give me the 30 or whatever the threshold is. And that's how I would see it if you said that I was getting a score at the end. - P011
			I totally understand what was said regarding the score. Having been put back many times and refused to be allowed to move on for GRS SRS surgery. You get to a point where you think what the hell have I got to do? - P004
			Yes, I was just very surprised when you said there was a score. I had absolutely no idea. What do you mean by a score? Is it a number? Literally, that's gonna come out of this like 42 in the Hitchhiker's Guide to the Galaxy or something what? - P001
			Understanding the consequence of the scores is important, it kind of implies that there's a pass or a fail, and I think one of the things that builds up over time often is when people get experiences of answering things in a certain way, they will pass on anecdotal information to other people about how you should answer the questions in order to get what you want. - P005

			I talked before about sort of answering strategically, but also you know again this trust in the system like I'm worried that if you do complain, it's like oh, look at this, we've got an awkward patient, so they'll go to the back of the list. So you sort of wanna answer and please them [clinician]. It's all about feeling that you've got to answer in a certain way. You've got to say something to make sure that you're not seen as an awkward patient or not really trans or whatever - P013
			I am on the opposite side... I have filled so many...forms out...that it has become an automatic process for me...From what I have heard, this is a very unique perspective. – P006
	Innovation Design	Accessibility	Accessibility is always the biggest thing. So if English isn't the first language, dyslexia, if they've got difficulties reading in general, if they've got sight issues. - P011
			And online, it's a lot easier accessibility-wise because you can change brightness, you can change sizes on screens and you can get everything to be read out to you, if that is easier. - P008
			I think that there's a lot of work showing differences in the way neurodivergent people respond to questionnaires and also specific difficulties with ambiguous wording that most neurotypicals resolve to the same meaning and neurodivergent people tend to sit and worry which meaning they should respond based on that. So, I guess that really that's really about the accessibility of the questions themselves. Have they been written in a way that takes account of those kinds of differences? – P012
	Innovation Complexity	PROM	One of the things that I did notice is an awful lot of repetition. And I know that you ask a question in several different ways to try and get to the root of an answer, but I did notice that I think I would find it difficult not to put a line through it and throw it away. - P005
Outer Setting	Local Conditions	Political Environment	Definitely trust and transparency from the NHS and wider government is at an all-time low for trans people. - P003
			Not only do we have to live with our gender dysphoria, but we are living in a time with an increasingly hysterical anti-trans moral panic. - P002
			Trans health care is just in a huge crisis at the moment. The waiting list, I would say the biggest part of it like getting through one of those places, is just impossible. And if you're not getting through them, then they are not getting healthcare. So I really feel like accountability should start like from the moment someone's referred, like they should be accountable from that moment, and it shouldn't just like, shrug and dismiss people. - P014
			Well, I think that a lot of the really big problems that gender clinics have faced, certainly from the point of view of like, you know, delivering good care, has been a failure to listen to patients and a failure to establish trusting relationships with patients. - P012

	Local Attitudes	GP	My experience of my GP's, and other people I've spoken to are in a similar position, is that it's difficult to access interim care through a GP whilst you're waiting for direct support from a gender identity clinic. It's kind of seen as they've handed the job on and I think if the information is being shared directly with some GP's, I'm not generalising about everyone, but I know this is fairly common, that it might be seen that you're already engaging with the process. Therefore, they don't need to do anything. It's more evidence that you know well, 'Why are you asking me for stuff, you're already being dealt with by the [gender service]' or whichever Gender Identity Clinic it is. So I think the audience for the information is really important that we get a choice about. Who it's shared with, and what it's being used for? It's just to understand really where we're coming from I guess. - P005
			I would definitely not fill a PROM in before or after a clinic meeting. Not a hope. To know this would go back to my wait time, primary GP surgery horrifies me, after the damage they have done to me. - P004
	External Pressure	Experience	What it comes down to, is an issue with all forms, particularly with the NHS is that it dehumanises the person that you're asking to fill in the form in. – P009
		Performance Measurement Pressure	I feel like the idea that the clinician, the clinic, the NHS is being held in some way accountable through the PROMs would be the thing that would make people want to fill them in more. - P012 If there was an obligation on the clinicians to abide by the results of the PROM, I'm not sure how exactly it could be implemented, but like if this goes lower than this score, then we should like aim to bring them up by this date, for example. - P014
Inner Setting	Communications	General	And then also, we did discuss about sending outcome measures to people on the waiting list, and it's partially good because you get in all that information while they're not being seen, but also a lot of people find it quite distressing - getting emails or letters from the Gender Identity Clinic thinking there's an appointment and that they've been referred, or something's changed with the hormones and everything, only for it to be just a questionnaire, which isn't something that I thought of until that was brought up. So that was a really interesting point to consider. - P011
			And there's just no information at all. Whenever I've got PROMs, it's just like this is a form - fill it out and give it back to us now. And that's it. - P013
			But you asked would I want to get this before my first appointment. I have been waiting for so long with little to no communication, if I just got this form with little to no context, obviously I know about PROMs because of this focus group, but if I got this PROM without context, I'd be like, they are marking me to put me in place. I want to speak to someone, I do not want to fill out this survey. So if I got this before, I would actually be irritated, and out of context of me not knowing about this, if I were

			to get this in the post I would be saying they are measuring us, why is this the case? - P003
			I just want to recall that it's become obvious that there is a very big need for transparency, especially around why PROMs are needed. - P006
		PROM Information	It might be worth putting on the PROM like, 'this is to understand this, and it will be used this way' - P003
			It is not clear what the objective is of the PROM. Whether we are trying to understand the condition, assess the service, or assess the patient and their possible benefits from the service. I think if you could make that clearer in the initial paragraph, I think a patient would be more comfortable in understanding what was required in their responses. - P001
			It's political. It's like we wanna know that if we're filling out stuff that's to do with healthcare, who is using this, what is it being used for, you know - to help improve patient care or is it being used to drive policy in a political way, to try and save money, to try and cut corners? – P013
			People are more likely to want to help their own care. So yeah, I think it's just an explanation at the top, which obviously it's like it's a lot of information to give, but it's necessary. So yeah, either having a paragraph or like a QR code to a video and just kind of yeah, explaining this is what a PROM is, this is why we're collecting the information and then kind of like you explained at the start - this is the confidentiality, this is the data breach. - P011
			I think what would be really good is if the PROMs had, like a tangible end goal. For example, if they say this will be used to produce a report that will be used for this, I think. The more factual it is, the better. – P014
		Tailoring	Do you wanna be contacted by e-mail? By post? By text message? Would you like a face-to-face appointment? That kind of thing to discuss your results if that's something that somebody would be interested in, and again if there's time available. - P011
			Reminder messages and say if you've still got this PROM, we'd like it back by this point and reminders might help people. - P005
	Structural Characteristics	Physical Infrastructure and Information Technology Infrastructure	I think there should definitely be a big mix of both [online and in-person administration] because some people wouldn't want to do it sat in the clinic with the time pressure. But also, some people don't have the money or the access to technology or the Internet, so therefore paper might be a lot easier. -P011
	Available Resources	Time	It is a difficult one with PROMs because they are going for personal questions. It needs to be an environment where you can ask for the help if you want it, but if you want that privacy, the helper leaves the room or goes and gets a cup of coffee or whatever. - P003

Individuals	Implementation Team Members	Peer Support	Just letting them [patients] know that if any kind of gender service has a peer support network, letting them know that that's available if anything on the PROM is more distressing to them, there's people that they can talk to. - P011
	Other Implementation Support	Organizations	I'm autistic and have ADHD, and I personally sometimes struggle to fill in forms. Pointing people to some organizations that could be of help might be useful. So, Citizens Advice is the most neutral one, but there could also be some like LGBT specific ones maybe depending on the area. – P014
Implementation Process	Assessing Needs	Innovation Recipients	You have to be able to take the PROM and say, look, you know, I'm not asking the computer to fill this in - I'm asking a person to fill this in. So what does that individual person need, not what does the PROM need because the PROM shouldn't be the thing that we're worried about, it should be the person that's filling it in. - P009
			It is about person-centred care. I mean, I understand the need to have robust clinical tools that can be applied across and that can actually show differences between people pre- and post-interventions, but it's about person-centred care, it's always gonna boil down to that. Essentially that people will have different needs, different accessibility needs that kind of thing and they will need to be asked what they are. - P008
			So I wouldn't know how best to implement PROMs, but I feel like it does need to be tread very delicately of how this PROM is being approached because you're either going to get data that's a gamified answer or you're just going to get data that's somehow being misled, or just imitating and offending the people answering the questions, I think that's where drawing that fine line is gonna be the biggest challenge. - P008
			Say for example, I get appointments every four months and even if it was a PROM at the four-month mark, for me personally, my answers are not going to change much at all - longer still would be more accurate, depending on how frequently you meet with your care team and how quickly you personally are progressing. Because I think obviously, each person has a need for different time periods where you fill PROMs out. - P006
	Engaging	Innovation Deliverers	I think there is a role for having a clinician involved in communicating about the PROM, partly for the benefit of the patient to have things explained. - P001
	Tailoring Strategies	Timing	Immediately after being like you just had your appointment, 'Here's a PROM' wouldn't work because for quite a lot of people, the sessions that they go to are quite distressing and emotional, and that's not something you want to immediately put yourself into doing is filling in a PROM. - P011

Appendix 4. Additional Healthcare Professional Supportive Quotes on Gender-Affirming Care PROM Implementation

CFIR Domain	CFIR Construct	Sub-Construct	Supporting Quote(s)	
Innovation	Innovation Complexity	PROM	The complexity of some PROMs would make it almost near impossible to doing a consultation - there's no way you could get through and meaningfully talk about it. But like the ones that I've seen in the past, maybe three or four or five questions, that could provide - like if it was thought about very clearly - could be helpful. – S008	
			It does add to the complexity and the burden of the consultation for the patient and for us [clinicians] as well because it's another thing to talk about and it's already quite a complicated consultation to start with, for many people. And I think that's OK, if there's some really clear usefulness of it. – S010	
			Sometimes PROMs are just so long, and people will just quit halfway through it. – S004	
			And the other thing is getting that balance of how often to get them [patients] to do it, to make sure we're getting the data enough to warrant its [PROM] usefulness but not to be overburdened by it. So, thinking about the intervals between collection sets as well. How useful it is, how soon, how long? – S003	
		Score	I will say that a PROM needs to be easy to add up and calculate. I've done some of the psychological measures before, where, like, oh, my God, you need a PhD in maths to try and figure out what the score is. I would like a PROM to be very straightforward and easy to score. I also used one and you had to go online and score it. It was honestly a nightmare. – S008	
			I think the idea of having an autonomous service for scoring is actually a good idea, because it takes away all the administrative hassle of having to do it. – S002	
			I can understand graphs. Yeah, but I could not if I had to do calculations all of that. – S009	
			If scoring is done as something that we could click on and see the whole of the graph and how it's working out, that'd be fantastic. If it was another thing that we had to hunt through billions of documents to find and understand the process before we started the work, that would just be a burden.– S010	
	Innovation Design	Accessibility	Making PROMs accessible to all groups, including people with intellectual disabilities or lower literacy skills, or making easy read versions is important. – S005	
			And perhaps if you could have spoken voice if need be. – S009	
	Innovation Cost			When you're on about the untameable costs, it's if something goes wrong. It's the cost about reputation as well. You know it then puts us into a negative way and people then aren't trusting of us and therefore the more they might be more reluctant to access our service. So we've got to look at it, not just the corporate reputation of [trust], but also with [clinic].-S003

			<p>It's all of these things that are unseen and people don't necessarily think about the doctor's time, the clinical time it costs for the person to sit and explain it to them, the cost it takes to send out any surveys. And the cost of the paper, the cost of the letter, the cost of postage returned, the time too, and if it is going to be taken from one system to another, if it has to be done manually, then that's another person's time. – S002</p> <p>How is this going to be interpreted by, say people in the NHS, organizations, or higher ups it. It will be a big ethical consideration in terms of like how do we try and harness to make sure that this does not cause any damage.-S004</p>
Outer Setting	Local Conditions	Political Environment	There is always paranoia with what you are going to do with this really personal information of mine. I see that's increased over recent times and I think it's because of the stuff that happens within politics and the media at the moment. People, you know, are much more on hyper alert for that. – S005
	Critical Incidents	Responses	<p>Or if a PROM is sent out beforehand, somebody completes it, sends it back to admin and then it looks very challenging if lots of things are scored highly on - then it has to be from a risk perspective, and a duty of care, would then be having to end up dealing with it before the patients actually arrive for the consultation. – S008</p> <p>The problem with [open text box for comments at the end of PROM] is if the patient writes, 'I'm going to kill myself'. You know what? We're gonna pick that up and what are we gonna do with that? – S010</p>
Inner Setting	Communications	PROM Information	<p>I think basically every single possible way that you can communicate on what PROMs are and what they are used for, you need to communicate it because people learn and take in information in very different ways and so I think you need to reinforce that message in every possible way that you can at every opportunity that you get. So, if you're sending out written information, it needs to be a paragraph. If you need more information, click on this link and you can watch a video. If you'd like to talk to someone about this, then please call. If you have any face-to-face meetings then it needs to be the first thing that you say is just to reiterate, make sure that everybody is aware that this is what this is, what it's for. This is why we're doing it, and if you have any issues with that then please you know. Communicate with us about it and let us help you. So every possible way that you can.-S002</p> <p>Making it clear how PROMs are going to benefit and help and why we're collecting this data and making it clear like we're not just collecting it for fun, what we're trying to achieve from it, I think will really help. -S004</p> <p>I'm wondering about disclaimers, so sort of saying this isn't this isn't something that has any political alignment or political agenda or anything. – S005</p> <p>Having it really clear about what the purpose of PROMs are or that you know if it is about evaluating the service that any you know, any acute problems they've got are not to be written on this form. – S008</p>

			So definitely if we're going to do it, you really need to help us to understand why we're doing it. Whether it's for the service to benefit or the patient or what it is, but that stage of change management is not complete in my view. – S010
	Access to Knowledge and Information	Benefit to Service Provision	I would hope it comes back to that initial conversation we were having, and I think it would be true of the clinicians as much as it would be of the clients at the clinic that it is important that they can see the value in it [PROMs] and they understand the purpose of it. -S002
			I get why outcomes are important and. And I think I don't think it would take much explanation to get the rest of the team to get them on board.- S005
			So my initial thought is like this kind of data, if we were able to create something, it would really be invaluable. Like currently there's not really this kind of data collected and like it would really show hopefully that we're helping and how we're helping and doing things. So see if waiting longer, does that actually decrease life satisfaction and actually being able to quantitatively prove a lot of these things, well not prove, to show a lot of these things I think would be very valuable, not just for research, but for clinically, so that we can go to NHS England, for example, and show like the data. - S004
	Culture	Recipient-Centeredness	You have to be really careful not to out a patient. So, if you sent it to an old address and they and they opened it, then they might say, 'Oh my goodness, I didn't realise they went to a gender clinic'. – S010
	Structural Characteristics	Physical Infrastructure and Information Technology Infrastructure	And I've been supportive of the electronic system depending on how much hybridity there is and how much support you might need from an app. Because if you've got a purely electronic system, you can automate those like alerts and stuff. Or you can automate it being sent out. – S004
			Having electronic and hard copy available is important, because not everyone has an e-mail or wants to use the computer or can afford Internet. – S007
Individuals	Available Resources	Time	Unfortunately, I think a lot of the time, the system doesn't support it, and it's not 5 minutes, it's 10 minutes. It's 15 minutes. And then if the system is down for any length of time, that means going back after your next appointment trying to remember what was said at the first appointment, so you review the PROM and that means your day is extended by half an hour, an hour, whatever. If you don't do it that same day, then it gets taken over to the next day. If you only work part time, it gets taken over to the next week and then suddenly you get this snowball where you know I can see that that would be a concern. – S002
			It is looking at appropriate use of time and it's going to take time away from that face-to-face contact with clients. – S004
	High-level Leaders	Senior Management	You need to get to senior management buy into this. So, it's not just seen as something that our that little Gender Clinic's gone off on a tangent again and done something a bit

	Implementation Facilitators		different, it needs to be something that's seen as being part of a strategy that's supported by the entire trust, and legitimate within the entire trust as something that is seen as being valid, because otherwise you know they won't be buying into it. – S002
			But I think there does need to be human behind PROMs, so it doesn't feel like we're just cold robots asking for your data. This [sending out PROMs] kind of aligns with the assistant psychologist job. -S004
			Or I don't know if admin could support with this. I think if we are going to send out paper copies, there will need to be admin support to send those out at the appropriate points and depending on how often we decide for these to be done-S003
			And even if it was only like a 15-minute time slot, having a dedicated member of staff who doesn't have any other role, could be a trained up. We're hopefully getting a like a medical assistant, but a medical secretary kind of person. But someone like that who has enough knowledge and skills to know what it's all about can deliver that, but has time and space. Where they can say you know there's X amount of clinicians doing appointments that day, and so there'll be 15 people needing this today. Here's your room. Here's your - it's all and it could be, you know, I'm just thinking who else could do this kind of role to take the burden off, but also ensure it gets done properly and within giving it the importance that it's due. Rather than trying to probe it in or squeeze it in or do it as an afterthought in, especially if some appointments are difficult or challenging or Breaking Bad news, it's oh, by the way, can you do this now? Isn't going to be particularly useful for anyone.-S001
			But then if someone is coming for a clinical appointment and there's nobody to support them to fill in the form, then either it falls on the clinician, which is not, I don't think is a good use of clinical time, or there needs to be an additional person who's available and flexible at that moment of the appointment when that finishes to instantly sit down with that person and help them and support them. -S002
Implementation Process	Assessing Needs	Innovation Recipients	It would be worth having when the first initial contact made, have a question say, 'Do you have any specific needs? Do you need the PROM adapted into specific formats? Please let us know what you would like and then we can change the text, send different text size, different colour.' We can make sure it's really readable, so asking the person first. -S003
	Engaging	Innovation Recipients	Having patients feel as though they're part of it. They'll benefit from it. And if they are gonna gain from this, then they will feel more engaged to do it and take part in the PROM, where the thing it's just us doing it for the sake of it, for the number crunch and it will be very hard for them. – S003
			And well, but the other thing I was thinking about was whether some people might feel reluctant to engage if they didn't really understand why it was being done or kind of what the purpose of it was or if it might be used in some negative way which might be

			like just - that might not be realistic. I mean, it might not be a grounded fear, but I guess there would need to be some explanation about it for people. – S006
			Because I think if I were to have a one-to-one conversation with a patient about it and explain why it's happening, I think there would be more buy in to it, but realistically, are we gonna be able to do that? – S005
	Reflecting & Evaluating		I think it would be good to have a regular focus group with patients, like, every six months or something just to see what they think. Because I think with something like this, it's not ever gonna be just one solution or one like a one-time thing. It needs to be sort of a continuous evolution. - S004
			Yeah, even if PROM implementation is, you know, maybe going to be evolving, but this is the start of the process or something like that. – S006