Exploring Patient and Staff Member Views on a 'Consent for Contact' system for Sexual Health Research: A Mixed Methods Study

Aliza Hudda[1,6] (0009-0007-7123-2422), Emily Bird[2] (0009-0005-1437-6513), Daisy Holmes[1] (0009-0001-9029-6313), Emma Khoury[3] (0000-0003-2559-2762), Joseph Massias[4] (0009-0002-1516-1088), Hannah Woods[5] (0009-0000-7020-6408), Angela Obasi[1,6] (0000-0001-6801-8889), Emily Clarke[1] (0000-0001-9340-1417)

Author affiliations

1. AXESS Sexual Health, Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK
2. Southport and Formby District General Hospital, Southport, UK
3. University Hospital Southampton, Southampton, UK
4. Harrogate and District Hospital, Harrogate, United Kingdom
5. University Hospital Lewisham, London, United Kingdom
6. Department of International Public Health, The Liverpool School of Tropical Medicine, Liverpool, UK

Aliza Hudda
AXESS Sexual Health, Liverpool University Hospitals NHS Foundation Trust, Liverpool, L7 8XP, United Kingdom
aliza.hudda@nhs.net

Emily Bird
Southport and Formby District General Hospital, Southport, United Kingdom
emily.bird2@merseywestlancs.nhs.uk

Daisy Holmes
AXESS Sexual Health, Liverpool University Hospitals NHS Foundation Trust, Liverpool, L7 8XP, United Kingdom
daisyholmes@doctors.org.uk

Emma Khoury
University Hospital Southampton, Southampton, United Kingdom
emma.khoury@uhs.nhs.uk

Joseph Massias
Harrogate and District Hospital, Harrogate, United Kingdom
joseph.massias1@nhs.net

Hannah Woods
University Hospital Lewisham, London, United Kingdom
hannah.woods14@nhs.net

Emily Clarke
AXESS Sexual Health, Liverpool University Hospitals NHS Foundation Trust, Liverpool, L7 8XP, United Kingdom

emily.clarke@liverpoolft.nhs.uk

Angela Obasi
Department of International Public Health, Liverpool School of Tropical Medicine, Liverpool, L3 5QA, United Kingdom
angela.obasi@lstmed.ac.uk

Correspondence to: Aliza Hudda, aliza.hudda@nhs.net

Word count: (2919 main text), (290 abstract)

No competing interest

This study was discussed with the Research Governance team of Liverpool University Hospitals NHS Foundation Trust and was determined to be the first stage of a service development project. NHS ethics approval was therefore not required, and it was approved by the Trust as a service development project.

EC conceived the idea for the study. EC, AO and AH contributed to study design and data collection tools. AH was the lead researcher, facilitated and conducted the research, and prepared early drafts of the paper. EB, DH, EK, JM and HW contributed to data collection and analysis. AH prepared the final manuscript with contributions from both AO and EC. All authors read and approved the final draft.

ABSTRACT

Background

Recruitment in sexual health research is challenging. This study explores the potential of a Consent for Contact system (C4C) - generic consent for research contact - to improve participant recruitment and engagement in sexual health research. Our objectives were to understand patient and staff understanding of research, their views on a separate C4C system, and their preferences for its acceptability in a sexual health clinic setting.

Methods

A two-stage study was conducted at a large urban UK sexual health clinic from November 2021 to July 2022. Stage 1 involved a self-completed questionnaire administered to all patients and staff. In Stage 2, semi-structured interviews (SSIs) further explored patient concerns and preferences. Survey data were analysed using chi-square and Fisher's exact test and thematic analysis was applied to free-text responses and SSIs.

Results

A total of 205/300 patient (68%) and 41/280 staff questionnaires (15%) were completed. Motivations for research participation included altruism and personal interest. Statistically significant differences were found between patients' and staff members' concerns on confidentiality and anticipated feeling of pressure to participate. The majority of staff (n=38, 93%) and half of patients (n=100, 49%) supported implementation of a sexual health C4C system. Participants recognised the potential benefits of a sexual health C4C system, including enhanced privacy and increased research opportunities. Concerns were raised about stigma, terminology, and signing-up methods.

Conclusion

This study found the C4C system has the potential to enhance participant recruitment and engagement in sexual health research, but implementation support is narrowly divided with concerns around privacy and sign-up processes. These insights call for a patient-centred design approach, emphasising clear communication and privacy. Future research should focus on implementing and evaluating a sexual health C4C system to further explore their effectiveness and acceptability in different contexts.

INTRODUCTION

Recruiting participants for clinical research is challenging,(1) and sexual health research faces further difficulties due to its sensitive nature.(2) Additionally, sexual health service users often present with transient symptoms leading to limited opportunities for participant recruitment and engagement.(3)

One promising approach to address these challenges is the 'Consent for Contact' (C4C) system, which involves obtaining generic consent from individuals to be contacted for research purposes.(4) C4C systems and disease-specific registers have been piloted in various specialities including mental health and dementia, asthma and multiple sclerosis (MS) research.(5-11) During the implementation of these C4C systems, factors around the set-up, recruitment process and levels of engagement in research were considered.(5-11) Positive feedback from staff and service users during the pilot of a C4C system within psychosis services highlighted its potential to streamline recruitment, empower participants and foster a more inclusive research environment.(5) Similarly, stakeholders, practitioners and patients living with MS were in favour of an MS register for altruistic reasons.(9) Furthermore, the CHARM (Centre for HIV/AIDS Research in Mental Health) patient registry indicates that C4C systems can be particularly useful for recruiting participants from marginalised populations or individuals living with HIV.(10) However, common concerns were identified including perceived pressure to take part in research, forced consent, difficulty leaving the C4C system, and confidentiality.(5-9,11)

Whilst these examples demonstrate the potential of C4C systems and provide implementation recommendations, its application in sexual health research remains

unexplored. Sexual health services face challenges using existing hospital C4C systems due to additional confidentiality requirements and the transient nature of many conditions, which may not be captured within a standard C4C enrolment process.(12)

We report a study to explore the possibility of using a C4C system to improve participant recruitment and engagement in sexual health research. We aimed to explore patients' and staff members' understanding of the term 'research'; their views on a separate C4C system for sexual health research; and their perspectives on how to make the C4C system acceptable within a sexual health clinic setting.

METHODS

Study design and recruitment

This two-stage study was conducted from November 2021–July 2022 at a large urban sexual health clinic which provides care to a diverse patient population in the North West of England. Participating staff members were from the clinic and other neighbouring clinics in the region. In Stage 1, an anonymous self-completed questionnaire comprising multiple-choice, Likert-scale and free-text responses was administered to all patients and staff (Appendix 1). The survey explored respondent's understanding of research, views and concerns related to a sexual health C4C system, and potential implementation strategies. Questionnaire design was informed by a literature review of previously piloted C4C systems and disease-specific registers and refined with continuous public patient involvement (PPI) and after piloting. The questionnaire explored understanding of and willingness to participate in research and why, views on a separate C4C system, recruitment logistics (e.g. sign-up process, number of research opportunities and registration checks), and participant demographics. All staff and

patients were eligible to participate in the survey. Patients were given an information sheet and offered a questionnaire at clinic check-in. The lead clinician emailed all staff with a Google Form link including the information sheet and online questionnaire. To maximise comparability, where possible, wording of questions for staff and patients were as similar as possible.

Following questionnaire data analysis, Stage 2 comprised 30–45 minutes patient semi-structured interviews (SSIs) to further explore concerns and implementation preferences. SSIs explored patient's definitions of research, concerns and expanded on specific themes identified from Stage 1 (Appendix 2). SSIs were conducted face-to-face or online by three interviewers (from diverse gender and ethnic backgrounds). Convenience and purposive sampling were used to recruit diverse SSI participants, until data saturation. Patient questionnaires asked willing participants to provide their contact details for a follow-up SSI. Participants were contacted by email or by text to arrange an SSI, given an information sheet and informed consent was obtained. SSIs were recorded, transcribed and deleted after transcripts were checked by the research team. No interview participants required repeat interviews, and none dropped out of the study. Staff SSIs were not performed.

Data analysis

Survey multiple-choice and Likert-scale categorical data were analysed using chi-square and Fisher's exact test on SPSS(13). Thematic analysis of survey free-text responses were performed independently to allow themes to emerge(14), with any discrepancies discussed with the research team. Following familiarisation with the SSI transcripts, two researchers

independently analysed and generated themes, with discrepancies discussed with the research team.

Research ethics

This study was discussed with the Research Governance team of Liverpool University Hospitals NHS Foundation Trust and was determined to be the first stage of a service development project. NHS ethics approval was therefore not required and it was approved by the Trust as a service development project.

RESULTS

Survey and SSI participant characteristics

A total of 205/300 patient questionnaires (68%) and 41/280 staff questionnaires (15%) were completed. Among the patient respondents, 102 (50%) identified as cis-male, 84 (41%) identified as cis-female, with the remaining participants not self-identifying. Median age was 35 years (IQR = 21-42 years), with 77 patients (38%) aged between 18-24 years. Among the staff respondents, 12 (29%) identified as cis-male, 27 (66%) identified as cis-female, with the remaining not self-identifying. Most staff respondents held senior positions, including 10 Consultants (24%) and 12 Advanced Clinical Practitioners (29%) and were based at the large urban sexual health clinic (n=27, 66%).

A total of 15 SSIs were completed, (11 cis-male; 4 cis-female). The majority (n=10) identified as White British and 6 were between the ages of 35-49 years. One participant had a learning disability and was interviewed alongside their caregiver; another was engaged in sex work (Table 1).

Table 1 Baseline sociodemographic characteristics of patients and staff survey demographics and patient SSI demographics			
Demographics	**Patient survey (n=205)**	**Patient SSI (n=15)**	**Staff survey (n=41)**
Gender identity			
Cis-male	102 (50%)	11 (73%)	12 (29%)
Cis-female	84 (41%)	4 (27%)	27 (66%)
Prefer not to say/No response	19 (9%)		2 (5%)
Age (years)			
18-24	77 (38%)	2 (13%)	
25-34	59 (29%)	4 (26%)	4 (10%)
35-49	35 (17%)	6 (40%)	19 (46%)
50-64	14 (7%)	3 (20%)	14 (34%)
65+	1 (0.5%)		1 (2%)
Prefer not to say/ No response	19 (9%)		3 (7%)
Sexual orientation			
Heterosexual male	42 (20%)		
Heterosexual female	64 (31%)		
MSM*	48 (23%)		
Bisexual male	8 (4%)		
Bisexual female	11 (5%)		
Prefer not to say/ No response	32 (16%)		
Ethnicity			
White Non-UK	7 (3%)		
White UK	149 (73%)	10 (67%)	
Black African	7 (3%)		
White and Black African/Caribbean	3 (1%)		
South/ East Asian	4 (2%)	1 (6%)	
Other	14 (7%)	4 (27%)	
Prefer not to say/ No response	21 (10%)		
Job Role			
Clerical			6 (15%)
Consultant			10 (24%)
Advanced Clinical Practitioner**			12 (29%)
Junior medical staff***			4 (10%)
Junior nursing staff			5 (12%)
Other			4 (10%)
Clinic setting(s)			
Large urban teaching hospital			27 (66%)
Small urban community centres			9 (22%)
Teaching hospital and community centre			2 (5%)
Other			3 (7%)
*MSM (men who have sex with men) **Advanced Clinical Practitioner defined as a senior nurse clinician ***Junior medical staff include junior doctors, senior house officers and registrars			

We organised our findings from the questionnaire and SSI analysis into the four key areas investigated in this study: understanding of research, willingness to participate in research, potential benefits and concerns of a sexual health C4C system, and implementation

preferences. Appendix 3 presents these categories, themes and relevant participant quotes in further detail.

Understanding of research

We evaluated patients' and staff members' understanding of research to determine the need for pre-explanation before C4C system enrolment. Of surveyed participants, 155 (76%) patients and 41 (100%) staff respondents provided meaningful definitions of research. Six themes were identified: 'Searching for new information' (45 patients, 29%), 'Research methods' (35 patients, 23%; 5 staff, 12%), 'Improving understanding' (30 patients, 19%; 5 staff, 12%), 'Improving healthcare service and practice' (16 patients, 10%; 31 staff, 76%), 'Data collection' (22 patients, 14%; 9 staff, 22%), and 'Investigating new treatments' (7 patients, 5%; 5 staff, 12%).

Research participation

Patient surveys assessed prior research participation, willingness to engage in future research, and underlying motivations. Twenty-five respondents (12%) reported previous research engagement.

Regarding future research participation, 82 participants (40%) expressed willingness, 53 (26%) indicated they would not consider involvement, 59 (29%) expressed uncertainty, and 11 (5%) did not respond. Factors influencing research participation were grouped into six themes: 'Personal health benefits,' 'Altruism,' 'Access to new medications,' 'Helping to progress research,' 'Research dependent,' and 'Individual circumstances'.

'Altruism' and 'Helping to progress research' emerged as the most predominant motivators. Patients perceived participation as a *'moral objective'* aimed at benefiting both individuals and the broader community (Patient Survey Participant (PSP) 63). Personal curiosity and desire for 'Personal health benefits', e.g. *'As a father of children in their late teens, I am interested'* (PSP 153). Within the 'Access to new medications' theme, patients frequently mentioned clinical trials such as for COVID-19, and especially Pre-Exposure Prophylaxis (PrEP) which was referenced in 5 patient surveys and 5 SSIs, e.g. '*to see the work and be part of the rollout'* (SSI Participant (SSIP) 13, 40M).

Barriers to research participation related to 'Individual circumstances' or 'Research dependent'. 'Individual circumstances' encompassed factors such as lifestyle and time commitments, pre-existing medical conditions (including learning difficulties), and financial pressures. Uncertainty around research objectives, associated risks and *'the level of commitment required'* (PSP 117) were categorised under the 'Research dependent' theme.

Likelihood of participation and views of a sexual health C4C system

One hundred patients (49%) expressed support and 74 (36%) were not in favour of a sexual health C4C system; 31 (15%) did not respond. Gender was not associated with support (χ^2 = 12.84, p = .012). From the staff questionnaires, 38 respondents (93%) expressed support, while 3 (7%) in clerical roles were not in favour.

Regarding the likelihood of joining a sexual health C4C system, 84 patients (41%) expressed willingness, 60 (29%) were uncertain, 48 (23%) would not join, and 13 (6%) did not provide a response. Among staff members, 25 (61%) believed patients were likely to join, 13 (32%) were

unsure, and 3 (7%) believed patients would not. Differences between staff and patients regarding the likelihood of patient participation in a sexual health C4C system were significant (χ^2= 6.9716, p = .0306).

Patients and staff were asked to rank their concerns regarding the C4C system (Table 2). Statistically significant differences were found between patients' and staff members' concerns around confidentiality (patients (n=53, 26%), staff (n=2, 5%)) and potential pressure to participate (patients (n=53, 26%), staff (n=4, 10%)).

Table 2 Patients and Staff perceived concerns on a sexual health C4C system

Patient and Staff Members concerns	Patients (n=205)	Staff (n=41)	p value
Confidentiality & information security	53 (26%)	2 (5%)	**.0013**
Too much contact with the research team	72 (35%)	9 (22%)	.0605
Poor understanding limiting informed consent	66 (32%)	8 (20%)	.635
Difficulty leaving the C4C system	68 (33%)	11 (27%)	.2733
Pressure into taking part in research	53 (26%)	4 (10%)	**.0016**

Perceived benefits, facilitators and barriers of the C4C system

Potential benefits related to: 'Confidentiality' and 'Supporting better research' (sub-themes included 'Enhancing participation', 'Recruitment', 'Accessibility and awareness' and 'Efficiency').

Patients valued the increased privacy and confidentiality offered by the C4C system, considering it a '*more secure*' option (PSP 14). Staff echoed this sentiment, emphasising that a dedicated C4C system would assure patients of the data safety and confidentiality standards associated with sexual health records, and enhance patients' departmental research engagement.

Participants recognised the C4C system's potential to facilitate expanded research opportunities, participant recruitment, and improve efficiency. Staff members were in favour of the streamlined approach and strategies to *'remove logistical issues'* (Staff Survey Participant (SSP) 7). Patients highlighted that the C4C system could directly target those interested in research and offer opportunities to '*people who otherwise wouldn't think to participate'* (PSP 168).

Motivation to participate in the sexual health C4C system related to: 'Altruism', 'Personal interest', and 'Choice'. Altruism was strongly evidenced e.g. *'making a difference for other people'* (SSIP 4, F42). 'Personal interest' motivated participants to join, as described by one patient, *'(sexual health research is) important as any other aspect of health'* (PSP 69). Both staff and patients felt that the element of choice was important - '*patients know exactly what they are agreeing to'* (SSP 28).

Perceived 'Stigma' associated with sexual health was the most common barrier. Fear and shame hindered participation, particularly among first-time attendees at sexual health clinics, -e.g. *'first time I've ever been here…everyone seems scared or shy'* (SSIP 8, M30). However, some participants saw the C4C system as an opportunity to challenge stigma, saying it is *'important to talk openly about sex and sexual health'* (PSP 119) and *'nothing to feel ashamed about'* (PSP 69).

Confidentiality emerged as both a facilitator and a barrier. While some participants expressed apprehensions about the system's intrusiveness, others appreciated its potential to enhance data security *'Data would be protected'* (PSP 160) *'because it's so separate from the rest of*

the NHS' (SSIP 14, 20M). Staff members shared these mixed opinions and believed that patients' rapport with the service could address confidentiality concerns.

Implementation preferences

Regarding C4C logistics, patients were more likely to prefer shorter enrolment times (p=.0001) and fewer prompts for enrolment in research (p=.0008). However, most patients found a 2 yearly registration check acceptable (n=130, 63%) (Table 3).

Table 3 Patients and Staff members opinions on acceptable logistics for a sexual health C4C system

Patient and Staff Members preference		Patients (n=205)	Staff (n=41)	p value
Enrolment time (minutes)	No more than 5	90 (44%)	9 (22%)	**.0001**
	No more than 10	66 (32%)	30 (73%)	
	No more than 15	24 (12%)	2 (5%)	
	No response	25 (12%)		
Number of research opportunities to be offered per year	1	49 (24%)	5 (12%)	**.0008**
	2-4	85 (41%)	32 (78%)	
	5-10	10 (5%)		
	Unlimited	29 (14%)	4 (10%)	
	No response	32 (16%)		
Acceptability of a 2 yearly registration check	Yes	130 (63%)	37 (90%)	**.0353**
	No	31 (15%)	4 (10%)	
	Unsure	18 (9%)		
	No response	26 (13%)		

Themes emerging from exploration of C4C logistics in patient SSIs were: 'Specific sexual health specific concerns', 'Choice', 'Flexibility', 'Discreet' and 'Individually tailored'.

'Specific sexual health concerns' sub-themes centred around the 'Terminology' and 'Sequencing of communication' around the C4C system. Participants expressed reservations about the connotations of the word 'consent' having a sexual context '*seems like physical*' (SSIP 7, 28M). Alternative names such as 'register' and 'database' were suggested, but one participant associated 'register' with the sex offender register. For two participants, the term 'database' was associated with data sharing and an impersonal touch *'just a number'* (SSIP

10, 40M). Concerns were also raised about signing up for the C4C system in the sexual health clinic waiting room. One participant felt that signing-up to the system before their appointment was anxiety-inducing '*you're uncomfortable, you've got an itch…you might not want to sign up'* (SSIP 13, M28).

'Choice', 'Flexibility', 'Discreet' and 'Individually tailored' were priorities for patients for timing and methods of signing-up and information frequency. Different sign-up methods, (face-to-face, online, via text or email) were important, as it provided autonomy and accommodated digital literacy and language barriers with patients expressing a range of opinions for and against each option.

DISCUSSION

Principal findings

To our knowledge, this is the first study exploring patients' and staff members' views on the potential of a sexual health C4C system. Our findings revealed that both patients and staff demonstrated a strong understanding of research. Altruism and the desire to contribute to research were prominent motivations for participating in research and joining the C4C system, possibly influenced by PrEP research impact.

This study found a divergent perspective concerning the acceptability of a sexual health C4C system between staff and patients. There is a marked contrast between the substantial support from staff members (n=38, 93%) and patients, with a narrow majority of 100 patients (49%) in favour of implementation, and a significant minority of 74 patients (36%) opposed. This split highlights a critical need for deeper engagement and dialogue to understand the

hesitations and expectations of patients. Notably, staff members seem to have overestimated patient enthusiasm for participation, indicating potential gaps in communication and understanding between patients and the healthcare team.

This divergence in views is further nuanced by the benefits and concerns perceived by different groups. While both staff and patients acknowledged that the C4C system could improve research processes and enhance patient engagement, patients specifically reported concerns about potential pressure to participate in surveys, which staff did not identify. The issue of confidentiality surfaced as both a barrier and a facilitator in the decision to engage with the C4C system; some participants were reassured by the privacy it promised, while others were apprehensive about the possibility of data sharing. Interestingly, despite these concerns, confidentiality did not emerge as a prominent theme during patient SSIs.

Specific sexual health concerns were identified, including terminology, signing-up methods (especially first-time clinic attendees), stigma and protective confidentiality. However, participants also thought that the C4C system could potentially challenge stigma associated with sexual health and the voluntary nature of the system appealed to patients and staff.
Patients and staff views differed significantly on the logistical set-up: patients preferred a quicker enrolment time and signing-up during their appointment. Patients also preferred 2-4 research opportunities per year and valued choice and discreet communication with the research team.

Strengths and limitations

Our study demonstrated several strengths. By utilising two stages of data collection involving patient surveys and SSIs (with PPI), we obtained a comprehensive understanding of patients' views, and to mitigate response bias we employed a diverse group of interviewers.

Despite this, our study has certain limitations. Firstly, it was conducted at a single site within a specific geographical region, which may restrict the generalisability of the findings. Additionally, the small sample size and underrepresentation of cis-female, trans, non-binary, and black, Asian and minority ethnic participants limit the diversity of perspectives captured. Secondly, this study inherently selected for patients who were willing to engage in research. This self-selection bias likely leads to an overestimation of patient support for the C4C system. Finally, no staff SSIs were conducted, so limiting our understanding of staff members' perspectives.

Comparison to other studies

Our study findings contribute to the existing literature on C4C systems and highlights the unique considerations and preferences specific to sexual health research. Similar to previous studies, implementing a specialty-specific C4C system has potential benefits including improving patient engagement and research efficiency.(5,10,15) Concerns expressed by our participants regarding stigma, confidentiality, and coerced study participation were echoed by a staff and service user study on a psychosis service C4C system.(5)

Patients emphasised clarity on data access, privacy protection, and a variety of signing-up strategies, aligning with previous research.(5,15-17) A preference for face-to-face interactions was evident as participants valued the personal touch and perceived credibility, with some comparing this favourably to other communication methods. Comparing the

CHARM registry to our findings, participants expressed a preference for phone calls, to avoid feeling pressured to participate and have the freedom to agree at their own pace and convenience.(10)

Factors such as choice, patient empowerment, and altruism significantly influenced participation, consistent with findings from other research registers.(9-10,13,16) Aligning with our preliminary staff and patients findings, staff found participant recruitment easier as patients were already engaged and receptive to research and this could be utilised when recruiting participants with intersecting identities and from marginalised communities.(10)

Although our study did not specifically investigate the impact of research opportunities on participants, this area warrants further investigation.

CONCLUSION

This study identifies the potential benefits of a C4C system in enhancing participant recruitment and engagement in sexual health research, yet it also reveals a division among patients, with a majority in favour and a notable minority with reservations. This underscores the importance of a patient-centred approach to the C4C system's design and implementation. By addressing concerns and ensuring choice, privacy, and confidentiality, involving patients in the design of a well-crafted C4C system is essential to expand research opportunities and enhance efficiency without underestimating patient perspectives. Future research should focus on implementing and evaluating a sexual health C4C system to further explore their effectiveness and acceptability in different contexts.

REFERENCES

1. Farrell, B., Kenyon, S., et al. (2018). The challenges of recruitment and retention of participants in large-scale, multi-centre research: The experience of the UK Stroke Research Network Trials Portfolio. Trials, 19(1), 569. doi: 10.1186/s13063-018-2936-2.
2. World Health Organization. (2015). Sexual health, human rights and the law. World Health Organization. Available at: https://www.who.int/publications/i/item/9789241564984
3. Jerome L, Potter K, McCarthy O, Palmer M, Knight M, Free C. A dynamic and collaborative approach to trial recruitment in safetxt, a UK sexual health randomised controlled trial. Clin Trials. 2022 Jun;19(3):251-258. doi: 10.1177/17407745221078882. Epub 2022 Mar 5. PMID: 35253453; PMCID: PMC9203664.
4. Sciences AoM. A new pathway for the regulation and governance of health research. *Academy of Medical Sciences* 2011. Available at: https://acmedsci.ac.uk/policy/policy-projects/a-new-pathway-for-the-regulation-and-governance-of-health-research
5. Papoulias C, Robotham D, Drake G, Rose D, Wykes T. Staff and service users' views on a 'Consent for Contact' research register within psychosis services: a qualitative study. *BMC Psychiatry* 2014; **14**(1): 377.
6. Grady K, Gibson M, Bower P. Can a 'consent to contact' community help research teams overcome barriers to recruitment? The development and impact of the 'Research for the Future' community. *BMC Med Res Methodol* 2019; **19**(1): 195.
7. Nwaru BI, Soyiri IN, Simpson CR, Griffiths C, Sheikh A. Building a recruitment database for asthma trials: a conceptual framework for the creation of the UK Database of Asthma Research Volunteers. *Trials* 2016; **17**(1): 264.
8. Langbaum JB, High N, Nichols J, Kettenhoven C, Reiman EM, Tariot PN. The Alzheimer's Prevention Registry: A Large Internet-Based Participant Recruitment Registry to Accelerate Referrals to Alzheimer's-Focused Studies. *J Prev Alzheimers Dis* 2020; **7**(4): 242-50.
9. Baird W, Jackson R, Ford H, et al. Holding personal information in a disease-specific register: the perspectives of people with multiple sclerosis and professionals on consent and access. *Journal of Medical Ethics* 2009; **35**(2): 92-6.
10. Elliott R. Weinstein & Daniel E. Jimenez (2023) Prioritizing recruitment: the benefits to using a disease registry to recruit older adults with HIV and intersecting identities, AIDS Care, 35:4, 624-628, DOI: 10.1080/09540121.2022.2085867
11. Robotham D, Riches S, Perdue I, et al. Consenting for contact? Linking electronic health records to a research register within psychosis services, a mixed method study. *BMC Health Services Research* 2015; **15**(1): 199.
12. FSRH Service Standards for Confidentiality in Sexual and Reproductive Health Services - May 2020. Available at: https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-confidentiality-in-srh-services/
13. IBM Corp. Released 2021. IBM SPSS Statistics for Macintosh, Version 28.0. Armonk, NY: IBM Corp

14. Byrne, D. A worked example of Braun and Clarke's approach to reflexive thematic analysis. Qual Quant 56, 1391–1412 (2022). https://doi.org/10.1007/s11135-021-01182-y
15. Grant A, Ure J, Nicolson DJ, et al. Acceptability and perceived barriers and facilitators to creating a national research register to enable 'direct to patient' enrolment into research: the Scottish Health Research Register (SHARE). *BMC Health Serv Res* 2013; **13**: 422.
16. Flood-Grady E, Clark VC, Bauer A, et al. Evaluating the Efficacy of a Registry linked to a Consent to Re-Contact Program and Communication Strategies for Recruiting and Enrolling Participants into Clinical Trials. *Contemp Clin Trials Commun* 2017; **8**: 62-6.
17. Grill JD, Holbrook A, Pierce A, Hoang D, Gillen DL. Attitudes toward Potential Participant Registries. *J Alzheimers Dis* 2017; **56**(3): 939-46.

Appendix 1 - Consent for Contact Patient Views Questionnaire

This information sheet describes a project that we are running to help improve the services we offer here at Axess Sexual Health – Please read it so you can decide if you would like to take part.

What is this questionnaire about?

Research is important to us at Axess Sexual Health because it helps us find new and better ways of supporting our patients. We want to be able to offer more opportunities to our patients to take part in research if they wish.

To do this we would like to develop a 'Consent for Contact' system for any Axess patients willing to be contacted in the future for potential research projects.

A 'Consent for Contact' system will be the first of its kind in sexual health. **This short questionnaire will help us design this new, separate Consent for Contact system in a way that works best for Axess Patients.**

What happens now?

Your participation is entirely voluntary. You do not have to complete the questionnaire if you do not want to. We are not asking for your name, so it is completely anonymous.

- If you are happy to take part, please complete the questionnaire then post it in the box at reception or give it to a member of staff.
- If there are any questions you don't want to answer, please leave them blank.

We will use the results of the questionnaire to design the service but nothing in our reports or publications will be able to be traced back to you.

We want to make this service as good as it can be for our patients and really would appreciate your honest feedback and suggestions.

For any queries, please email: aliza.hudda@nhs.net or talk to a member of staff in clinic.

The questionnaire begins on the next page. Thank you for your time.

Part 1 - Please complete the following questions on what research means to you.

1. What does **'research'** mean to you?

2. Have you been part of any health research projects before?

 Yes

 No

If *Yes*, what made you want to take part?

If *No*, would you be interested in taking part in health research?

3. Would you consider taking part in a research project in the future?

 Yes

 No

 Unsure

Please explain why.

Part 2 – The following questions ask about your views on the benefits and challenges of taking part in research.

What is Consent for Contact?

Consent for Contact is a secure database of patient volunteers who are willing to be contacted about current and future research projects. When research projects are approved, researchers can find people who might be a good match for the projects by checking the medical records that are stored in this database. Researchers can then contact patients directly to see if they would like to take part in the research. Participation in research projects is voluntary and joining the Consent for Contact system doesn't commit you to taking part, it just means that we can contact you to tell you about a research project that you could take part in if you wish.

The Liverpool University Hospitals NHS Foundation Trust already has a Consent for Contact system. However, sexual health data is very sensitive and needs extra security. We therefore

want to create a separate Consent for Contact register just for patients seen at our sexual health services.

1. Do you think it would be good for us to have a separate Consent for Contact System?
   - ☐ Yes
   - ☐ No

2. If *Yes*, what might be the benefits of Consent for Contact System?

3. How likely would you be to participate in a **sexual health** Consent for Contact system?
   Please choose one option

Yes, definitely	Yes, probably	Not sure	No, probably not	No, definitely not
☐	☐	☐	☐	☐

Please give reasons why

4. Do you have any of the following concerns about the Consent for Contact system:

a. I am worried that the research team will contact me too often
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
☐	☐	☐	☐

b. I am worried about feeling pressured into taking part in research
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
☐	☐	☐	☐

c. I am worried that I will be asked to agree to something I don't fully understand
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
☐	☐	☐	☐

d. I am worried that I will change my mind and it will be difficult to leave the Consent for Contact database
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
☐	☐	☐	☐

e. I am worried that the system will not keep my healthcare information secure and confidential
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
□	□	□	□

5. Do you have any more comments about your concerns?

Part 3 – The following questions ask about your views on the set up of the Consent for Contact process.

The sexual health Consent for Contact system will be run by the research team members at Axess. Information about the Consent for Contact register will be available at the reception desk and with the clinical team. We aim to approach all our patients to sign up at the reception desk.

1. How long would you be willing to spend enrolling in the Consent for Contact process?
Please only choose one option

No more than 5 minutes	No more than 10 minutes	No more than 15 minutes
□	□	□

2. If you are eligible, how many research opportunities should the Consent for Contact team tell you about per year?
Please only choose one option

1	2-4	5-10	Unlimited
□	□	□	□

3. We would check your registration details and that you are still happy to be part of the Consent for Contact system **every 2 years**. Does this sound acceptable to you?

Yes	No	Unsure
□	□	□

If *No* or *Unsure*, please give reasons why.

Part 4 – These are general questions about you

We are not asking for your name, so all of your answers are confidential. This is just to make sure that we hear from a wide range of people as we create a Consent for Contact system.

1. **Which best describes you?**

- Male
- Female
- Prefer not to say
- Other – please specify

2. **What is your age?**

- 18-24
- 25-34
- 35-49
- 50-64
- 65+
- Prefer not to say

3. **What is your ethnic group?**

- White British
- White Irish
- White Gypsy or Irish traveller
- White and Black African
- White and Black Caribbean
- Black Caribbean
- Black African
- Bangladeshi
- Indian
- Pakistani
- Chinese
- Arab

- Other – please specify
- Prefer not to say

4. **What is your sexual orientation?**

- Heterosexual
- Homosexual
- Bisexual
- Other – please specify
- Prefer not to say

Thank you for completing this questionnaire

The next section is for people who are happy to be contacted for interview. If you do not think you would like an interview, then please post it in the box at reception or give it to a member of staff.

Part 5 - Volunteers for Phone interviews

Once we have the results of our questionnaires, we would like to explore some of the issues raised in more detail so that we can fully understand our patients' opinions.

If you are happy for us to phone you for a short interview about our proposed 'Consent for Contact' project, please complete the following questions.

This information will be kept separate from your survey response so your questionnaire responses remain confidential.

If you **don't want** us to phone you about this, please leave this section blank and hand the questionnaire back to a staff member.

1. **Are you happy to be contacted to arrange a phone call to discuss your opinions in more detail?**

- Yes
- No

2. **Which best describes you?**

- Male
- Female
- Prefer not to say
- Other – please specify

3. **What is your age?**

- 18-24
- 25-34
- 35-49
- 50-64
- 65+

4. **Please can you provide the following so we can arrange to contact you for a short interview?**

Contact Number:

E-mail:

All responses will be kept confidential and stored securely.

Thank you very much for your participation!

Consent for Contact Staff Views Questionnaire

This information sheet describes a project that we are running to help improve the services we offer here at Axess Sexual Health – Please read it so you can decide if you would like to take part.

What is this questionnaire about?

Research is important to us at Axess Sexual Health because it helps us find new and better ways of supporting our patients. We want to be able to offer more opportunities to our patients to take part in research if they wish.

To do this we would like to develop a 'Consent for Contact' system for any Axess patients willing to be contacted in the future for potential research projects.

A 'Consent for Contact' system will be the first of its kind in sexual health. **This short questionnaire will help us design this new, separate Consent for Contact system in a way that works best for Axess Patients.**

What happens now?

Your participation is entirely voluntary. You do not have to complete the questionnaire if you do not want to. We are not asking for your name, so it is completely anonymous.

- If you are happy to take part, please complete the questionnaire then post it in the box at reception or give it to a member of staff.
- If there are any questions you don't want to answer, please leave them blank.

We will use the results of the questionnaire to design the service but nothing in our reports or publications will be able to be traced back to you.

We want to make this service as good as it can be for our patients and really would appreciate your honest feedback and suggestions.

For any queries, please email: aliza.hudda@nhs.net or talk to a member of staff in clinic.

The questionnaire begins on the next page. Thank you for your time.

Part 1 - Please complete the following questions on what research means to you.

4. What does **'research'** mean to you?

5. Have you been part of any health research projects before?

 Yes

 No

If *Yes*, what made you want to take part?

If *No*, would you be interested in taking part in health research?

6. Would you consider taking part in a research project in the future?

 Yes

 No

 Unsure

Please explain why.

Part 2 – The following questions ask about your views on the benefits and challenges of taking part in research.

What is Consent for Contact?

Consent for Contact is a secure database of patient volunteers who are willing to be contacted about current and future research projects. When research projects are approved, researchers can find people who might be a good match for the projects by checking the medical records that are stored in this database. Researchers can then contact patients directly to see if they would like to take part in the research. Participation in research projects is voluntary and joining the Consent for Contact system doesn't commit you to taking part, it just means that we can contact you to tell you about a research project that you could take part in if you wish.

The Liverpool University Hospitals NHS Foundation Trust already has a Consent for Contact system. However, sexual health data is very sensitive and needs extra security. We therefore

want to create a separate Consent for Contact register just for patients seen at our sexual health services.

6. Do you think it would be good for us to have a separate Consent for Contact System?
   - ☐ Yes
   - ☐ No

7. If *Yes*, what might be the benefits of Consent for Contact System?

8. How likely would you be to participate in a **sexual health** Consent for Contact system?
   Please choose one option

Yes, definitely	Yes, probably	Not sure	No, probably not	No, definitely not
☐	☐	☐	☐	☐

Please give reasons why

9. Do you have any of the following concerns about the Consent for Contact system:

f. I am worried that the research team will contact me too often
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
☐	☐	☐	☐

g. I am worried about feeling pressured into taking part in research
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
☐	☐	☐	☐

h. I am worried that I will be asked to agree to something I don't fully understand
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
☐	☐	☐	☐

i. I am worried that I will change my mind and it will be difficult to leave the Consent for Contact database
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
☐	☐	☐	☐

j. I am worried that the system will not keep my healthcare information secure and confidential
Please choose one option

Not at all (very low)	Slightly (low)	Some (moderate)	Extremely (very high)
□	□	□	□

10. Do you have any more comments about your concerns?

Part 3 – The following questions ask about your views on the set up of the Consent for Contact process.

The sexual health Consent for Contact system will be run by the research team members at Axess. Information about the Consent for Contact register will be available at the reception desk and with the clinical team. We aim to approach all our patients to sign up at the reception desk.

4. How long would you be willing to spend enrolling in the Consent for Contact process?
Please only choose one option

No more than 5 minutes	No more than 10 minutes	No more than 15 minutes
□	□	□

5. If you are eligible, how many research opportunities should the Consent for Contact team tell you about per year?
Please only choose one option

1	2-4	5-10	Unlimited
□	□	□	□

6. We would check your registration details and that you are still happy to be part of the Consent for Contact system **every 2 years**. Does this sound acceptable to you?

Yes	No	Unsure
□	□	□

If *No* or *Unsure*, please give reasons why.

Part 4 – These are general questions about you

We are not asking for your name, so all of your answers are confidential. This is just to make sure that we hear from a wide range of people as we create a Consent for Contact system.

5. **Which best describes you?**

- Male
- Female
- Prefer not to say
- Other – please specify

6. **What is your age?**

- 18-24
- 25-34
- 35-49
- 50-64
- 65+
- Prefer not to say

7. **What is your ethnic group?**

- White British
- White Irish
- White Gypsy or Irish traveller
- White and Black African
- White and Black Caribbean
- Black Caribbean
- Black African
- Bangladeshi
- Indian
- Pakistani
- Chinese
- Arab

- Other – please specify
- Prefer not to say

8. What is your sexual orientation?

- Heterosexual
- Homosexual
- Bisexual
- Other – please specify
- Prefer not to say

Thank you for completing this questionnaire

The next section is for people who are happy to be contacted for interview. If you do not think you would like an interview, then please post it in the box at reception or give it to a member of staff.

Appendix 2 – Patient SSI topic guides

Thank you very much for agreeing to be interviewed today. My name is xxxxx and I'm a doctor at the University of Liverpool. I'm working with the research and clinical teams at Axess Sexual Health on a project that we are running to help improve the services we offer.

Hopefully you've had the chance to read the email we sent, but I'm going to tell you a bit about this interview and then if you're OK to go ahead I will ask you a couple of questions about research in general. Then I will tell you about the project and then ask you some questions about how we should design it. Does that sound OK? This is going to take about 30 minutes in total.

Research is important to us at Axess Sexual Health because it helps us find new and better ways of supporting our patients. We want to be able to offer more opportunities to our patients to take part in research if they wish. To do this we would like to develop a 'Consent for Contact' system for any Axess patients willing to be contacted in the future for potential research projects. A 'Consent for Contact' system will be the first of its kind in sexual health. We've already asked around 200 patients to answer a questionnaire and we now want to explore some of the issues raised by patients in more detail, which is why we want to interview some patients. This will help us design this new, separate Consent for Contact system in a way that works best for Axess Patients.

Your participation in this interview is entirely voluntary. We are not asking for your name, so it is completely anonymous. If you are happy, we would like to record this interview. We will then transcribe or type up what was said and destroy the recording. If you decide at any point that you want to stop the interview just let me know and you can do so. If there are any questions you don't want to answer you can just let me know. If you decide after the interview that you don't want us to include your data there is information about how to contact us to do this on the information sheet that we've sent you. We will use the results of the interviews to help us design the service but nothing in our reports or publications will be able to be traced back to you. We want to make this service as good as it can be for our patients and really would appreciate your honest feedback and suggestions.

Does that make sense? Do you have any questions at this point? Are you OK for me to start recording the interview now? I'm going to ask you a couple of questions about research in general.

Start recording….

1. **What do you understand by the word research and what does research mean to you?**
   Prompts: Have you *heard of any research trials? What are the different roles patients might have in research? Have you heard about any changes in treatments being offered due to research?*

If they have no idea what research is – give brief description of research, "The term research means different things to different people, but is essentially about finding out new knowledge that could lead to changes to treatments, policies or care."

Thank you. I'm going to tell you a bit about the Consent for Contact project now.

Consent for Contact is a secure database of patient volunteers who are willing to be contacted about current and future research projects. When research projects are approved, researchers can find people who might be a good match for the projects by checking the medical records that are stored in this database. Patients will be directly contacted to see if they would like to take part in the research. Participation in research projects is voluntary and joining the Consent for Contact system doesn't commit patients to taking part, it just means that they can be contacted about any potential research projects. Signing up or not won't affect the care we give patients in any way.

The Liverpool University Hospitals NHS Foundation Trust already has a Consent for Contact system. However, due to the privacy around sexual health data, we want to create a separate Consent for Contact register just for patients seen at our sexual health services.

Does that make sense? Do you have any questions at this point? Can I ask you some questions about how we should design this now please?

2. **If you are a patient signed up to the Consent for Contact system, what would this mean for you?**

3. **What should we name the system? Do you think 'Consent for Contact' make sense or should we call it Interest in Research or something else? Should we describe it as a system, register, database or something else?**

4. **How would you like to receive information about signing up to the Consent for Contact system? Examples could include a leaflet, posters in the waiting room, a short video, a website, or a staff member could tell you about it.**

5. **Would you rather receive this information in clinic or by text to your phone?**

When you come to a sexual health clinic, your visit is confidential. This means that we do not share any information without your consent and your notes are private. The Consent for Contact system would also be confidential and will be managed by our own research team who are based in the clinic. No one else will have access to your information.

6. **Do you have any concerns about your confidentiality/ privacy?**

7. **When it comes to signing up to the Consent for Contact system, when would you want to do this? Would you prefer to sign up before you're seen in clinic, during your clinic appointment, or after your appointment?**

8. **How would you want to sign up to the Consent for Contact system? Would you prefer to do it yourself by going to a website, responding to a text message, or at a self-check in computer? Or should we ask you in clinic, either at reception or during your appointment?**

There are lots of different types of research, some involve questionnaires or interviews, others include taking blood and giving new medications.

9. **Would you prefer to consent to be on the register to be contacted about all types of research or would you prefer to give consent just to some types of research types when registering?**

Once you are signed up to the system, we will contact you every 2 years to make sure that you are happy to still be on our system and we would want to contact you about research that you may be interested in.

10. **Would you prefer to receive a text (opt in or out), or phone call?**

If we had a possible trial that patients on our Consent for Contact system might be interested in participating in, our research nurse would want to contact them about this.

11. How would you be happy to be contacted? Would you prefer to receive a text or phone call? If we texted you, what kind of information would you want to be included?

12. Would you want to hear about what research is going on in the department even if it is not directly applicable to you? And if so, how would you like us to tell you about this – examples could be a newsletter, website, or video.

Thank you very much for your time today. That's the end of my questions. Is there anything else you want to say about this or any questions you want to ask me?

We'll use what you've told us to help us design the consent for contact system. Thank you very much for helping us improve our clinic.

Appendix 3 – Themes and illustrative quotes from patient surveys and patient SSIs	
Themes	**Illustrative quotes**
Understanding of research	
Improving healthcare service and practice	**[1]** *'Exploring new ways to do things better'* (Patient questionnaire) **[2]** *'They research loads and they bring in some new things to improve health'* (SSI)
Improving understanding	**[1]** *'Looking into topics unknown in order to increase knowledge of a* subject' (Patient questionnaire) **[2]** *'Ways of trying to find what's effective with working how to change and improve practice'* (SSI)
Data collection	**[1]** *'Collecting data for development of knowledge'* (Patient questionnaire) **[2]** *'Do a study to verify whether that was true or false'* (SSI)
Investigating new treatments	**[1]** *'To research medical drugs on the public'* (Patient questionnaire) **[2]** *'Monitor different people's kind of reactions to things that you're looking at* (SSI)
Searching for new information	**[1]** '*Searching previously unknown information for person/group gain'* (Patient questionnaire) **[2]** *'People can find out stuff they probably didn't already know'* (SSI)
Research methods	**[1]** *'Investigation – progress answering questions, innovation, new treatment'* (Patient questionnaire) **[2]** '*Control groups' 'Interview people'* (SSI)
Previous participation in research*	
Personal health benefits	**[1]** *'COVID-19 release test scheme pilot'*
Altruism	**[1]** *'Want to help others'* **[2]** *'Science is important. I want to enable it.'* **[3]** *'As it is beneficial to the medical field and can further medicine'*
Access to new medications	**[1]** *'To be allowed medication that would otherwise be unavailable'* **[2]** *'Free medication and helping it become available on NHS'*
Helping to progress research	**[1]** *'Wanted to help with COVID vaccine development'* **[2]** *'Supportive research to find better/more targeted treatment and service'*
Individual circumstances	**[1]** *'Job doesn't allow to take certain medications'*
Research dependant	**[1]** *'Depends on the project and risks'* **[2]** *'Depends on the research and objectives'*
Benefits of the C4C system	
Confidentiality	**[1]** *'Improve peace of mind for potential participant'* (patient questionnaire)
Supporting better research	**[1]** *'Allows new cases to support data that could potentially help'* (patient questionnaire)
Enhancing participation	**[1]** *'More people can take part'* (patient questionnaire) **[2]** *'People can disclose whether they want to be contacted so likely to be more willing to participate'* (patient questionnaire)

Recruitment	**[1]** *'easy to target right group'* (patient questionnaire)
Accessibility and awareness	**[1]** *'Quickly accessible research volunteer base'* (patient questionnaire)
Efficiency	**[1]** *'You're not wasting time contacting people who aren't interested'* (patient questionnaire)
Facilitators to participating in the C4C system	
Altruism	**[1]** *'To give back some scientific answers' (patient questionnaire)* **[2]** *'You will be able to help some people along the line somehow'* (SSI)
Personal interest	**[1]** *'Previous success with the trial I was involved with'* (patient questionnaire) **[2]** *'I am a Maths researcher myself, so research means a lot to me it's my job'* (SSI)
Choice	**[1]** *'You're not wasting time contacting people who aren't interested'* (patient questionnaire) **[2]** *'One of the things that made me say that I'd be happy to be considered…was well the kind of voluntary nature of it'* (SSI)
Barriers to participating in the C4C system	
Stigma	**[1]** *'Very sensitive and scared of my family finding out'* (patient questionnaire) **[2]** *'I understand that it would scare some people because…it is quite a touchy subject for some people'* (SSI)
Facilitators and barriers to participating in the C4C system	
Confidentiality	**[1]** *'Reservations about data security and data integrity' (patient questionnaire)* **[2]** *'Sexual health is kept so confidential and I think there about right about it…just doesn't have that where I can speak to the GP'* (SSI)
Research dependant	**[1]** *'Depends on project'* (patient questionnaire) **[2]** *'Depends on study'* (patient questionnaire)
*All illustrative quotes from this theme from patient surveys	