Responding to the increased genetic risk associated with customary consanguineous marriage: developing an expert consensus statement and principles for service design and delivery

Delphi Study

*Required

Participant Information Sheet (12/4/18, Version 3)

If you have already read this information sheet and have no questions please skip to Section 2 to give your consent.

What is the project's purpose?

In populations where it is common for people to marry close relatives there is a higher incidence of autosomal recessive genetic disorders than in those in which reproductive partners are usually unrelated. Research has shown that many affected individuals are poorly informed of these risks and that appropriate services are often not accessible. In recent years, a number of local level responses have developed across England but these are variable in form, content and longevity. A more coordinated, national response is needed to support more consistent practice and encourage the sharing of knowledge. This project has been initiated by a stakeholder group working across Sheffield, Manchester, Bradford and London, with the aim of developing an expert consensus statement and principles for service design and delivery in response to this area of unmet need.

We aim to:

(1) explore the extent to which it is possible to establish common inter-professional principles for the design and delivery of service responses in the area of consanguinity (close relative marriage) and genetic risk.
(2) identify a set of principles upon which there is sufficient consensus to warrant the production of a national guidance document.
(3) highlight areas/issues where inter-professional differences of opinion warrant further debate and dialogue.

The project will last 7 months from May to December 2018.

Why have I been chosen?

You are being invited to contribute to the project because we believe you have important insights to share. We are inviting a range of people who will offer different and complementary perspectives on the issues.

Do I have to take part?

Taking part is entirely up to you.

If you do not want to take part, you need do nothing more. If you do decide to contribute you will be emailed further information about how to contribute to the project via the online survey and workshop. You will be free to withdraw at any time without giving a reason.

What will happen to me if I take part?

The survey will involve 3 rounds and completion of each round should take between 15 and 45 minutes depending on how much information you wish to contribute.

This is Round 1. Below you will be asked to provide suggestions in response to a series of open-ended questions. This round is designed to gather a wide range of statements on what the priorities are for the design and delivery of service responses to this issue.

In Round 2 and 3, you will be presented with the combined statements from the group and asked to score each of them according to how strongly you agree or disagree with them.

While we would like people to contribute to all 3 rounds if at all possible, this is not a requirement and you may decide to contribute to Round 1 but not to subsequent rounds, or to participate in Rounds 2 and 3, but not Round 1.

Following Round 3 of the online survey, we will convene a face-to-face workshop on July 3rd 2018. Participants who are able to will come together in Sheffield for a workshop in which we will discuss and debate the findings from the online survey and seek to produce a draft of a consensus statement and set of principles for this area of service design and delivery. The workshops will be structured and last 3 to 4 hours with refreshments.

Individuals who are unable to attend the workshop but would like to contribute to the production of the consensus document will be given the opportunity to comment on the draft as it is produced.

What will happen to the data/information I provide to the project

The data you provide will be held by the University for the purposes of research which is legally deemed to be a task in the public interest. As we will be collecting some data that is defined in the legislation as more sensitive (ethnic identity), we also need to let you know that we are applying the following condition: ‘processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (Article 9(2)(j)).

If you complete the online forms, we will hold the following personal information about you: name, professional role, organisational affiliation, age-group, ethnicity, gender, region of work and email address. This information will be stored together with your answers to the Delphi exercise for the duration of the study period (up to December 2018). We need to store this information together so that we can send you your personalised responses in Round 3.

All the data you provide will be stored on the University’s secure network with access only available to the research team members via University login and password. Research team members will adhere to the data security procedures established by the University of

Sheffield and all researchers who have access to your personal data will complete University of Sheffield data security training.

Beyond the end of the project period, we will detach your personally identifiable data (name, email address and organisational affiliation) from your responses and store these separately so that your answers can not be linked to you personally. The anonymised data will then be stored for at least 10 years within the University of Sheffield secure data archive – ORDA. The anonymised stored data will be available in an open and controlled manner for future research. Data storage will allow any data verification to take place should the need arise during the process of publishing the research findings.

Only aggregated data with no personally identifiable information, will be shared outside of the research team. Any data included in reports or publications from the project will not be identifiable as relating to you. However, if you wish, your name and organisational affiliation can be reported in project outputs to acknowledge your contribution. You will be given the opportunity to decide whether or not you wish to be acknowledged in this way.

In some exceptional circumstances it may be necessary for the researchers to break confidentiality, for example if we become aware of illegal activity or if we feel that you or another individual is at risk of harm. If this situation arises, we will always discuss it with you prior to disclosing any information to a third party.

The 'Data Controller' for this project is the University of Sheffield and the Data Protection Officer is Anne Cutler.

What are the possible risks/disadvantages of taking part?

We have not identified any significant risks in taking part in this study, although we recognise that participation will involve a significant time commitment.

We will ask all participants in the face-to-face workshop not to pass any of the information shared during group discussions to anyone outside of the group. However, we cannot guarantee that people outside of the research team will maintain this confidentiality.

It is possible that some of the discussions may become heated or that participants may become upset. Researchers will do their best to ensure that a respectful and supportive environment is maintained at all times.

What are the possible benefits/advantages of taking part?

By participating in the consensus exercise you will be making an important contribution to the development of a national-level guidance document. If you wish, your name can be included as a contributor on any products that are developed through this process. There are no other immediate benefits for people participating in the project but it is hoped that the process will be interesting and informative.

What if I'm not happy with things or have a question about the study or my data?

If you have any concern about this research or any complaint you should first contact the Principal Investigator:
Professor Sarah Salway, Department of Sociological Studies

Elmfield, Northumberland Road, Sheffield, S10 2TU. s.salway@sheffield.ac.uk
0114 222 6438

If you are not satisfied with the response, then you should contact:
Professor James Wilsdon, Faculty of Social Sciences
Director Impact and Engagement
ICOSS, 219 Portobello, Sheffield, S1 4DP
j.wilsdon@sheffield.ac.uk
0114 222 8343

For any concern or query relating to the storage and use of your personal data, please contact the University's Data Protection Officer:
Anne Cutler
University's Secretary's Office
University of Sheffield
Western Bank
Sheffield S10 2TN
A.Cutler@sheffield.ac.uk
0114 22 21117

What will happen to the results of the research project?

Early findings will be shared at the workshop in July. This workshop will determine the form and content of the consensus statement or set of principles to be produced and disseminated. We hope to finalise this document/product by December 2018. We also anticipate producing an academic paper for publication in a journal.

Who is organising and funding the research?

This research is funded by the University of Sheffield and the NIHR CLAHRC for Yorkshire & Humber.

Who has ethically reviewed the project?

This project has been ethically approved via the ethics review procedure of the Department of Sociological Studies at the University of Sheffield.

Contact for further information

Principal Investigator:
Professor Sarah Salway, Department of Sociological Studies
Elmfield, Northumberland Road, Sheffield, S10 2TU. s.salway@sheffield.ac.uk
0114 222 6438

Consent Form

1. **I confirm that I have read and understand the information sheet dated 12/04/2018 (version 3) for this study. I have had the opportunity to consider the information, ask questions and, if needed, have had these answered satisfactorily.** *

   Mark only one oval.

   ◯ Agree

2. **I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without any of my legal rights being affected.** *

   Mark only one oval.

   ◯ Agree

3. **I understand what personal data will be collected about me and how this will be stored. I am aware of how I can make a complaint or raise concerns about the handling of my personal data.** *

   Mark only one oval.

   ◯ Agree

4. **By proceeding to the next section, you are agreeing to participate in this part of the study. Please check the box below to confirm that you are happy to take part** *

   Tick all that apply.

   ☐ I consent to taking part in the study

Your background details

5. **Your Name** *

   _____

6. **Your Surname** *

   _____

7. **Please enter your email address below ensuring no typos** *

   _____

8. **How would you describe your ethnic group?** *
Mark only one oval.

- Asian/Asian British: Bangladeshi
- Asian/Asian British: Pakistani
- Asian/Asian British: Indian
- Asian/Asian British: Chinese
- Asian/Asian British: Any other Asian background
- Black/Black British: African
- Black/Black British: Caribbean
- Black/Black British: Any other Black/African/Caribbean background
- White: English/Welsh/Scottish/Northern Irish/British
- White: Gypsy or Irish Traveller
- White: Irish
- White: Any other White background
- Mixed/multiple ethnic groups: White and Black Caribbean
- Mixed/multiple ethnic groups: White and Black African
- Mixed/multiple ethnic groups: White and Asian
- Any other Mixed/multiple ethnic background
- Arab
- Other
- Prefer not to say

9. **What is your age?** *
Mark only one oval.

- <25
- 25-34
- 35-44
- 45-54
- 55-64
- 65+
- Prefer not to say

10. **In what capacity are you responding?** *
Mark only one oval.

- In your work / professional capacity
- As a member of the public

11. **Region of residence (if general public) or region of employment** *
Mark only one oval.

- ◯ London /Greater London
- ◯ South East
- ◯ South West
- ◯ North East
- ◯ North West
- ◯ East of England
- ◯ West Midlands
- ◯ East Midlands
- ◯ Yorkshire and the Humber
- ◯ Other

12. **If responding in your work capacity, what is your area of work (please choose one that best describes your focus)** *
Mark only one oval.

- ◯ N/A - responding as a member of the public
- ◯ Clinical Genetics
- ◯ Health Visiting
- ◯ General Practice (medical)
- ◯ Nursing - primary care or community
- ◯ Other Primary Care
- ◯ Midwifery
- ◯ Paediatrics (medical)
- ◯ Other secondary care / hospital
- ◯ Social Care
- ◯ Community Development
- ◯ Equality and Diversity
- ◯ Public Health
- ◯ Health services / health systems
- ◯ Other - please specify below

13. **If none of the above options describe your area of work, please specify**

14. **If responding in your work capacity, how would you describe your role (choose the best one)?**
Mark only one oval.

- ◯ N/A- responding as a member of the public
- ◯ Service or Programme Manager
- ◯ Commissioner (strategic purchaser)
- ◯ Administrator
- ◯ Practitioner (delivering services/input to patients or the public)
- ◯ Trainer / capacity development / consultant (delivering services/input to other professionals)
- ◯ Researcher/academic
- ◯ Other

15. **If none of the above options describe your role, please specify below**

_____

16. **Is this the first time you are responding to this form?** *
Mark only one oval.

- ◯ Yes
- ◯ No - I have already provided responses but would like to add more now

Contributing your ideas on principles for service design and delivery

For each of the areas below please list as many statements as you wish that describe priorities for service development in response to the increased genetic risk associated with customary consanguineous (close relative) marriage.

Please think broadly about what should, or should not, characterise the design and delivery of service responses in this area.

You may want to include statements that describe the content of services (what should be provided), the processes of delivering services (who, how and where services should be provided), and/or broader system changes needed to support the new developments.

Please make your responses as clear and concise as possible.

Please do not list things that would already be ‘business as usual’ for services across the country. The aim here is to identify the ways in which service responses ought to be developed.

Please avoid technical language or add an explanation where technical language is unavoidable.

You will have more suggestions to make in some areas than others - include as many, or as few, statements as you like in each section.

Example Statements

Community level action:

There should be no activity at all at community level related to this issue because the risk of upsetting community members is too high.

All activity at community level should be undertaken in close partnership with local third sector community based organisations.

All staff working on this issue at community level must be both culturally sensitive and have detailed genetic understanding.

The content and format of community-level information materials should be standardized across the country.

Please enter as many statements as you wish under each of the categories below.

You can leave sections blank if you have no suggestions to make in some areas.

Please number each of your statements within a category - 1. xxxxxxx; 2. xxxxxx; 3. xxxxxx and so on, so that we can clearly identify each one.

Don't worry too much about putting statements into the 'correct' category - all the statements will be reviewed and sorted once we have everyone's suggestions. The categories are intended to prompt you to think broadly about the issues.

17. **Community Level Action**

18. **Genetic Services Development**

19. **Primary Care**

20. **Secondary care and the wider health system**

21. **Referral systems and pathways**

22. **Communication, information and resources**

23. **Provision for families affected by this issue (where there is a known recessive disorder)**

24. **Provision for other people within communities practising customary consanguineous (close relative) marriage but where no recessive condition has been identified**

25. **Provision for members of the general public (outside of affected communities)**

26. **Leadership and coordination of service responses and initiatives (local, regional and national levels)**

27. **Training and support to healthcare or other staff involved in activities**

28. **Monitoring, evaluation and indicators of success for service developments**

29. **Research related to this area of work**

30. **Anything else you'd like to mention**

Thank you very much for taking time to contribute to this exercise

We will be in touch with Round 2 in mid May.