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- Patient co-research and patient and public involvement in epilepsy research is achievable.
- 33 items of preconception care were identified as essential through a consensus Delphi process.
- Evaluation of preconception care interventions for women with epilepsy and health professionals involved in their care is warranted.
- Our findings highlight the need for targeted messaging to raise awareness of the importance of preconception care, encourage health professional engagement and direct women to appropriate evidence-based resources and support.

The study rationale to investigate preconception care for women with epilepsy was a response to the recommendations made in three governmental publications:

- The Confidential Enquiry into Maternal Deaths
  - The most recent MMBRACE-UK 2016-2018<sup>1</sup> reported deaths related to SUDEP had almost tripled, and few had received preconception care.
- The Medicines and Healthcare products Regulatory Agency Valproate guidance
  - The Valproate scandal has raised new challenges for women who may experience poor seizure control due to avoiding valproate, or due to stopping it prior to or during pregnancy.
- Public Health England (2018)<sup>2</sup> "Making the Case for Preconception Care Planning and preparation for pregnancy to improve maternal and child health outcomes" recognizing the frequent missed opportunity to intervene ahead of pregnancy.

Preconception care interventions to include any educational, health promotion (condition management), or counselling interventions (or a combination of these) targeting women with epilepsy, with the intention of improving preconception health outcomes<sup>4</sup>.

This mixed methods Delphi study with consensus meeting (fig. 1) aims to answer the research question:

- For women with epilepsy aged 16-50 years in the UK, what are the essential elements of preconception care that will improve outcomes along their preconception care pathway?

The study objectives are to:

- identify the essential preconception care interventions
- identify the key stages in the care pathway that they should be delivered
- gain an understanding of the preconception care outcomes of importance to women with epilepsy

1. We engaged in patient and public involvement and collaborated with patient organisations to inform development of the study methods and study materials (including multi-model recruitment via NHS sites, NIHR CRN, social media and snowball techniques).
2. We systematically reviewed preconception interventions reported in a mixed methods review to include items important to stakeholder groups reported in qualitative studies<sup>4</sup>.
3. We invited women their partners and family to participate in interview and focus group (co-moderated with the patient researcher) (table 1).
4. We generated a long list of items of preconception care, process and outcomes (fig. 2) and categorised into Domains based on the taxonomy of the COMET initiative<sup>5</sup> (table 2).
5. We *a priori* defined consensus and prospectively registered the study on the COMET database.
6. We used DelphiManager software to run a two round Delphi online survey.
7. We held an online Consensus meeting of 30 participants from all groups, with independent chair to facilitate discussion using consensus methods informed by the James Lind Alliance.

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graph TD; S1[Literature review  
Patient and Public  
involvement] --> S2[Interviews and Focus  
groups]; S2 --> S3[Surveys  
(Delphi)]; S3 --> S4[Consensus  
meeting];
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• Stage 1

• Stage 2

• Stage 3

• Stage 4

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graph TD; A[Long list of items] --> B[Survey 1 (45 items)  
Rate items & add additional items  
(own views)]; B --> C[Responses analysed  
2 new items added, & amendments to 24 items]; C --> D[Survey 2 (47 items)  
Re-rate items (considering others views)]; D --> E[Consensus meeting];
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The flowchart illustrates the iterative Delphi process for item selection. It begins with a 'Long list of items' (blue box), which leads to 'Survey 1 (45 items)' (light blue box) where items are rated and additional items are added based on own views. This leads to 'Responses analysed' (light green box) where 2 new items are added and amendments are made to 24 items. This leads to 'Survey 2 (47 items)' (green box) where items are re-rated considering others' views. Finally, the process concludes with a 'Consensus meeting' (green box).

- **Interview and focus groups (n=58)**
  - 3 focus groups (n=17)
    - Shared facilitation with the patient co-researcher
  - 35 interviews (n=41)
    - 10 women and their partners
    - 2 bereaved parents
    - 2 interviews with extended family

- 10 pilot interviews
- PPI
- Young persons advisory panel
- Professional and voluntary stakeholder representatives

1. Access and Availability of Preconception Care
2. Contraception Review
3. Information Needs
4. Managing pregnancy and seizure related risk
5. Optimising seizure control
6. Preconception care pathway
7. Support for planning

**Stage 1**

- Preconception care items were identified from systematic review and PPI
- 23 papers were eligible for review & verbatim items were recorded

**Stage 2**

- 58 participants shared lived experience in interview and focus group
- Thematic analysis identified domains and items and processes of care

**Stage 3**

- 45 items were selected from results of stages 1 & 2 for Round 1 Delphi
- Consensus sought from 248 participants completing both Delphi Rounds 1 & 2 ranking 47 items (2 new items included from the free text responses in Round 1) (table 3)

**Stage 4**

- Review consensus and ratify 31 items as essential for inclusion (Table 4, for consensus discussion)
- Sixteen items ranked by 30 representative participants in online Delphi Consensus finding agreement of an additional 5 items for inclusion, and 2 items desirable/optional

Characteristic	Round 1, n=296	Round 2, n=248
Sex		
Male	54	44 (17)
Female	264	207 (83)
Stakeholder group		
Patients	153	126 (51)
Healthcare professionals	128	110 (44)
Voluntary members	15	12 (5)
Country		
England	272	215 (86)
Northern Ireland	17	12 (5)
Scotland	11	12 (5)
Wales	15	11 (4)

[Consensus IN] [Consensus OUT] Stakeholder groups: Healthcare professionals [blue square] Patient (representing women, their partners and family) [pink square] Voluntary [green square]

Consensus IN ESSENTIAL 5 items included at the consensus meeting		DISCUSSION ABOUT PREFERENCE AND NEED FOR AND USE OF CONTRACEPTION		INFORMATION ABOUT THE CONSEQUENCES OF TAKING ANTI-SEIZURE MEDICATION IN PREGNANCY AND THE RISK OF DISABILITIES IN THE FUTURE BABY AND CHILD		ADDRESS ANTI-SEIZURE MEDICATION CONCERNS FOR FUTURE BABY		ASSES THE NEED TO CHANGE ANTI-SEIZURE MEDICATION IN PREPARATION FOR FIRST OR SUBSEQUENT PREGNANCY		PERSONALISED PREGNANCY PATHWAY IDENTIFYING THE STEPS TO PREPARE FOR PREGNANCY AND SETTING IN BETWEEN SUBSEQUENT PREGNANCY, SETTING OUT THE STAGES OF INTERVENTIONS TO OPTIMISE PREGNANCY OUTCOME		PROMOTING THE OPPORTUNITY FOR THE PATIENT TO ATTEND CLINIC APPOINTMENTS WITH THOSE INVOLVED IN HER PLANS FOR PREGNANCY		Consensus vote Delphi OUT Consensus discussion raised need for further research		INFORMATION ABOUT THE BENEFITS OF IMPROVING PHYSICAL HEALTH BEFORE AND IN BETWEEN PREGNANCY	
PROVIDING AN INDIVIDUALISED, PERSON-CENTRED, FLEXIBLE NEEDS-LED SERVICE	88.4%	DISCUSSIONS ABOUT THE OPPORTUNITIES FOR LONG-ACTING REVERSIBLE CONTRACEPTION WHEN PREPARING FOR PREGNANCY, IN BETWEEN, AND AFTER PREGNANCY	71.3%	INFORMATION ABOUT THE GUIDELINES FOR TAKING THE VITAMIN SUPPLEMENT FOLIC ACID AHEAD OF PREGNANCY PLANS	91.7%	ADDRESS CONCERNS ABOUT SEIZURES OCCURRING BEFORE, DURING AND AFTER PREGNANCY	97.7%	REVIEW OF THE EFFECTIVENESS OF ANTI-SEIZURE MEDICATION TO MAINTAIN SEIZURE CONTROL BEFORE, DURING AND AFTER PREGNANCY	96.9%	SUPPORTING INDIVIDUALISED PLANS FOR PREGNANCY THROUGH SHARED DECISION-MAKING AND FLEXIBLE DISCUSSIONS WHICH ARE RESPONSIVE TO CHANGING CIRCUMSTANCES	86%	ASSESS PSYCHOLOGICAL AND EMOTIONAL SUPPORT NEEDS IN PREPARATION FOR PREGNANCY	70.5%	NOTIFICATIONS AND REMINDERS FOR APPOINTMENTS AND FOLLOW-UP SERVICES	68.6%	INFORMATION ABOUT THE UK EPILEPSY AND PREGNANCY REGISTER	58.6%
STRAIGHTFORWARD, QUICK AND EASY REFERRAL PROCESS TO ACCESS SUPPORT WHEN PLANNING A PREGNANCY AND WHEN PREGNANCY INTENTIONS DISCLOSED	88.8%	DISCUSSIONS TO SUPPORT PLANNING FOR THE WITHDRAWAL OF CONTRACEPTION	72.8%	INFORMATION ABOUT THE BENEFITS OF PLANNING PREGNANCY FOR THE PATIENT AND HER PARTNER AS FUTURE PARENTS, AND FOR THE FUTURE BABY	86%	ADDRESS CONCERNS ABOUT THE NEED FOR ANTI-SEIZURE MEDICATION CHANGES IN PREGNANCY	97.7%	REVIEW TOLERANCE OF CURRENT ANTI-SEIZURE MEDICATIONS BEFORE, DURING AND AFTER PREGNANCY	95.2%	MULTIDISCIPLINARY TEAM APPROACH TO PRECONCEPTION CARE	84.1%	Consensus meeting vote OPTIONAL / Desirable		TO INCREASE AWARENESS OF PRECONCEPTION CARE SERVICES THROUGH ADVERTISEMENT	61%	ASSESSMENT OF THE SUPPORT NEEDED TO INCREASE CONFIDENCE TO PLAN FOR PREGNANCY	56.9%
ADDITIONAL EDUCATION AND TRAINING OF HEALTHCARE PROFESSIONALS ABOUT PRECONCEPTION CARE FOR WOMEN WITH EPILEPSY	86.5%	INFORMATION ABOUT THE OPPORTUNITY OF BREASTFEEDING WITH EPILEPSY	83.2%	RECOGNITION OF THE SENSITIVE CONTENT OF RISK INFORMATION WITH THE POTENTIAL TO CAUSE DISTRESS	81.6%	ASSESSES DIAGNOSIS TO OPTIMISE EPILEPSY MANAGEMENT AHEAD OF FIRST AND IN BETWEEN PREGNANCY	96%	TO OFFER OPPORTUNITIES TO EXPLORE PREGNANCY GOALS OF OPTIMISING SEIZURE CONTROL BEFORE, DURING AND AFTER PREGNANCY	92%	OPPORTUNITY TO EXPLORE CONCERNS RELATING TO PREGNANCY WITH EPILEPSY	94.3%	INFORMATION ABOUT FUTURE PARENTING AND CHILD CARE	68.5%	INFORMATION ABOUT INHERITANCE AND EPILEPSY	54.2%	DISCUSSION OF PREGNANCY EXPECTATIONS AND ACCESS TO LIVED EXPERIENCES	56.1%
SERVICES TO SUPPORT CONTINUITY OF PRECONCEPTION CARE	78.5%	INFORMATION ABOUT WHAT TO DO ON THE DISCOVERY OF PREGNANCY	97.6%	SUPPORTING PERSONALISED RISK ASSESSMENT OF TREATMENT AND SEIZURE-RELATED RISKS FOR THE WOMAN AND A FUTURE BABY IN PREPARATION FOR PREGNANCY	91.6%	ASSESSES OPPORTUNITY FOR PLANNED ANTI-SEIZURE MEDICATION WITHDRAWAL AHEAD OF PREGNANCY	92%	EXPLORE THE SAFETY OF OTHER MEDICATIONS USED TO MANAGE CONDITIONS COMMONLY ASSOCIATED WITH EPILEPSY	91.1%	OPPORTUNITIES FOR SHARED DECISION-MAKING IN PREPARATION FOR PREGNANCY	82.8%	ASSESSES INFORMATION NEEDS AND EXPLORE PRIOR KNOWLEDGE	74.9%	INFORMATION ABOUT ONLINE PROGRAMMES TO SUPPORT PLANNING A PREGNANCY	31.1%	OPPORTUNITIES TO ASSESS THE SUPPORT NEEDED IN PREPARATION FOR THE TRANSITION TO BECOMING A MOTHER AND FAMILY BUILDING	64.5%
INFORMATION REGARDING CONTRACEPTION AND ANTI-SEIZURE MEDICATION	93.2%	INFORMATION ABOUT THE LONG-TERM EFFECTS OF ANTI-SEIZURE MEDICATION ON CHILD DEVELOPMENT	98.9%	SUPPORTING PERSON-CENTRED COMMUNICATION OF RISK INFORMATION FOR THE PATIENT AND HER PARTNER (AND, AS FEEL APPROPRIATE, PARENTS, EXTENDED FAMILY, FRIENDS AND CAREERS)	88.8%	ASSESSES PATIENT NEED FOR ANTI-SEIZURE MEDICATION BEFORE, DURING AND AFTER PREGNANCY	96.4%	ADVANCED PLANNING FOR PREGNANCY, TO START PLANNING AHEAD OF TIME, IN ADVANCE OF FORMAL PLANS TO START TRYING FOR PREGNANCY	85.2%	<h2>4. Conclusions</h2> <p>Barriers to planning pregnancy include misunderstandings about what preconception interventions entail and the timing of implementation. The identification of the essential items of preconception care can inform targeted health messaging. We will review ways to test feasibility of the preconception care pathway and way to measure outcomes.</p>							