

Lacking capacity to consent in emergencies related to child birth

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		<input type="checkbox"/> Protocol
Registration date 06/12/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/12/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

This research is in 2 phases.

Phase1: Lacking capacity in an obstetric emergency, a retrospective study of maternal capacity.
Phase2: Lacking capacity in an obstetric emergency, a randomized controlled trial investigating whether prior information about obstetric emergencies improves later decision making capacity.

The Mental Capacity Act (MCA) 2005 was introduced to protect patients' autonomy and to provide for those lacking capacity. It has significant implications for consent in obstetric emergencies.

Due to the nature of obstetric emergencies, informed consent is challenging. Fear of fetal well-being, severe labour pains, strong opiates and emotional (dis)stress all affect capacity. Formal assessment of capacity takes considerable time, which may compromise fetal outcome through undue delay.

We recently conducted an audit and found that the majority of women interviewed within 24 hrs of an obstetric emergency, had no recollection of the consent process or risks of complications. Many admitted to not reading the consent form at all.

In phase1, we assess a mother's ability to give informed consent in an emergency by conducting interviews within 24 hrs of birth, using a capacity assessment tool designed by us that incorporates basic principles of the MCA, based upon maternal recall of events.

In phase2: we are testing whether written information, supported by verbal counselling, before an emergency has occurred improves women's decision making ability when an emergency occurs subsequently.

Women admitted for induction of labour or early labour will be randomized to receive additional information (intervention) or not (control). Those women who end up in theatre for an instrumental or caesarean delivery will be interviewed within 24 hrs to assess their capacity at the time of emergency.

Usual practice is to take consent when an emergency arises.

This study will be conducted at Glan Clwyd Hospital and will last approximately 12 months. BCUHB will be the sponsor.

Contact information

Type(s)

Scientific

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Additional identifiers

Integrated Research Application System (IRAS)

183899

Protocol serial number

IRAS 183899

Study information

Scientific Title

Lacking Capacity in Obstetric Emergencies

Study objectives

A timely intervention in the form of written information supported with verbal counselling improves women's decision making ability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wales REC 4, 27/11/2015, ref: 15/WA/0273

Study design

Phase 1: Observational cross-sectional retrospective case assessment

Phase 2: Randomised controlled trial

Primary study design

Intentional

Study type(s)

Other

Health condition(s) or problem(s) studied

Women's health

Interventions

All women who have been to theatre for an obstetric emergency delivery (code 1 or code 2) are assessed and interviewed using the R-CAT tool to assess their capacity in retrospect. This is done ideally as soon as possible and within 24 hours after the emergency event had happened.

The R-CAT tool involves reviewing patient notes for details about the delivery (such as reason for going to theatre, urgency, and use of pain relief) and an interview with the patient. The interview takes approximately 40 minutes to complete and involves asking questions about the events around the delivery to find out what patient can recall and what she understood at that time.

Phase 2:

Women will be randomized to one of two groups using the online system of randomization facilitated by the R&D department of BCUHB.

Control group: Women will be treated in the routine manner as per national guidelines with no additional information or intervention and if she ends up in theatre for emergency delivery, then will be approached by the research team to make an assessment of her capacity in retrospect, using our specially designed R-CAT tool which combines the principles of Mental Capacity Act 2005 with McArthur's capacity assessment tool. This assessment will be done within 24 hours of delivery.

Intervention group: Women will receive written information with verbal counselling regarding the possible obstetric emergency procedures. If she continues to deliver normally and does not need to go to theatre, nothing needs to be done, however if she does need to go to theatre as an Obstetric emergency and have delivery in theatre, This patient post delivery will be assessed by using the R-CAT tool to make a retrospective assessment of her capacity at the point she was taken to theatre. This assessment is done as soon as possible after the delivery but within 24 hours of patient having been to theatre.

All participants are interviewed within 24 hours of delivery, otherwise there is no other follow up.

Intervention Type

Other

Primary outcome(s)

Phase 1 and 2:

Capacity is measured using the R CAT tool within 24 hours of delivery.

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/09/2017

Eligibility**Key inclusion criteria**

Phase 1:

1. Aged 16 years and over
2. Singleton live pregnancy
3. ≥ 36 weeks pregnancy
4. Those who have been to theatre for an obstetric emergency delivery

Phase 2

1. All women admitted for induction of labour or in very early labour judged not to be under the influence of opiate analgesia
2. Aged 16 years and over
3. Singleton live pregnancy
4. ≥ 36 weeks pregnancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

Female

Key exclusion criteria

Phase 1 and 2:

1. Under 16 years of age

2. Learning disability
3. Organic mental disorders
4. In significant pain or under the influence of opiate analgesia

Date of first enrolment

01/01/2016

Date of final enrolment

01/08/2017

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre**Glan Clwyd Hospital**

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Sponsor information

Organisation

Betsi Cadwaladr University Health Board

ROR

<https://ror.org/03awsb125>

Funder(s)

Funder type

Research organisation

Funder Name

Betsi Cadwaladr University Health Board

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Interim results article		29/01/2021	06/12/2021	Yes	No