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# A user survey of an early prototype handheld novel pain measurement device

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| **Submission date**<br>11/10/2026 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>13/10/2026 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>12/10/2026 | **Condition category**<br>Other | |

**Plain English summary of protocol**

Background and study aims
The purpose of this research project is to improve the measurement of pain in healthcare. If pain can be measured better, it may help improve the management of pain.

Who can participate?
Health professionals working in the Rosie Hospital, Cambridge. Healthy antenatal or postnatal women who are inpatients in the Rosie antenatal or postnatal wards and not receiving active care or therapy.

What does the study involve?
An interview survey of opinion of volunteer participants of the value, function and form of a prototype pain measurement device which participants will be encouraged to handle and use.

What are the possible benefits and risks of participating?
There are no direct personal benefits of participating. There should be no expected risks from participation.

Where is the study run from?
Cambridge University Hospitals (Rosie Hospital)

When is the study starting and how long is it expected to run for?
October 2026 to March 2027.

Who is funding the study?
Obstetric Anaesthetists' Association

Who is the main contact?
Dr Jim Bamber, Consultant anaesthetist, james.bamber1@nhs.net

## Contact information

**Type(s)**

Principal investigator, Public, Scientific

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# Additional identifiers

**Integrated Research Application System (IRAS)**
363382

# Study information

**Scientific Title**
A user survey of an early prototype handheld novel pain measurement device

**Study objectives**
A non-clinical user evaluation survey of an early prototype of a handheld novel pain measurement device for patient use. The information obtained from this survey will be used to guide prototype development and provide non-clinical information for a future application for approval for an early feasibility study of the prototype.

**Ethics approval required**
Ethics approval required

**Ethics approval(s)**
Approved 03/09/2026, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8241; cambridgesouth.rec@hra.nhs.uk), ref: 26/EE/0192

**Primary study design**
Observational

**Secondary study design**
A qualitative user survey to understand the opinions of health professionals and patients about the design and function of an early prototype device for pain measurement

**Study type(s)**

**Health condition(s) or problem(s) studied**

Opinions of health professionals and patients about the design and function of an early prototype device for pain measurement

### Interventions
A qualitative study involving an interview survey of opinion of volunteer participants of a prototype pain measurement device . All survey interactions will be one-to-one conducted by the study investigator.
The participants will be recruited in the Rosie Hospital from health professionals and from healthy inpatients on antenatal and postnatal wards who are not receiving active care or treatment.
The sampling strategy will be combination of purposive and convenience sampling with a intended sample size of 15 in each group (health professionals and patients).
All participants will be given a prototype device to handle and use. The purpose of the device and its function will be explained by the investigator. The participants will be encouraged to use the device but without causing any self-discomfort.
The survey about the device will involve a structured questionnaire using paper and pen completed by the participant supervised by the investigator. It is expected that completion of the questionnaire by the participant will require less than 30 minutes. There will be some differences between in the structure of the questionnaire used for the survey of the opinion of health professional volunteers and the questionnaire used to survey the opinion of patient volunteers with regards to questions about the participants. To ensure uniformity of the questions about usability of the device, the other questions are similar for both groups.
No identifying data will be collected from either group.
Participants will be able to complete the questionnaires anonymously without direct observation and in confidence.

### Intervention Type
Other

### Primary outcome(s)
1. Completion of questionnaire measured using a questionnaire at a single time point

### Key secondary outcome(s)

### Completion date
31/03/2027

## Eligibility

### Key inclusion criteria
1. Any health professional who is working in the local centre and whose job role is likely to involve pain assessment of patients as judged by the investigator will be invited to participate in the survey
2. Healthy women who are inpatient in the local centre on the antenatal and postnatal wards and who are not receiving active care or therapy at the time of the invitation for inclusion
3. English speaking

### Healthy volunteers allowed
Yes

### Age group

Mixed

### Lower age limit
18 Years

### Upper age limit
120 Years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Health professionals whose work would not be expected to involve patient pain assessment and those to decline the invitation to participate
2. Patients who are unwell or receiving active ongoing treatment
3. Patients who have a disability or condition that will preclude or inhibit their ability or to cause any discomfort to use the prototype device
4. Women who cannot understand, read or speak English
5. Women who are in distress of any kind or who are in pain
6. Women who are not inpatients on the antenatal or postnatal ward

### Date of first enrolment
26/10/2026

### Date of final enrolment
31/03/2027

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Cambridge University Hospitals NHS Foundation Trust**
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

## Sponsor information

**Organisation**
Cambridge University Hospitals NHS Foundation Trust

**ROR**
https://ror.org/04v54gj93

# Funder(s)

**Funder type**

**Funder Name**
Obstetric Anaesthetists' Association

**Alternative Name(s)**
The Obstetric Anaesthetists’ Association (OAA), The OAA, The Obstetric Anaesthetists’ Association, OAA

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not expected to be made available