Plan Overview

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Title: FRESH: A cross-sectional, multi-arm survey of the implementation, experience, and perceived impact of the 'Fresh Eyes' approach to intrapartum fetal monitoring in the UK

Creator: MEGAN HYSLOP-PEART

Principal Investigator: Professor Penny Bee

Data Manager: Meg Louise Hyslop-peart

Project Administrator: Meg Louise Hyslop-peart

Contributor: Kylie Watson, Soo Downe, Alexander Heazell

Affiliation: University of Manchester

Template: University of Manchester Generic Template

ORCID iD: 0000-0002-5600-0400

Project abstract:

This study explores the implementation and perceived impact of the 'Fresh Eyes' approach to intrapartum fetal monitoring in maternity units across the UK. Fresh Eyes is a safety process where a second midwife or obstetrician reviews fetal monitoring (cardiotocography [CTG] or intermittent auscultation [IA]) to provide an independent opinion. Although recommended in national guidance, its use has never been formally evaluated, and variation exists in how it is practised.

The project involves a national, cross-sectional, multi-arm survey with three groups: (1) fetal monitoring leads, (2) frontline maternity staff, and (3) women and birthing people. Survey questions were co-designed with a Patient and Public Involvement and Engagement (PPIE) group and mapped to Normalisation Process Theory (NPT). Recruitment will be via social media, professional networks, and parent groups, with no NHS sites, staff, or records involved.

Data collected will include anonymised survey responses only, hosted initially on REDCAP for the staff facing surveys and Survicate platform for its multi language use before being securely exported to University of Manchester storage. The findings will provide insight into national practice, inform future research, and contribute to improvements in maternity safety and inclusivity.

ID: 186361

Start date: 01-12-2025

End date: 30-09-2026

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FRESH: A cross-sectional, multi-arm survey of the implementation, experience, and perceived impact of the 'Fresh Eyes' approach to intrapartum fetal monitoring in the UK

Manchester Data Management Outline

- 1. Will this project be reviewed by any of the following bodies (please select all that apply)?
 - Ethics

2. Is The University of Manchester collaborating with other institutions on this project?

• Yes - Part of a collaboration and not handling data

The University of Manchester is the sole sponsor and the only institution handling, storing, and managing research data. However, one of the academic supervisors (Professor Soo Downe, University of Central Lancashire) is based at another institution and contributes academic expertise. UCLan will not handle, store, or own any of the research data. All data management responsibilities remain with the University of Manchester.

3. What data will you use in this project (please select all that apply)?

- Acquire new data
- · Generate textual supporting information only

The project will collect new, anonymised survey data from three groups: fetal monitoring leads, frontline maternity staff, and women/birthing people. Supporting textual information (e.g. survey instruments, mapping tables to Normalisation Process Theory, PPIE notes, recruitment materials) will also be generated. No existing research data will be re-used.

4. Where will the data be stored and backed-up during the project lifetime?

- Other storage system (please list below)
- P Drive (postgraduate researchers and students only)

Data will be collected via two survey platforms: Survicate for the women's arm (chosen for its ability to auto-adapt to device language) and REDCap for the staff arms (fetal monitoring leads and frontline clinicians). Once collected, data from both platforms will be exported, cleaned, and stored securely on the University of Manchester P drive/OneDrive, which provides automatic back-up. Access will be restricted to the student researcher and supervisory team. No personal or identifiable data will be

collected. All data will be anonymised at entry, and raw data will be permanently deleted from Survicate and REDCap after export.

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5. If you will be using Research Data Storage, how much storage will you require?

• < 1 TB

The dataset will be small, comprising anonymised survey responses and associated documentation (e.g. survey instruments, translation records, mapping tables). Total storage requirements are expected to be well under 1GB far below the <1 TB threshold..

6. Are you going to be receiving data from, or sharing data with an external third party?

No

No external data will be received or shared. All data will be newly collected for this project and managed within University of Manchester systems. Translations of study documents will be undertaken by professional translation services (MFT or UoM-approved), but these services will not handle or access any participant data.

7. How long do you intend to keep your data for after the end of your project (in years)?

• 5 - 10 years

Data will be securely stored for 5 years after project completion, in line with the University of Manchester Research Data Management Policy. As the project is due to conclude in September 2026, data will be retained until 30 September 2031, after which it will be permanently deleted.

Guidance for questions 8 to 13

Highly restricted information defined in the <u>Information security classification</u>, <u>ownership and secure information handling SOP</u> is information that requires enhanced security as unauthorised disclosure could cause significant harm to individuals or to the University and its ambitions in respect of its purpose, vision and values. This could be: information that is subject to export controls; valuable intellectual property; security sensitive material or research in key industrial fields at particular risk of being targeted by foreign states. See more <u>examples of highly restricted information</u>.

If you are using 'Very Sensitive' information as defined by the <u>Information Security</u> <u>Classification, Ownerships and Secure Information Handling SOP</u>, please consult the <u>Information Governance Office</u> for guidance.

Personal information, also known as personal data, relates to identifiable living individuals. Personal data is classed as special category personal data if it includes any of the following types of information about an identifiable living individual: racial or ethnic

origin; political opinions; religious or similar philosophical beliefs; trade union membership; genetic data; biometric data; health data; sexual life; sexual orientation. Please note that in line with <u>data protection law</u> (the UK General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate <u>ethical approval</u> in order to use identifiable personal data.

- 8. What type of information will you be processing (please select all that apply)?
 - Anonymised personal data

The project will process only anonymised survey responses. No names, contact details, or other direct identifiers will be collected. Demographic information will be limited to non-identifiable categories (e.g. professional role, parity, ethnicity, language), which will be analysed in aggregate. No special category personal data, signed consent forms, audio, or video will be collected.

9. How do you plan to store, protect and ensure confidentiality of any highly restricted data or personal data (please select all that apply)?

- Where needed, follow University of Manchester guidelines for disposing of personal data
- Anonymise data
- Store data on University of Manchester approved and securely backed up servers or computers

All survey data will be anonymised at the point of collection. Data will be exported from the survey platforms (Survicate for the women's arm; REDCap for the staff arms) and stored securely on the University of Manchester's P drive/OneDrive, which provides automatic back-up. Access will be restricted to the student researcher and supervisors using UoM login credentials. Raw data will be deleted from the survey platforms after export. Data will be retained for 5 years post-project (until 30 September 2031) and then permanently deleted in line with University policy.

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

Not applicable

No identifiable personal information will be collected. Survey responses will be anonymised at the point of entry, and no contact details will be requested. Participant Information Sheets will explain that participation is anonymous and that data cannot be withdrawn after submission.

11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?

• No

Anonymised survey data will be accessed only by the student researcher and supervisory team within

the University of Manchester. No identifiable or sensitive information will be collected, and no data will be shared with institutions or organisations outside the University. Findings will be disseminated in aggregate form only (e.g. dissertation, publications, conferences).

12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

Not applicable

Not applicable. The project does not involve the collection or sharing of personal information. Only anonymised survey data will be collected, and this will be stored and analysed within University of Manchester systems.

13. Are you planning to use the personal information for future purposes such as research?

No

No. The project will not collect identifiable personal information. All survey responses will be anonymised at entry and used only for the purposes of this MClinRes dissertation study.

14. Will this project use innovative technologies to collect or process data?

• Yes, and innovative technologies will not collect or process personal data (please list the innovative technologies below)

The project will use two online survey platforms: Survicate (for the women's arm) and REDCap (for the staff arms). These tools support accessibility (e.g. Survicate auto-adapts to device language) and secure online data capture. No identifiable personal data will be collected. Survey responses will be anonymised at entry and securely exported to University of Manchester storage.

15. Who will act as the data custodian for this study, and so be responsible for the information involved?

The data custodian will be Meg Hyslop-Peart (student researcher), who will manage the collection, storage, and analysis of the anonymised survey data. Oversight will be provided by the Chief Investigator (Kylie Watson) in line with University of Manchester sponsorship and governance requirements.

16. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

2025-09-12

Project details

What is the purpose of your research project?

The purpose of this project is to evaluate the implementation and perceived impact of the *Fresh Eyes* approach to intrapartum fetal monitoring in UK maternity services. Fresh Eyes is a safety process where a second clinician reviews fetal heart rate monitoring (cardiotocography [CTG] or intermittent auscultation [IA]) to provide an independent opinion. Although recommended in national guidance, it has never been formally evaluated and practice varies widely.

This study will use a national, cross-sectional survey with three groups: (1) fetal monitoring leads, (2) frontline maternity staff, and (3) women and birthing people. The survey has been co-designed with a Patient and Public Involvement and Engagement (PPIE) group and mapped to Normalisation Process Theory (NPT).

The findings will provide insight into how Fresh Eyes is being used, its perceived value, and barriers or facilitators to implementation. Results will inform future research and contribute to improvements in maternity safety and inclusivity.

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

This project will follow the University of Manchester Research Data Management Policy (2021), which requires all researchers to maintain a Data Management Plan, ensure secure data storage, and plan for retention and disposal of research data.

The following related University policies are also relevant:

- Records Management Policy and Retention Schedule
- Data Protection Policy (2025), ensuring compliance with UK GDPR and the Data Protection Act 2018
- Intellectual Property Policy (2025)
- IT Policies and Guidelines, including the Information Security Classification and Handling SOP
- University of Manchester:
 - Research Data Management Standard Operating Procedure
- University of Manchester Publication Policy

No external funder or departmental or group-specific policies apply, as this is a student dissertation project.

Responsibilities and Resources

Who will be responsible for data management?

The student researcher, Meg Hyslop-Peart, will be responsible for the day-to-day management of research data, including secure collection, storage, anonymisation, and retention in line with University policy. Oversight will be provided by the Chief Investigator, Kylie Watson, who will ensure that the Data Management Plan is followed and updated as required. Supervisors, including Professor Alex Heazell and Professor Soo Downe, will advise on research conduct but will not handle or store

data directly.

What resources will you require to deliver your plan?

The resources required are minimal. Data collection will use two secure online survey platforms: Survicate (for the women's arm) and REDCap (for the staff arms). The University of Manchester provides approved storage via the OneDrive/Research data storage, which includes automatic back-up and controlled access. Professional translation services will be used to produce validated translations of study posters and survey materials into priority languages. No specialist equipment or additional technical resources will be required beyond standard University IT facilities.

Data Collection

What data will you collect or create?

The project will generate new, anonymised survey data from three participant groups: fetal monitoring leads, frontline maternity staff, and women/birthing people. The survey data will include closed-response items (e.g. multiple choice, Likert scales) and open-text responses, covering views on the implementation and impact of the Fresh Eyes approach to intrapartum fetal monitoring. Supporting documentation will also be created, including survey instruments, mapping tables to Normalisation Process Theory constructs, and translation records.

No existing datasets or third-party data sources will be used. Data will be collected in digital form via online survey platforms (Survicate for the women's arm, REDCap for staff arms) and exported as CSV/Excel files for cleaning and analysis.

The total dataset is expected to be small (well under 1 GB), requiring minimal storage capacity. Data will be stored on the University of Manchester P drive/OneDrive, which provides secure, backed-up access. Sustainability and re-use will be supported by retaining cleaned, anonymised datasets, together with supporting metadata and documentation, for five years post-project.

How will the data be collected or created?

Data will be collected using two secure online survey platforms: Survicate (for the women's arm) and REDCap (for the staff arms: fetal monitoring leads and frontline clinicians). Both platforms provide structured data capture with features such as mandatory fields, branching logic, and skip patterns to reduce the risk of incomplete or inconsistent responses. Survey instruments were co-designed with a Patient and Public Involvement and Engagement (PPIE) group and reviewed by supervisors to ensure clarity and quality prior to launch.

All surveys will be delivered in digital format, and responses will be automatically captured and stored on the respective platforms. Data will then be exported into standard formats (CSV and Excel) for cleaning and analysis. No community-specific data standards apply, but data will be documented with a data dictionary to define variables, coding schemes, and response categories.

During the project, data will be organised in structured folders on the University of Manchester P drive/OneDrive, with clear naming conventions (e.g. date, version, file type) and version control for working documents. Only cleaned, final datasets will be retained for analysis. Quality control will be supported by pre-testing survey instruments, piloting branching logic, and maintaining consistency

through standardised coding and mapping to Normalisation Process Theory constructs.

Documentation and Metadata

What documentation and metadata will accompany the data?

The dataset will be accompanied by a range of documentation to ensure it is understandable and reusable in the future. This will include:

- **Survey instruments**: full copies of the questionnaires for all three arms (fetal monitoring leads, frontline staff, women/birthing people), including branching logic and skip patterns.
- **Data dictionary**: listing each variable, full question wording, coding scheme, and response categories, with notes on variable type (numeric, categorical, free text). This will be prepared in Excel to support SPSS analysis.
- **Supporting materials**: participant information sheets, consent wording, recruitment posters, and translation records.
- **Readme file**: summarising key details such as dataset title, creators, contributors, dates of creation, file formats (CSV, Excel), and conditions of access/retention.

Metadata will capture methodological details, including survey design, sample population, and mapping to Normalisation Process Theory constructs. This will be recorded in a standardised "readme" text file stored alongside the datasets.

No formal community metadata standard exists for survey data of this type; however, best practice guidance (DataCite schema and DCC recommendations) will be used to ensure that files are clearly identifiable, searchable, and reusable.

All data and documentation will be stored in the University of Manchester P drive/OneDrive, using a structured folder system with version control. Supporting materials (e.g. survey instruments, participant information sheets, data dictionary, README file) will be stored alongside the datasets to ensure transparency and reproducibility. At project completion, the final anonymised dataset and associated documentation will be retained for 5 years in University storage (until September 2031).

Ethics and Legal Compliance

How will you manage any ethical issues?

This project involves surveys with clinicians and women/birthing people about intrapartum fetal monitoring practices. Ethical approval will be obtained from the University of Manchester Research Ethics Committee (UREC). Following discussion with the HRA Queries line, NHS REC/HRA approval is not required, as recruitment will not take place via NHS staff or patient records, all survey questions reviewed and protocol, prior to outcome decision NHS REC/HRA not required.

All data will be collected anonymously. Surveys will not request names, contact details, or other direct identifiers. Demographic information (e.g. professional role, ethnicity, parity, language) will be recorded in non-identifiable categories and analysed only in aggregate and will be pseudonymised and kept in a separate file, as this is not needed for analysis, as these details are to demonstrate characteristics of participants as a whole, not linking them to their answers or NHS Trusts, to ensure

we can demonstrate scale of coverage, how far survey reached, and variability of backgrounds. Consent will be obtained digitally at the point of entry, with information sheets explaining that participation is anonymous and data cannot be withdrawn once submitted.

To protect confidentiality, survey responses will be anonymised at entry, exported to University storage, and the raw data deleted from survey platforms (Survicate, REDCap). Anonymised datasets will be retained securely for five years post-project (until September 2031) and then permanently deleted. Findings will be disseminated only in aggregate form, with quotations from free-text responses presented in a way that prevents identification.

Data will not be publicly shared due to the sensitivity of the topic and the risk of deductive disclosure. Instead, only anonymised and aggregated results, alongside survey instruments and supporting documentation, may be made available through publications or repositories.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

All data generated in this study will be new and collected specifically for the Fresh Eyes survey. No third-party datasets will be reused, so no copyright or IPR restrictions from external sources apply. In line with the University of Manchester Intellectual Property Policy (effective 1 April 2025), the University will own the intellectual property arising from this project. The student researcher will be recognised as the data creator, with the Chief Investigator providing oversight, but ownership of the research data rests with the University.

Because the survey concerns sensitive clinical practice and women's experiences, individual-level datasets will not be made publicly available. Only aggregate, anonymised findings and supporting documentation (e.g. survey instruments, mapping tables) will be disseminated through the dissertation, academic publications, and conference presentations.

If supporting materials are deposited in an open repository (e.g. University of Manchester Figshare), they will be licensed under an appropriate open licence such as Creative Commons Attribution (CC BY 4.0) to enable reuse with attribution. Raw anonymised datasets will not be licensed or shared publicly due to the risk of deductive disclosure.

Storage and backup

How will the data be stored and backed up?

All data will be stored using University of Manchester approved systems with automatic back-up. Survey data will initially be collected via Survicate (for the women's arm) and REDCap (for the staff arms). Following export, raw data will be permanently deleted from the survey platforms.

Anonymised datasets and associated documentation will be stored on the University of Manchester P drive/OneDrive, which is automatically backed up **daily** by IT Services to secure servers in multiple locations. Data will be organised into structured folders with controlled access restricted to the student researcher and supervisory team.

No data will be stored on USB sticks, CDs, or external hard drives. Where temporary local storage on a University-managed laptop is required for analysis, files will be encrypted and immediately backed up to the University servers. No paper data will be collected.

The data do not include identifiable personal information and therefore do not require storage in the University's Data Safe Haven. All storage and handling will comply with University IT policies and the Information Security Classification and Handling SOP. Data will be retained until September 2031, in line with University retention requirements, and then permanently deleted.

How will you manage access and security?

Access control and roles

- Data custodian: Meg Hyslop-Peart (student). Oversight: CI (Kylie Watson).
- Access is limited to the student and supervisory team via University of Manchester accounts only (least-privilege). No external collaborators will access the data.

Storage and backup

- Working and master copies stored on UoM OneDrive/P drive (managed, backed up daily by IT Services).
- No USB sticks/external drives. Temporary local copies (if any) on a password-protected, encrypted device and immediately synced back to UoM storage.

Collection and transfer

- Collection via Survicate (women's arm) and REDCap (staff arms).
- Surveys configured to **avoid collecting identifiers** (e.g., names, emails, IP addresses).
- Export over secure, encrypted connections to UoM storage; delete raw data from Survicate/REDCap after verified export.

Encryption and network security

- Data encrypted at rest on UoM storage and in transit (TLS).
- Remote access only via authenticated UoM services; VPN used where required by policy.
- Personal devices, if used temporarily, must have full-disk encryption enabled.

Risk and mitigation

- Risks: loss/theft of device, unauthorised access, platform metadata capture, accidental disclosure.
- Mitigations: least-privilege access; MFA on UoM accounts; no identifiers collected; platform settings reviewed to disable IP/device capture; versioned, read-only master files; secure deletion after retention.

Sensitive data and Safe Haven

- No identifiable personal data will be collected; therefore the **Data Safe Haven is not required** .
- All handling complies with UoM IT Policies and the Information Security Classification & Secure Handling SOP.

Audit/retention

- Access restricted to named users; changes tracked via OneDrive version history.
- Data retained until **30 Sept 2031**, then securely and permanently deleted per Records Retention Schedule.

Selection and Preservation

Which data should be retained, shared, and/or preserved?

The Fresh Eyes survey will generate anonymised quantitative and qualitative data from three survey arms (fetal monitoring leads, frontline staff, and women/birthing people). Raw exports from Survicate and REDCap will be securely deleted once cleaned datasets have been created and verified. The following will be retained:

- Cleaned, anonymised datasets in tabular formats (CSV/SPSS).
- Supporting documentation including survey instruments, participant information sheets, data dictionary, metadata/README file, and translation records.
- Aggregate analyses, including summary statistics and thematic coding.

All retained data will be stored in University of Manchester-managed storage and preserved for five years after project completion (until September 2031) in line with the University's Research Data Management Policy and Records Retention Schedule.

Due to the sensitive nature of the data and the risk of deductive disclosure, individual-level datasets will not be publicly shared. Aggregate findings, anonymised quotations, survey instruments, and associated documentation may be in the Principal Investigator's data storage. University of Manchester's research repository is under a Creative Commons Attribution (CC BY 4.0) licence, to support validation and teaching reuse.

No additional resources or repository fees are anticipated. Preparation for deposit will involve anonymisation, production of a data dictionary, and creation of metadata in line with University guidance.

What is the long-term preservation plan for the dataset?

The cleaned, anonymised datasets will be preserved in University of Manchester-managed storage for five years after project completion (until September 2031), in line with the University's Research Data Management Policy and Records Retention Schedule. Supporting documentation will be created by the researcher, including survey instruments, participant information sheets, a README file, a data dictionary, and translation records, to ensure the dataset is fully interpretable and reusable.

Given the sensitive nature of the data, individual-level survey responses will not be shared publicly. Instead, aggregate findings, anonymised quotations, and supporting documentation will be deposited in the Principle Investigator's University of Manchester's institutional research repository, which provides persistent identifiers (DOIs), long-term preservation infrastructure, and a Creative Commons Attribution (CC BY 4.0) licence for reuse. This ensures that key outputs remain accessible, citable, and reusable beyond the lifetime of the project.

No additional charges or external resources are anticipated. Preparation for deposit will include anonymisation, verification of cleaned datasets, and production of supporting documentation in line with University and Digital Curation Centre guidance to ensure that the materials are findable, accessible, interoperable, and reusable (FAIR).

Data Sharing

How will you share the data?

Cleaned, anonymised datasets and supporting documentation will be shared via the University of

Manchester's institutional repository (Figshare) once the project is complete, subject to any conditions of ethical approval. Data will be accompanied by appropriate metadata, a README file, and a data dictionary to ensure discoverability and re-use.

Only anonymised, non-identifiable data will be deposited. No raw personal information will be shared. Access will therefore be unrestricted and public, with a DOI assigned by Figshare to allow the dataset to be cited in future research and teaching.

The dataset will be made available at the point of thesis submission and/or publication of results, with no embargo anticipated beyond this point. Researchers, students, clinicians, and policymakers will be able to access and reuse the data under a CC BY licence, ensuring both openness and appropriate acknowledgement of the source.

This approach ensures alignment with the University's Open Research position and supports the wider dissemination of findings to improve maternity care practices.

Are any restrictions on data sharing required?

No restrictions on data sharing are anticipated beyond the need to protect participant confidentiality. All datasets will be fully anonymised prior to deposit, with no direct identifiers retained. Consent materials will explicitly state that anonymised data may be shared for research and teaching purposes.

As a result, the cleaned datasets can be deposited in the University of Manchester's Figshare repository and made openly available without access restrictions. There will be no need for data sharing agreements or non-disclosure arrangements, since no personal or sensitive information will be included.

The data will be available from the point of thesis submission and/or publication of findings. Persistent identifiers (DOIs) will be assigned to enable citation and tracking of reuse.

Potential re-uses include secondary analysis of survey implementation, methodological comparisons with other studies of intrapartum monitoring, or teaching on maternity care research. By depositing in open, non-proprietary formats accompanied by documentation, reuse will be facilitated across disciplines.