Plan Overview

A Data Management Plan created using DMPonline

Title: Scoping review: Does current evidence justify or challenge the use of the Fresh Eyes approach for intrapartum fetal monitoring in maternity services?

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Template: University of Manchester Generic Template

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Project abstract:

Objective: The objectives of this scoping review are to map the extent and nature of the evidence surrounding the “Fresh Eyes” approach to intrapartum fetal heart rate monitoring, explore how existing literature supports or challenges its use, and identify gaps in knowledge across effectiveness, acceptability (including for women, birthing people, and birth companions), feasibility, equitability, and affordability.

Introduction: “Fresh Eyes”, where a second clinician reviews fetal monitoring (Cardiotocograph (CTG) or intermittent auscultation (IA)) when a woman is in labour, is widely promoted in UK maternity safety policy and national guidelines, yet its empirical basis is unclear. National reports have repeatedly highlighted problems in interpretation and escalation of fetal monitoring, accelerating adoption of “Fresh Eyes” despite limited formal evaluation.

Inclusion criteria: Human studies in intrapartum settings involving maternity clinicians and/or service users where “Fresh Eyes” or a comparable second-review process is used or described.

Methods: Following the Joanna Briggs Institute (JBI) methodology for scoping reviews, six databases and grey literature will be searched (1999–present, no language limits). Two reviewers (MHP, DF) will independently screen and chart data, disagreements will be resolved by discussion, or an additional reviewer (SD). Results will be presented narratively with tables and figures in line with Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) will guide reporting.

Keywords: bias reduction; clinical escalation; labour; maternity safety; midwives; obstetricians; second reviewer; team decision-making, human factors

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Scoping review: Does current evidence justify or challenge the use of the Fresh Eyes approach for intrapartum fetal monitoring in maternity services?

Manchester Data Management Outline

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

- None of the above

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

- Yes - Part of a collaboration and not handling data

This project is a scoping review conducted by the University of Manchester in collaboration with the University of Central Lancashire. The review follows the Joanna Briggs Institute (JBI) methodology and PRISMA-ScR reporting guidelines.

The University of Manchester is the lead institution and will manage all data. Professor Soo Downe (University of Central Lancashire) will act as a methodological advisor and support resolution of screening or data-charting disputes but will not access or handle any data directly.

No personal or participant data will be collected. All data consist of secondary, publicly available literature identified through database and grey literature searches (MEDLINE, Embase, CINAHL Plus, Scopus, MIDIRS, PubMed). Bibliographic records will be managed in EndNote for de-duplication and Rayyan for screening. Extracted data will be stored securely in a University-managed OneDrive folder using a structured Excel data-charting form.

The dataset will contain no identifiable information. On completion, the finalised data-charting sheet, PRISMA flow diagram, and summary tables will be uploaded to the University of Manchester Research Repository and linked to the OSF registration.

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

This project will re-use existing, publicly available data in the form of published and grey literature related to the “Fresh Eyes” approach to intrapartum fetal monitoring. The review will not involve new data collection or human participants.

Sources will include research articles, reports, guidelines, and policy documents identified through searches of MEDLINE, Embase, CINAHL Plus, Scopus, MIDIRS, and PubMed, alongside grey literature from NHS England, NICE, NHS Resolution, RCOG, and the UK Fetal Monitoring Network.

New data will take the form of textual supporting information generated through data extraction and charting, including summary tables, PRISMA flow diagrams, and narrative syntheses. These materials will be created and stored in Excel and Word formats within a secure University-managed OneDrive folder.

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

- Other storage system (please list below)
- University of Manchester Research Data Storage Service (Isilon)

Onedrive, with plans to move to Research data storage once supervisor Penny Bee has set this up.

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

- < 1 TB

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

- No

No external data will be received from, or shared with, any third party.

This project is a scoping review using only publicly available literature. No personal, confidential, or proprietary data will be exchanged.

While Professor Soo Downe (University of Central Lancashire) is involved as a methodological advisor, she will not access or handle any data directly. All data management and storage will be conducted by the University of Manchester.

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 retained for a minimum of 5 years after project completion, in line with University of Manchester research data management policy and NIHR guidance.

All materials are non-personal and consist of secondary, publicly available data extracted from published and grey literature. The final dataset (data-charting Excel file, PRISMA flow diagram, and synthesis tables) will be archived in the University of Manchester Research Repository and linked to the project's OSF registration, ensuring long-term accessibility and transparency.

No sensitive or confidential data are included, so there are no ethical restrictions on retention or sharing.

Guidance for questions 8 to 13

Highly restricted information defined in the Information security classification, ownership and secure information handling SOP 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 examples of highly restricted information .

If you are using 'Very Sensitive' information as defined by the Information Security Classification, Ownerships and Secure Information Handling SOP, please consult the Information Governance Office 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 data protection law (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 ethical approval in order to use identifiable personal data.

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

- No confidential or personal data

This project will not involve the processing of any personal, confidential, or special category data. No identifiable, pseudonymised, or anonymised participant data will be collected or used.

All materials consist of **secondary, publicly available information** obtained through searches of published and grey literature (e.g. journal articles, national reports, clinical guidelines). No NHS or other restricted datasets will be accessed, and no external data providers impose security requirements.

All records and extracted data (bibliographic and textual) will be stored securely in University-managed systems (OneDrive and EndNote).

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

- Not applicable

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

- Not applicable

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

- Not applicable

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

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

- No

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

- No

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

Penny Bee

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

2025-10-20

Project details

What is the purpose of your research project?

The purpose of this project is to map and synthesise existing evidence on the *Fresh Eyes* approach to intrapartum fetal monitoring within maternity services. The review aims to identify how this approach has been defined, implemented, and evaluated, and to explore evidence relating to its effectiveness, acceptability, equitability, and feasibility across different care settings.

Findings will inform future research and guideline development on fetal monitoring safety practices and contribute to evidence-based improvements in maternity care.

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

This project will comply with the following University, national, and methodological policies and

standards on data management, sharing, and security:

- University of Manchester Research Data Management Policy
- University of Manchester Information Security Policy
- UK GDPR and Data Protection Act (2018) – as no personal data are handled, compliance focuses on secure storage and appropriate handling of secondary, non-personal data
- UKRI Concordat on Open Research Data (2016) – for principles of transparency and responsible data sharing
- Joanna Briggs Institute (JBI) methodology for scoping reviews (Peters et al., 2020) – defines standards for transparency, reproducibility, and data reporting
- PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines (Tricco et al., 2018) – for reporting and documentation
- Open Science Framework (OSF) registration requirements – the protocol is preregistered under embargo, ensuring traceability and open access to data post-completion
- University of Manchester Library Open Access Policy – governs sharing of outputs and data archiving via the University Research Repository

No funder- or consortium-specific data sharing agreements apply, as the study is unfunded and uses only publicly available sources.

Responsibilities and Resources

Who will be responsible for data management?

Penny Bee, Meg Hyslop-Peart, Danny Fenton

What resources will you require to deliver your plan?

- **Software & services (no new purchase anticipated)**
  - **EndNote 21** (UoM licence) for reference management and de-duplication.
  - **Rayyan** (free) for independent screening.
  - **Microsoft 365** (UoM licence: OneDrive, Excel, Word) for secure storage and data-charting.
  - **SPSS/Excel** (UoM licence) for simple descriptive summaries/figures.
  - **OSF** (free) for protocol registration and linking to outputs.
  - **UoM Research Repository (Pure)** for dataset/outputs deposit (no charge).

  Storage, backup & security
  - Primary storage in **UoM OneDrive**, with automatic versioning and backup; EndNote libraries stored within the same workspace.
  - No highly restricted or personal data are processed; HRDS / Data Vault not required.

  Open access & dissemination
  - Publication via **UoM read-and-publish agreements** where eligible (e.g., Springer Nature/BMC).
  - **Open Research & Open Access teams** will advise on OA routes and repository deposit (no repository fees anticipated).

  Training & support

- Use of **UoM Library** training/guides on systematic searching, EndNote, PRISMA-ScR, and research data management.
- Methodological standards per **JBI** and **PRISMA-ScR** to ensure reproducibility and documentation.

Preparation for deposit

- Time allocated to tidy the data-charting Excel file, codebook/README, PRISMA flow diagram, and summary tables prior to repository upload.
- **Costs**
  - No new hardware or paid software required.
  - No anticipated repository or storage charges; APCs expected to be covered by UoM OA agreements (if applicable).

Data Collection

What data will you collect or create?

This scoping review will generate new **secondary data** derived from publicly available published and grey literature. No identifiable personal or clinical data will be collected.

The types of data to be created include:

- **Bibliographic data** – exported search results from databases such as MEDLINE, Embase, Scopus, CINAHL, and OpenGrey, saved in RIS, CSV, or Excel formats.
- **Screening data** – records of inclusion and exclusion decisions from title/abstract and full-text screening in Rayyan, exported in CSV or Excel format.
- **Extracted data** – evidence tables summarising study characteristics, methodology, outcomes, and key findings, created in Excel or Word.
- **Documentation** – the review protocol, PRISMA-ScR checklist, PCC framework, search strategy logs, and data extraction templates, stored as Word and PDF documents.
- **Analytical materials** – coding frameworks, synthesis matrices, and summary notes to support thematic mapping and interpretation, produced in Word or Excel.
- **Research notes** – reflective notes and records from supervisory or PPIE discussions, stored in Word, PDF, or plain text format.

All files will be saved in standard, non-proprietary formats (CSV, TXT, PDF/A, DOCX, XLSX) to ensure long-term accessibility, following the UK Data Service guidance.

The total expected storage requirement is **no more than 5 GB**, including exported search results, documentation, and analysis outputs. All data will be stored on the **University of Manchester's secure research drive**, with regular backups and version control applied.

How will the data be collected or created?

This project will not generate new empirical or participant data. It will re-use existing, publicly available literature to produce a structured and transparent evidence map on the Fresh Eyes approach to intrapartum fetal monitoring.

Data sources

Published research articles and reviews will be identified through searches of MEDLINE, Embase,

CINAHL Plus, Scopus, MIDIRS, and PubMed. Grey literature will be sought from NHS England, NICE, NHS Resolution, RCOG, and the UK Fetal Monitoring Network, alongside professional reports, policy documents, and commentaries relevant to the topic.

Data created

New data will take the form of textual and tabular supporting materials, including:

- A structured data-charting spreadsheet (Excel/CSV) containing study characteristics, settings, participant groups, and key findings coded against predefined domains (effectiveness, acceptability, feasibility, equity, affordability, and emotional safety).
- A PRISMA flow diagram (PDF/PNG) documenting the search and screening process.
- A summary table (Word/Excel) describing the range and types of evidence identified.
- A narrative synthesis outlining main patterns, gaps, and implications.

Data organisation and quality assurance

All files will be stored within a clearly structured OneDrive project folder, with subfolders for *search logs, screening, extraction, analysis,* and *outputs*. Consistent naming conventions will be applied (e.g. YYYYMMDD_filename_version), and version control will be maintained automatically through OneDrive. Only one master version of each dataset (e.g. FRESH_DataChart_v1.xlsx) will be retained for analysis, with older versions archived.

Quality and consistency of data collection will be assured through:

- A **standardised data-charting template** based on JBI and PRISMA-ScR guidance.
- A **data dictionary** describing each variable and coding decision.
- **Double-checking of data extraction** for 10% of studies by a second reviewer to ensure accuracy and consistency.
- **Peer review of the search strategy** by the supervisory team prior to data collection.
- **Audit trail documentation**, recording all decisions about inclusion, coding, and revisions.

Formats and storage

All files will be saved in non-proprietary, open formats (CSV, DOCX, PDF, PNG) within the University-managed OneDrive workspace. Files are automatically versioned and backed up, ensuring security and sustainability. Total data volume is expected to be small (<1 GB).

Re-use and preservation

As all data originate from publicly available sources, there are no copyright or IP restrictions on inclusion, provided full citation is maintained. The data-charting file, PRISMA diagram, and synthesis tables will be deposited in the University of Manchester Research Repository and linked to the OSF registration, ensuring long-term preservation and re-use. These outputs will have long-term value for other researchers exploring fetal monitoring practices, maternity safety, and evidence mapping in perinatal care.

Documentation and Metadata

What documentation and metadata will accompany the data?

Documentation to be provided:

- A **README file** (Word/PDF) describing:
  - The project title, authors/contributors, and affiliations.
  - Version/date of data release and corresponding OSF registration link.

    - Overview of the study purpose, methodology (JBI scoping review approach), and PRISMA-ScR reporting standards.
    - Description of data-charting variables and coding structure.
    - File inventory and explanation of file formats.
    - Instructions for reuse, including citation and attribution guidance.
- A **Data Dictionary / Codebook** embedded in the Excel data-charting file, listing each field (e.g., study ID, design, country, population, concept, context, domain coding) and definitions used.
- A **PRISMA flow diagram** documenting the number of records identified, screened, included, and excluded.
- A **Methodology summary** detailing the search strategy, inclusion/exclusion criteria, and analytical framework.

Metadata standards:

- Metadata will follow **Dublin Core** and **University of Manchester Research Repository (Pure)** requirements, including fields for title, creator, contributor, date, type, keywords, and access conditions.
- When deposited in the repository, standard metadata will be auto-generated and supplemented with descriptive keywords: *scoping review, maternity safety, fetal monitoring, Fresh Eyes, intrapartum care, UK*.

All documentation will be stored alongside the data files in the project's OneDrive folder and uploaded to the repository to support discoverability, interpretation, and reuse.

Ethics and Legal Compliance

How will you manage any ethical issues?

This project does not involve human participants, personal data, or confidential information. It is a scoping review that uses only secondary, publicly available sources, such as published research articles, reports, and policy documents.

As such, formal ethical approval is not required, and no consent or anonymisation processes are applicable. This position has been confirmed through the University of Manchester's Research Ethics Decision Tool and aligns with institutional and JBI guidance for evidence syntheses.

All data will be managed securely within University of Manchester OneDrive and EndNote, with access restricted to the review team (Meg Hyslop-Peart and Danny Fenton). Professor Soo Downe will act as a methodological advisor only and will not handle or store data.

The data will contain no identifiable information, and all materials derived from published or grey literature will be fully cited. Outputs (data-charting files, PRISMA diagram, and synthesis tables) will be made openly available in the University Research Repository and linked to the OSF registration, supporting transparency and reuse without ethical or privacy risks.

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

All data included in this scoping review will be drawn from publicly available and properly cited third-party sources, such as peer-reviewed articles, reports, and policy documents. No unpublished, confidential, or proprietary data will be used.

The copyright of the original publications will remain with the respective authors and publishers. Any material quoted, summarised, or reproduced (e.g., figures or tables) will be used under the principles of fair dealing for research and review and will include full citation and attribution.

The newly created data, such as the data-charting Excel file, PRISMA flow diagram, and summary tables, will be original outputs of this project. Copyright for these materials will rest with the University of Manchester as the lead institution and will be shared under a Creative Commons Attribution (CC BY 4.0) licence upon deposit in the University Research Repository, enabling open access and reuse with proper acknowledgment.

No intellectual property restrictions are anticipated, and no commercial exploitation is planned.

Storage and backup

How will the data be stored and backed up?

All project data will be stored in University of Manchester-managed OneDrive, which provides secure cloud-based storage with automatic versioning, synchronisation, and daily backup to University servers. This ensures data integrity and recovery in case of accidental loss or corruption.

EndNote reference libraries and the Excel data-charting file will be saved within the same OneDrive workspace to maintain consistent backup. Local copies (e.g., on institutional laptops) will synchronise automatically with the secure cloud environment.

No data will be stored on personal devices or external drives. Access will be limited to the review team via University login credentials, and all files will remain within the University’s managed digital environment throughout the project.

How will you manage access and security?

All project data will be stored within University of Manchester-managed systems that comply with institutional information security standards. The primary storage location will be OneDrive for Business, which provides encrypted, cloud-based storage with automatic backup, version control, and access limited to authorised users.

Access will be restricted to the review team: Meg Hyslop-Peart (Lead Researcher, University of Manchester) and Professor Penny Bee (Academic Supervisor, University of Manchester). Professor Soo Downe (University of Central Lancashire) will act as a methodological advisor and will not access or handle any data directly.

Data will not be stored on personal devices or removable media. EndNote reference libraries, Rayyan screening files, and Excel data-charting sheets will be maintained within the University’s secure digital environment.

As no personal or sensitive data are collected, the risk is minimal. Upon project completion, the final data files (data-charting spreadsheet, PRISMA flow diagram, and synthesis tables) will be deposited in the University of Manchester Research Repository and made publicly accessible via the linked OSF registration.

This project adheres to the University of Manchester Information Security Classification, Ownership and Secure Information Handling SOP.

Selection and Preservation

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

All data will be organised within a clearly structured folder hierarchy on the University of Manchester Research Drive (RDS), which is being set up by the project's Principal Investigator, Professor Penny Bee. Temporary working files will be stored in OneDrive for Business during active analysis, and then transferred to the RDS for long-term preservation before the end of the project.

File organisation and naming conventions
Files will be stored in subfolders reflecting the project workflow: *search logs, screening, extraction, synthesis,* and *outputs*. Naming conventions will follow a consistent format: YYYYMMDD_filename_version (e.g. 20250412_DataChart_v2.xlsx).
Older versions will be archived in a dedicated "Archive" folder to maintain traceability while avoiding duplication.

Version control
Version control will be managed through OneDrive's automatic history function during active work and through manually logged version numbers in filenames. A changelog document will summarise key revisions and updates. Only one master dataset (e.g. FRESH_DataChart_FINAL.xlsx) will be retained for analysis to ensure clarity and consistency.

Quality assurance and documentation
To ensure the accuracy and consistency of data collection:

- A **standardised data-charting template** will be used, based on JBI and PRISMA-ScR guidance.
- A **data dictionary** will define each variable and coding rule.
- **Double-checking of extracted data** will be conducted for 10% of included studies by a second reviewer.
- The **search strategy** will be peer reviewed by the supervisory team prior to execution.
- An **audit trail** will be maintained, recording all screening, inclusion, and data extraction decisions.

Preservation and sustainability
Upon completion of the project, the curated dataset (data-charting file, PRISMA diagram, and summary tables) will be deposited in the University of Manchester Research Repository and linked to the project's OSF registration for open access. Any materials that cannot be publicly shared will be retained on the RDS under the supervision of Professor Bee, ensuring secure, long-term preservation in accordance with University policy.

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

On completion of the review, the final dataset — including the data-charting spreadsheet, PRISMA flow diagram, summary tables, and supporting documentation (README file, data dictionary, and metadata) — will be archived in the University of Manchester Research Repository (Pure).

This repository provides secure, long-term digital preservation, assigns a persistent DOI, and ensures compliance with University and national open research policies. The repository guarantees continued accessibility, metadata indexing, and preservation for a minimum of ten years, with automated migration to sustainable file formats if required.

The dataset will also be linked to the project's OSF registration, ensuring transparency and discoverability. All materials will be released under a Creative Commons Attribution (CC BY 4.0) licence, allowing reuse with appropriate citation.

No personal, sensitive, or restricted data are included, so there are no ethical or legal barriers to long-

term preservation or sharing.

Data Sharing

How will you share the data?

All project outputs will be shared openly and transparently following completion of the review. The final dataset — including the data-charting spreadsheet, PRISMA flow diagram, summary tables, and supporting documentation (README file, data dictionary, and metadata) — will be uploaded to the University of Manchester Research Repository (Pure).

Upon deposit, the repository will assign a persistent DOI and make the files openly available under a Creative Commons Attribution (CC BY 4.0) licence, allowing others to reuse, adapt, and cite the materials appropriately.

A direct link to the repository record will also be added to the project's Open Science Framework (OSF) registration, ensuring long-term visibility and discoverability.

As the review uses only secondary, publicly available data, there are no restrictions on data sharing. Any figures or quotations from third-party publications will remain subject to the original authors' copyright and will be fully cited.

Are any restrictions on data sharing required?

No restrictions on data sharing are required.

This project uses only secondary, publicly available sources, and the data generated (data-charting spreadsheet, PRISMA flow diagram, summary tables, and supporting documentation) will contain no personal, confidential, or commercially sensitive information.

All outputs will be made openly available through the University of Manchester Research Repository (Pure) and linked to the Open Science Framework (OSF) registration under a Creative Commons Attribution (CC BY 4.0) licence.

Any third-party materials (e.g., figures or direct quotations) will remain under their original copyright, but all will be properly cited. No legal, ethical, or intellectual property barriers exist that would restrict sharing or reuse of the dataset.