Plan Overview

A Data Management Plan created using DMPonline

Title: Assessing quality of care in retrospective review of maternity care

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Template: DCC Template

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Project abstract:

Clinical case review is a central tenet of clinical governance at the local institutional level (e.g., Mortality and Morbidity Meetings) and, in many jurisdictions, at a state- or country-wide level (e.g., Consultative Council on Obstetric and Paediatric Mortality and Morbidity Committee reviews – see Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM) | Safer Care Victoria). These reviews aim to identify opportunities for improvement by retrospective assessment of the clinical record; commonly this review is undertaken by a single clinician. The outcome may result in sanction of an individual or group of practitioners and, in the context of Statutory Duty of Candour legislation, lead to an apology to a family for the harm caused. Furthermore, a number of Australian and UK maternity scandals have at their core, retrospective review of pregnancies and births that have identified profound gaps in care.

Unfortunately, the judgments of the quality of care in all of these governance approaches may be influenced, to a greater or lesser extent, by the retrospective nature of the review and the impact of hindsight and outcome biases.

Bias is defined as a preference toward or away from an idea or action.

· Hindsight bias is the tendency, after an event, to retrospectively overestimate the predictability of an outcome.

· Outcome bias is the tendency to more harshly judge actions based on what transpires.

Hindsight and outcome biases have been shown to significantly influence the retrospective assessment of quality of care in Emergency Depts 1,2, in the operating theatre 3 and in general medicine 4; these biases contribute to negative judgements of the care that may be unjustified when considered prospectively from the perspective of the clinician who did not have the benefit of knowing the outcome.

The aim of this study is to assess how prevalent hindsight and outcome biases are when maternity clinicians (doctors and midwives) are asked to review the quality of care of 5 hypothetical maternity case scenarios. These scenarios will be presented with a range of outcomes (good or bad) and the study will assess how knowledge of the outcome influences the assessment of the quality of care and the apparent predictability of the outcome.

- It is expected that when presented with the same clinical details but variable outcomes, clinicians will imperceptibly judge the same care more harshly when associated with a

poor outcome (outcome bias).
- Furthermore, it is expected that clinicians asked to assess how predictable the outcome was will consider the outcome more predictable when the outcome is poor (hindsight bias).

ID: 163421

Start date: 25-11-2024

End date: 31-05-2025

Last modified: 08-11-2024

Assessing quality of care in retrospective review of maternity care

Data Collection

What data will you collect or create?

ResearchManager (RM) proprietary software will be used for this on-line survey. RM is developed in Microsoft .NET framework using ASP.Net. RM user interface contains components from Progress TelerikRadControl for ASP.NET AJAX
All RM data stored on behalf of the customer is solely the property of the PI supported by a signed Processing Agreement
This software has been chosen as it has been used in a similar study and supports randomisation of questions to participants.
Responses to an on-line survey will include:

1. 5 'tick-box' responses related to consent
2. 8 demographic questions with 'tick box' responses
3. 10 'tick-box' response to questions
4. 5 percentage figures

There will be no free text
The above will be collected from approx. 300 participants.
These data will be in megabytes and exportable to Excel, Word, pdf or SPSS format (.sav)
Data volumes will be megabytes posing no concerns for volume, access, preservation or sharing.

How will the data be collected or created?

Use testing of the survey will be completed before the survey goes live. During testing, data capture and transfer reliabilty will be tested.
Once the survey goes live, responses will be reviewed intermittently by the PI using a 2-factor authentication access with a 6-digit password

Documentation and Metadata

What documentation and metadata will accompany the data?

The full study protocol will be available, for reference, for the research team throughout the study. The final protocol will be stored in SharePoint at the Dept of Health, Victoria.
Contemporaneous notes will be taken throughout the study in a Microsoft Word document which will be stored on SharePoint

All notes and data will be anonymous.
A README.txt file will be created to track the file characteristics of the study. Specifically, this will record the name of each file and the location where it is stored.

Ethics and Legal Compliance

How will you manage any ethical issues?

ACCORD Research and Development sponsorship has been sought for this study. Approval form the Edinburgh Medical School Research Ethics Committee (EMREC) will be sought before the study commences.

The Dept of Health and Dept of Families, Fairness and Housing Human Research Ethics Committee - Victoria Australia has approved this study
The PI has an up-to-date Good Clinical Practice certificate

Consent
Consent will be taken electronically. Invitees will be provided with an electronic participant information sheet which they will be able to download and retain a copy of. Invitees will be asked to confirm their consent to participate as well as for their anonymised data to be used for analysis, presentation and publication. Participants can withdrawal from the study at any point prior to submission of data. As the data will be provided anonymously, participants will not be able to withdraw after data submission.

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

RM data stored on behalf of the customer is solely the property of the PI supported by a signed Processing Agreement

Storage and Backup

How will the data be stored and backed up during the research?

Hardware/software security
RM servers are located in secured and certified data centers in Australia.
RM datacenters are Tier 3+ and certified for ISO 9001, 14001,ISO 27001:2013, NEN7510 and ISAE 3402.
Within the secure area of our datacenters there are RM specific secured cabinets which are only accessible for authorized RM staff.

Hardware/software security
Internet connection between client and RM is securedthrough certificates from Sectigo.

Secure connection
RM has a continuous mirrored dedicated back up server on asecure location (3 months storage). The backups areencrypted (AES 256).
RM has a weekly full backup to a dedicated server on a securelocation (3 months storage). The backups are encrypted (AES 256).
RM has a daily incremental backup.
Backup restore is tested periodically.

How will you manage access and security?

RM has a role based access management system.
SSO connection based on SAML is available.
2FA is available for accounts using username and password.A 6 digit code is part of 2FA.
Authorisation to perform certain operations within theapplication are assigned to specific roles and can beenforced on application, tool, study, site and patient level.
Level of password strength can be enforced by the RMsystem administrator.
Password change policy can be enforced for a specificperiod by the RM system administrator.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All data will be retained for 5 years and saved on a password protected computer at the Dept of Health, Victoria Australia

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

Data will be deleted after 5 years

Data Sharing

How will you share the data?

The output from this study will include a peer reviewed journal publication.
Source data (all anonymised) will be available to other researchers upon request.

Are any restrictions on data sharing required?

No

Responsibilities and Resources

Who will be responsible for data management?

The PI will be responsible for all data management

What resources will you require to deliver your plan?

This research is supported by a paid sabbatical under the terms of the Australian Medical Assocation specialist contract.
No other funding has been sought
Software costs (less than A$1000) will be covered by the PI using Continuous Medical Education funding resources

Planned Research Outputs

Dissertation - "Masters of Patient Safety and Clinical Human Factors"

A 3-year on-line course - University of Edinburgh

Planned research output details

Title	DOI	Type	Release date	Access level	Repository(ies)	File size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Masters of Patient Safety and Clinical Human Facto ...		Dissertation	Unspecified	Open	None specified		None specified	None specified	No	No