

Project Information Statement (Practice Staff)

GooD4Mum: Toward reducing type 2 diabetes onset among women with previous gestational diabetes, a general practice-based trial of a quality improvement collaborative program

University of Melbourne Department of General Practice and Primary Care & Monash Centre for Health Research and Implementation

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Information for General Practice Staff (intervention group)

Invitation to participate: General Practice Staff

Thank you for your interest in participating in this research project funded by the National Health and Medical Research Council, with cash or in-kind support from Diabetes Australia and the Australian Government Department of Health, RACGP and Diabetes Victoria. Please take the time to read this information carefully before deciding whether you would like to be part of this study.

What is this research about?

GooD4Mum is a general practice quality improvement collaborative program to improve general practice workflow to optimise management of women who have had gestational diabetes mellitus (GDM). It offers free, remotely delivered training and supported quality improvement cycles for clinicians and staff to increase skills and capacity to promote behavioural change and prevent diabetes among women with past GDM.

You will be given free access to the Future Health Today digital platform that can assist GPs, practice nurses, diabetes educators and practice managers to create a recall register which also shows useful information so that your GDM patient population can be better understood, and their management optimised.

The 18-month project involves quarterly attendance of one or more staff/clinicians at online learning workshops which support your practice's completion of quality improvement Plan-Do-Study-Act (PDSA) cycles. The PDSA activities are associated with accredited Continuing Professional Development (CPD) points. You or others at your practice will also be invited to contribute to research activities to evaluate barriers and enablers and sustainability of GooD4Mum, these may include focus group sessions or interviews and some evaluative surveys. In addition, we ask that a member of your practice nominate as the Practice Champion.





What will I be asked to do?

As a participant in this study, we would like to invite you to participate in the following activities:

- Quarterly online learning workshops with staff from other participating general practices, the first of which will provide training in use of Future Health Today and review the Good4Mum Handbook. Each workshop is anticipated to last for one hour and will be followed by a 5-10 minute online evaluation survey.
- Contribute to quarterly quality improvement activities (PDSA cycles). On average, each activity is expected to take around 1-2 hours, plus an additional 30 minutes to write up the activity. Some quarters a minimum of two activities are planned, but you may elect to undertake more (and gain recognition for more CPD hours). Activity suggestions are designed to be useful and will include your practice regularly recording information ('audit data') and recalling identified patients to provide targeted diabetes prevention support.
- Study evaluation interviews or practice focus groups about your experience of the implementation of GooD4Mum in your general practice. These **optional** interviews are expected to take approximately 30 minutes or a focus group may take 30-45 minutes.
- Optional: Complete a questionnaire at two to four timepoints over the 18-month trial. The questionnaire measures how GooD4Mum has been implemented and adopted and takes around 25 minutes.

Participating practices will also enable secure sharing of approved **de-identified** electronic medical record data into the Patron data repository at The University of Melbourne. This data will allow us to evaluate the impact of Good4Mum on patient management by comparing it to data from matched control practices that are providing patients with care as usual. See <u>www.gp.unimelb.edu.au/datafordecisions</u> for more information.

Will I get anything for taking part?

All staff or clinicians who participate in an interview receive a \$30 gift voucher. In addition, each survey respondent will be entered into a draw to win a \$100 gift voucher at each timepoint when the survey is due (i.e. four chances to win if four surveys are completed). Your practice will also receive \$1000 for participating in the project.

GPs participating in online learning workshops, audit and quality improvement cycles will be credited with 3.5 accredited Continuing Professional Development (CPD) hours **per quarterly activity cycle**. Additional self-logged hours can be claimed for extra time spent on GooD4Mum activities.

Quarterly certificates of completion will be issued by the GooD4Mum Collaboratives Coordinator to all participants registered on the GooD4Mum activity form related to the PDSA quality improvement activities. Practice nurses, diabetes educators and practice managers can use these to claim CPD with their accreditation providers. The certified hours will be agreed between the individual and the GooD4Mum Collaboratives Coordinator.

What are the possible benefits?

In the next ten years more than half a million Australian women are expected to develop gestational diabetes, 60% will go on to develop type 2 diabetes within 10-20 years.[1] In 2015 the GooD4Mum pilot demonstrated great improvement in rates of blood glucose screening of women with a history of GDM. The current trial has improved on the pilot. The new GDM recall registers will streamline identification and management of women who have had GDM and weave education and quality improvement into practice workflow. There is potential for greater numbers of women at risk of developing diabetes to be proactively managed on prevention pathways. The Quality Improvement Collaborative methods encourage supportive peer-to-peer and peer-to-expert support and learning.

What are the possible risks?

We believe that there are minimal risks to participants. The GDM recall register will enable identification of women with pathology consistent with GDM but no recorded diagnosis. The GooD4Mum team will explain how this happens and provide strategies for dealing with this if it is clinically appropriate to recall these women.

It is possible that during discussion in the interactive collaborative learning workshops you or others might feel uncomfortable discussing factors about how diabetes is managed in general practice or be concerned about peer judgment. The workshops will be facilitated by experienced researchers who will be able to mitigate such risks.





It is possible that during interview or focus group discussion you might feel uncomfortable discussing factors about how diabetes is managed in general practice. You will be free to skip questions or pull out of the interview / focus group at any time. Given the small number of practices that will be participating in the study, it is possible, despite all efforts and the use of pseudonyms, that participating healthcare providers may be recognised.

Do I have to take part?

No. Participation is completely voluntary. You will be asked to sign a consent form before participating in the project. You are free to terminate your participation at any stage of the project; however, any data that has already been collected will not be able to be withdrawn. Your decision to participate will not impact on your relationship with the research group, University of Melbourne, Monash University or any other research partners.

What will happen to information about me?

Learning workshops, interviews and focus groups will be recorded and transcribed, and survey input collated, this will be used to evaluate the implementation of Good4Mum so we can know what works and what needs improvement. In all records used in our analysis your name and that of your GP clinic will be replaced by a pseudonym or code. We will have access to limited data from your practice's electronic medical record, only fields required to measure outcomes; all fields are anonymised and the data can only be accessed in a locked-down, secure server that does not allow data export. We will also access a Future Health Today report that summarises how the software has been interacted with (for example, how many times the point of care tool was activated on a given day).

As set out in the Agreement signed by your practice at commencement of the study, we will be accessing information from the Diabetes Victoria Life! program administrators on the number of referrals they have received for women with GDM relating to your practice. This information is provided in a manner so that we can link the referrals back to your practice but still retain your practice anonymity to the researchers analysing the data.

You will not be identifiable in publications resulting from this study. Digital data (including audio recordings of interviews and focus groups, and video from online learning workshops) will be stored on a secure, password protected folder at The University of Melbourne or Monash University, only accessible to ethics committee approved researchers and staff. Any non-digital data will be stored in locked filing cabinets at the Department of General Practice and Primary Care, University of Melbourne or the Monash Centre for Health Research and Implementation. Data collected may also be used in future projects that are closely related to this project. All data generated during this project will be stored securely for fifteen years from the time of publication arising from use of the data. Data will then be disposed of in keeping with University policy.

Will I hear about the results of this project?

If you would like to be sent information about results of the study, please indicate on the consent form, we will provide a summary of the results at the conclusion of the study as well as a copy of publications that result from the research. Results will also be presented at conferences and published on the GooD4Mum and/or Data for Decisions websites.

Where can I get further information?

If you would like more information about the project, please contact the research team: Email: <u>G4M-project@unimelb.edu.au</u> or phone (03) 8344 4361 Web: www.mchri.org.au/good4mum

Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne (ID 24863). If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project.





* GooD4Mum Chief Investigators and research staff:

- Professor Douglas Boyle, Dr Rachel Canaway, Dr Rochelle Sleaby, Wendy Shepherdley and Christine Chidgey, Department of General Practice and Primary Care, The University of Melbourne;
- Professor Helena Teede and Dr Samantha Olenski-Kozica, Monash Centre for Health Research Implementation, Monash University, and Dr Siew Lim, Health Systems and Equity, Eastern Health Clinical School, Monash University;
- Professor Vincent Versace, Deakin Rural Health, Deakin University;
- Associate Professor Sharleen O'Reilly, University College Dublin (and Deakin University).
- Professor Jane Speight and Dr Amelia Lake, Australian Centre for Behavioural Research in Diabetes;
- Professor Mark Morgan, Bond University;
- Professor Emily Callander, University Technology Sydney;
- Dr Dale Ford, GP.

1. AIHW. Diabetes: Australian facts - Gestational Diabetes: Australian Institute for Health and Welfare; 2023 [cited 2023 31 August]. Available from: https://www.aihw.gov.au/reports/diabetes/contents/total-diabetes/gestational-diabetes.



