



Explanatory Statement

Title	Clinical Insights for Use in General practice: Pilot
Project Sponsor	Eastern Melbourne Primary Health Network (EMPHN)
Chief Investigator	Prof. Denise O'Connor
Other investigators	Dr Matthew Quigley, Dr Kealan Pugsley, Prof Ilana Ackerman, A/Prof Alexandra Gorelik, Dr Kitty Yu, A/Prof Noah Ivers, Mr Jamie Supple
Project ID	45818

Part 1.

1. About this research project

This research project is a collaboration between researchers at Monash University and the Eastern Melbourne Primary Health Network (EMPHN). It is a pilot study that uses the clinical data from clinical information systems (e.g., Best Practice, Medical Director, ZedMed). This data is uploaded by general practices in the EMPHN catchment to the Population Level Analysis and Reporting (POLAR) database. The data will be used to generate feedback reports for two topics:

1. Chronic Kidney Disease (CKD) screening in people at high risk of CKD
2. Secondary prevention of cardiovascular disease (CVD) in people who have experienced an ischaemic stroke or a Transient Ischaemic Attack (TIA)

The concept is to provide feedback using routinely collected POLAR data for reflection. GPs can apply this feedback in ways that they find useful. Some GPs may want to review their feedback to see how they compare with their peers. Others might wish to use it to inform Quality Improvement (QI) activities. This research project will investigate the feasibility, acceptability, and user experience of receiving feedback reports for general practices within the EMPHN catchment.

Privately (GP) owned general practices in the EMPHN catchment can choose to take part in this pilot study. The GP owner of these practices will be invited to receive their own individual feedback report. They will also be invited to take part in evaluation activities about the feedback report.

Other GPs working in participating practices can choose to be sent a feedback report. They can also take part in evaluation activities about the feedback report.

Other staff (including a Practice Manager and a Practice Nurse) who work in participating practices can choose to take part in evaluation activities. These activities will explore the impact of the feedback reports on clinical practice workflow and systems.

2. Eligibility criteria

2.1. Eligible practices

General practices are eligible to participate in the Clinical Insights Program pilot study if they are:

1. Privately (GP) owned general practices within the EMPHN catchment.
2. Currently using POLAR database.
3. Seeing adult patients with diabetes/hypertension and/or patients who have experienced a stroke or TIA.
4. Not an urgent care clinic.

3. What does my participation involve?

What you are being asked to do will depend on your role in the general practice.

Knowing what is involved will help you decide if you want to take part in the research. Participation in this research is voluntary. You do not have to participate if you do not want to.

Please carefully read the section below. Ask questions about anything that you don't understand or want to know more about. Contact details are provided at the end of this document.

You and your practice are invited to take part in this research project, Clinical Insights for use in general practice: Pilot. You have been invited because you are a practising GP who owns a general practice in the EMPHN catchment area and have submitted an expression of interest for this pilot study.

This pilot study will use the clinical data from your clinical management system that your practice routinely uploads to POLAR. This data will be used to generate individual feedback reports for the clinical topics (CKD screening in people at high risk of CKD and/or secondary prevention of CVD after stroke/TIA).

(a) Providing practice-level consent

For your practice to take part in this pilot study, you will need to give permission for Outcome Health (the POLAR data custodians) to use your POLAR practice data. This data will be used to generate a feedback report for 1 or 2 of the clinical topics. If you choose to receive feedback for one topic in your practice, you will be asked to nominate a preference. This preference will also apply to any other GPs participating at your practice.

We will notify EMPHN of practice-level consent to participate in the pilot and share your email address with them. Your email address will be stored on a secure EMPHN Microsoft Teams shared drive. EMPHN will also use your email address to send you a practice onboarding kit. This includes general information about the study, and templates that may be helpful for providing information and assisting in recruiting other staff within your practice. If you wish, you can nominate a staff member to be the practice liaison for this pilot study. If you choose to do this, the practice liaison's email address will also be shared with EMPHN, and they will receive the onboarding kit as well.

Other GPs working in your practice will be invited to take part in the pilot study by receiving an individual feedback report and participating in Monash-led evaluation activities. Other practice staff who are not GPs (including a Practice Manager and one Practice Nurse) will be invited to take part in the evaluation activities to help determine if there are impacts on clinical practice workflows and systems.

The participation (or non-participation) of other GPs and practice staff is completely voluntary. They must remain free to choose whether to take part or not. If your practice participates in this research, the Monash University team will reimburse your practice \$1,000 to assist with the increased administrative time spent on pilot-related activities at the practice level. Your practice will need to invoice Monash University to receive this reimbursement, with full details provided in the onboarding kit.

(b) Feedback report and evaluation

You will also be asked to agree to receive an individual feedback report as a practising GP, and to participate individually in the evaluation of the pilot. This will involve a 15-minute electronic survey and a 45-minute online interview with a member of the research team.

You will be asked to provide personal details, including the following:

- Full name
- Nominated email address for delivery of the feedback report
- Practice name and address

- Clinical Information System Login
- RACGP registration number (to be eligible for claiming Continuing Professional Development (CPD) hours)*
- POLAR Login

* You will have the option to share your personal information with EMPHN so that you can receive assistance claiming CPD hours for taking part in this study and completing a mini-audit.

These details will be used to generate and send you your individual feedback report. Outcome Health (POLAR data custodians) will send this report to you, and these details will be shared with Outcome Health through a secure encrypted platform. The email you provide is where your individual feedback report will be sent.

After receiving your report, the Monash University research team will use your email address to contact you about the evaluation activities. They will provide you with a link to a brief (15-minute) online survey and arrange a 45-minute online semi-structured interview. The interview will be conducted by a member of the research team over Zoom at times that suit you, including after hours if needed. The survey and interview will explore how acceptable and feasible you found the feedback reports, as well as your experience as a feedback user.

The survey will also ask you for current demographic information (age bracket, gender, geographic location (metropolitan/regional/rural), current clinical role and years practising as a GP). This information will only be shared with people outside the research team in a de-identified manner. Please see section 10 for further details on how your information will be handled.

Additionally, Outcome Health will provide a summary of your POLAR user data (e.g., access and time on page) with the research team. This information provides insights regarding the feasibility and acceptability of POLAR access, as embedded in the Clinical Insights report.

You will be asked whether you would like to receive an email with the findings of this study and whether you consent to EMPHN contacting you about future research projects.

The Monash University team will provide you with a \$155 e-gift card as a token of appreciation for completing the 15-minute survey and the 45-minute interview. You will receive this e-gift card after the completion of the interview.

Consent

If you decide you want to take part in the research project, you will be asked to sign the online consent form. By signing it, you are telling us that you:

- Have read this Explanatory Statement.
- Understand what you have read.
- Consent to your practice taking part in the research project.
- Consent to the use of data uploaded from your clinical management system to POLAR for the purpose of generating feedback reports for individual GPs in your practice who consent to receive a feedback report.
- Have indicated whether you wish your practice to receive feedback for one or two clinical topics.
- Have indicated a topic preference if you have chosen for the practice to receive feedback for one topic.
- Consent to the use of your personal information as described.
- Consent to receive an individual feedback report as a GP based on based on the POLAR data from the clinical management system used at your practice.
- Consent to Outcome Health providing a summary of your POLAR user data (e.g., access and time on page) with the research team.
- Consent to participate in the pilot study evaluation as described.
- Have received consent to provide the email address of the practice liaison, if you choose this option.

If you agree to participate in the study, a member of the research team will send you an electronic copy of this Explanatory Statement, along with your completed consent form. You may also download an electronic copy of this Explanatory Statement to keep if you wish.

4. Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be asked to sign the online Consent Form.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with EMPHN or the researchers.

5. What are the possible benefits of taking part?

By participating, you will provide invaluable clinical expertise to help determine the acceptability, feasibility, and user experience of receiving feedback materials in general practice. Your participation can also help guide the development of future

feedback materials to optimise their usefulness for GPs and other staff at practices in the EMPHN catchment area.

6. What are the possible risks and disadvantages of taking part?

By participating in this research, you would be committing to participate in the 15-minute survey and the 45-minute interview, as described in Section 3 (above).

As you will be commenting on prototypes of feedback tools, there are minimal risks and disadvantages to taking part, other than the time spent participating.

7. What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw, you will be asked to complete and sign an electronic 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional information from you, although information already collected will be retained to ensure that the results of the research project can be measured properly. You should be aware that data collected up to the time you withdraw will form part of the research project results.

Practices that withdraw before invoicing and receiving reimbursement towards pilot-related administrative time associated with participation will not be paid.

Individuals who withdraw before completing both evaluation activities (the 15-minute survey and the 45-minute interview) will not receive the \$155 e-gift card.

8. Could this research project be stopped unexpectedly?

No, there are no foreseeable reasons for this project to be stopped unexpectedly.

9. What happens when the research project ends?

Findings from the overall research project are expected to be made available through academic publications. Information provided by participants will be reported in a deidentified manner so that it cannot be attributed to individual participants. Participants can inform the research team on the consent form if they wish to be notified of any publications arising from this research and will receive copies when they are available.

Part 2.

How is the research project being conducted?

10. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using personal information about you for the purposes of the research project, as outlined in section 3.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the information you provide cannot be directly attributed to you.

Survey data, POLAR user data, transcripts, recordings, and all other study data that can identify you will be treated as confidential and securely stored by Monash University, only accessible to members of the research team. All study data will be retained in digital format for a period of 5 years before they are irreversibly deleted. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

11. Complaints and compensation

It is not anticipated that any risk of adverse events will occur because of this project. However, if you experience any distress or psychological injury because of participating, you should contact the research team as soon as possible. You will be assisted with arranging appropriate support.

12. Who is organising and funding the research?

This research project is being funded by the Commonwealth of Australia Department of Health and Aged Care and conducted jointly by Monash University researchers and EMPHN. No member of the research team will receive a personal financial benefit from your involvement in this research, other than their ordinary wages.

13. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Monash University HREC. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

14. Further information and who to contact

The person you may need to contact will depend on the nature of your query.

Research contact person

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Reviewing HREC approving this research

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