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Appendix 1

This appendix was part of the submitted manuscript and has been peer reviewed. It is posted as supplied by the authors.

Appendix to: Crossland L, Upham SJ, Janamian T, et al. Trial of the Primary Care Practice Improvement Tool: building organisational performance in Australian general practice and primary health care. *Med J Aust* 2016; 204 (7 Suppl): S15-S21. doi: 10.5694/mja16.00121.

Appendix 1 Primary Care Improvement Tool (PC-PIT): Protocol for the trial of the PC-PIT to determine validity and use of the tool in practice

Aims of the trial

This is Phase 2 of study to develop pilot and now trial the Primary Care Practice Improvement Tool (PC-PIT) in a range of primary health care settings, practice sizes and business models in Australia. A validation of the PC-PIT will be undertaken with 20 participating general practices nationwide.

Study design

General practices in Queensland urban, regional and rural areas representing a range of practice sizes (< 2; 2 < 5; 5 < 10; 10+ full time equivalent GPs) and business models will be sampled from a group of volunteering general practices responding to information and expressions of interest advertisements. A diagram of the full trial process is provided in Figure 3, at the end of the protocol.

Stage 1: Practice managers in 20 general practices will be supplied with a link to the online PC-PIT and a guide for using the PC-PIT in practice. They will be given one week to become familiar with the PC-PIT and the process of the trial. Practices managers will then provide the link to the online PC-PIT to all practice staff. Staff will be given 10 working days to complete it.

Stage 2: After the completion of the PC-PIT, onsite Independent Practice Visits will be conducted by two researchers; one of whom is independent to the study team. The researchers will use the following methods to determine how the practice meets each element on the PC-PIT:

(i) Rating the 13 elements of the PC-PIT against objective indicators using an Evidence Assessment Form. The two researchers will independently complete an Evidence Assessment Form for each practice by reviewing documented practice evidence which will include but not limited to: Policy and Procedures Manuals; Human Resource Manuals; Practice Communication Books and records; complaints documentation; practice meeting minutes; patient population data reports; clinical data management systems.

(ii) Identifying and reviewing information such as the existence of quality improvement committees; scheduled meetings with the focus of discussing quality improvement; meeting minutes and other evidence of quality improvement work within the practice.

(iii) Completing semi-structured interviews with practice manager s and practice nurses (as available) in order to document the background (including previous professional training) and the explore the personal experiences of practice managers in undertaking performance improvement and QI, including perceived barriers and enablers to this. The interviews will include details of the most recent internal practice QI activities; improvements identified and

achieved. It will also explore practice involvement in external QI activities and programs, such as participation in accreditation; the Collaboratives and programs and activities run by Medicare Locals.

Stage 3: The completed online PC-PIT surveys will be scored using a 'whole of practice' aggregated rating for each of the PC-PIT elements. Where the practice is large enough (that is, ≥11 full-time practice staff); the researcher will also provide aggregated scores by employee group (for example: contracted versus full-time staff; or by staff groups, namely administration; clinical and allied health staff).

Results from the aggregated staff completed online PC-PIT surveys and the ratings from the Independent Practice Visit will be provided to each of the practice in a short combined PC-PIT Report. The report will assist practices to identify an area for improvement and strategies to achieve it. Practices will continue with their Plan-Do-Study-Act cycle (PDSA) using their individual PC-PIT reports and feedback from the independent visits.

As part of the Independent Practice Visit, semi-structured interviews will be conducted with practice managers and practice nurses (where available) in order to explore their perceptions of their role in improving practice performance; the resources they require to support this role; the most appropriate ways they can be supported to undertake quality improvement; barriers and enablers to internal practice led quality improvement (such as perceptions of the training and support needed in conjunction with the PC-PIT and practice incentives (both financial and non-financial) to undertake quality improvement.

Changes to the PC-PIT: After the comparison analysis of all qualitative and questionnaire data, the researcher will then make any changes required to the online PC-PIT.

Study population

General practices will be drawn from the range of self-selecting general practices and primary health care clinics in Australia. These will be practices that attended the webinar and who responded to expression of interest distributed via the study partner organisations.

Total numbers and number within any subgroups

Each practice will include the subgroups of: practice management; administration and reception; medical; allied health. Exact numbers cannot be determined.

Eligibility criteria

Inclusion/exclusion criteria

All practices registering interest through the Expression of Interest (EOI) form will be included as participants in the trial; to a total of 20 practices.

Study Outcomes

Primary outcomes

Validation of the PC-PIT in private general practice including the identification and understanding of the key factors contributing to how the PC-PIT is scored and used in small (< 10 full time equivalent staff) and large (≥ 10 full time equivalent staff) practices.

The training and support needs identified by Practice Managers in order to undertake quality improvement, using the PC-PIT.

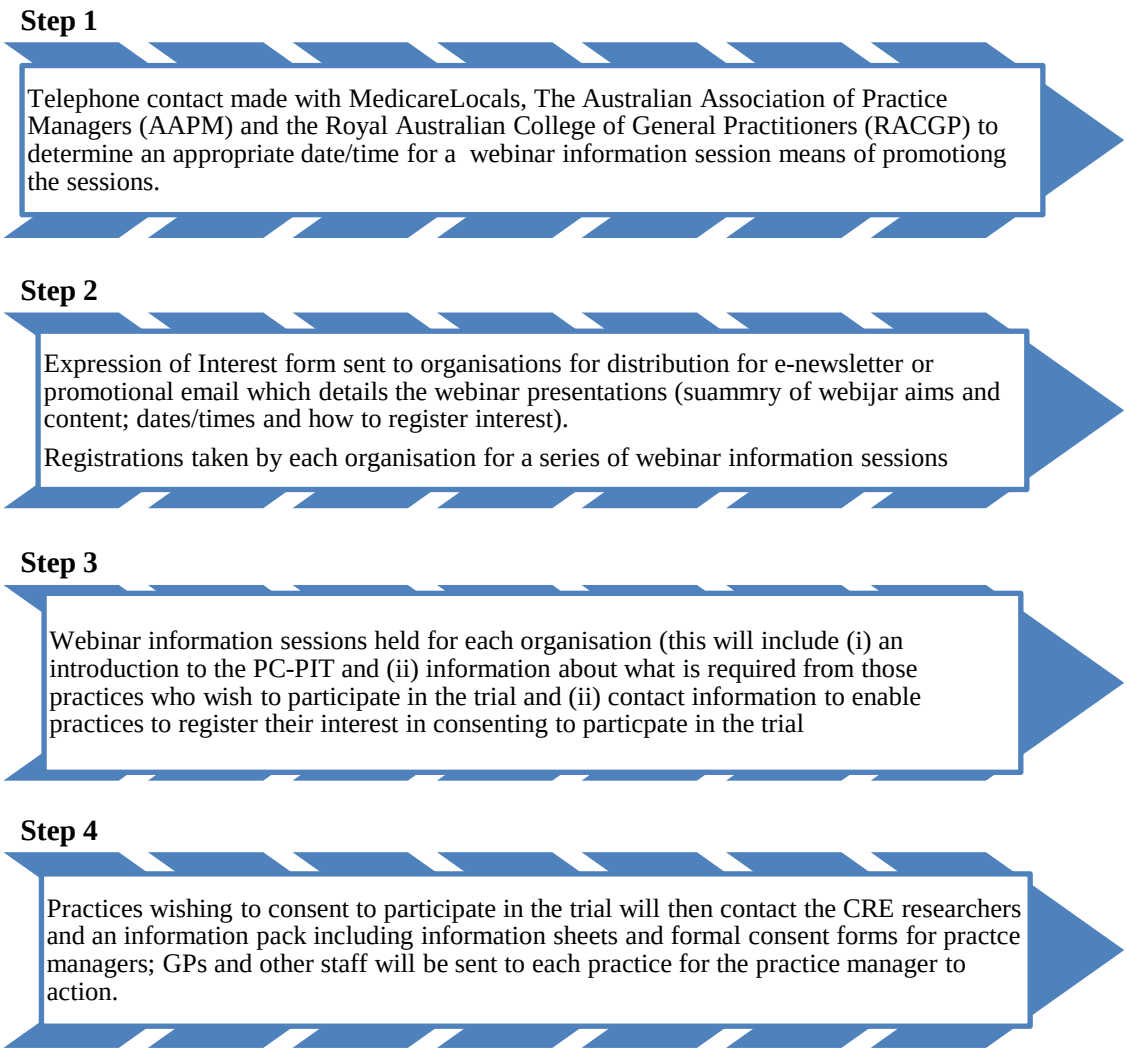
Study procedures

Recruitment of participants

Recruitment of practices will be undertaken through a national EOI which will be developed by the researchers .The researchers will forward the EOI to the following organisations for inclusion in their publications, e-newsletters and notifications: the Australian Association of General Practice (AAPM); the rural workforce agencies; the Royal Australian College of General Practitioners (RACGP) and the Medicare Locals. The EOI will include details about how the practice manager and/or principle GP can register interest to participate in the trial. As many practices as possible will be invited to trial the PC-PIT. However, the researchers will work with 20 practices to conduct the validation process which will include the independent practice visits.

Once 20 practices have been selected, an information pack will be sent to them which will include an introduction to the trial and its aims and purpose; the role of practice managers in the trial; summary information sheets and consent forms for all practice staff. Practices will be followed up via telephone and email to ensure that written consent forms are signed and returned.

Figure 1 Recruitment Process



Describe exactly what will happen once participants have enrolled in the study

Practice managers will be provided with an online guide to using the PC-PIT in practice. This session will introduce Practice managers to PC-PIT form; its use as a quality improvement tool in general practice; interpreting the automatically generated practice report and score and how it should be used in concert with the RACGP Plan-Do-Study-Act (PDSA) cycle to plan and implement an improvement. It will also provide information on, and links to other resources including guides for coaching in quality improvement; a leadership capability measure and existing resources related to quality improvement and initiating change in health care.

Practice managers will be given access to the online PC-PIT and will then make this available to all practice staff. Staff in each practice will be given up to 10 working days to complete the online PC-

PIT. Practice staff will confidentially rate each of the 13 elements against a "best practice" definition of each element and a 1-5 sliding Likert slide; where 1 indicates the staff members perceives the practice does not meet the best practice definition of the element, through to 5 which indicates the staff member perceives the practice entirely meets the best practice definition of the element.

After the completion of the PC-PIT, the independent onsite practice visits will be conducted by two researchers, one of whom is independent to the study team. The researchers will use the following methods to determine how the practice meets each element on the PC-PIT:

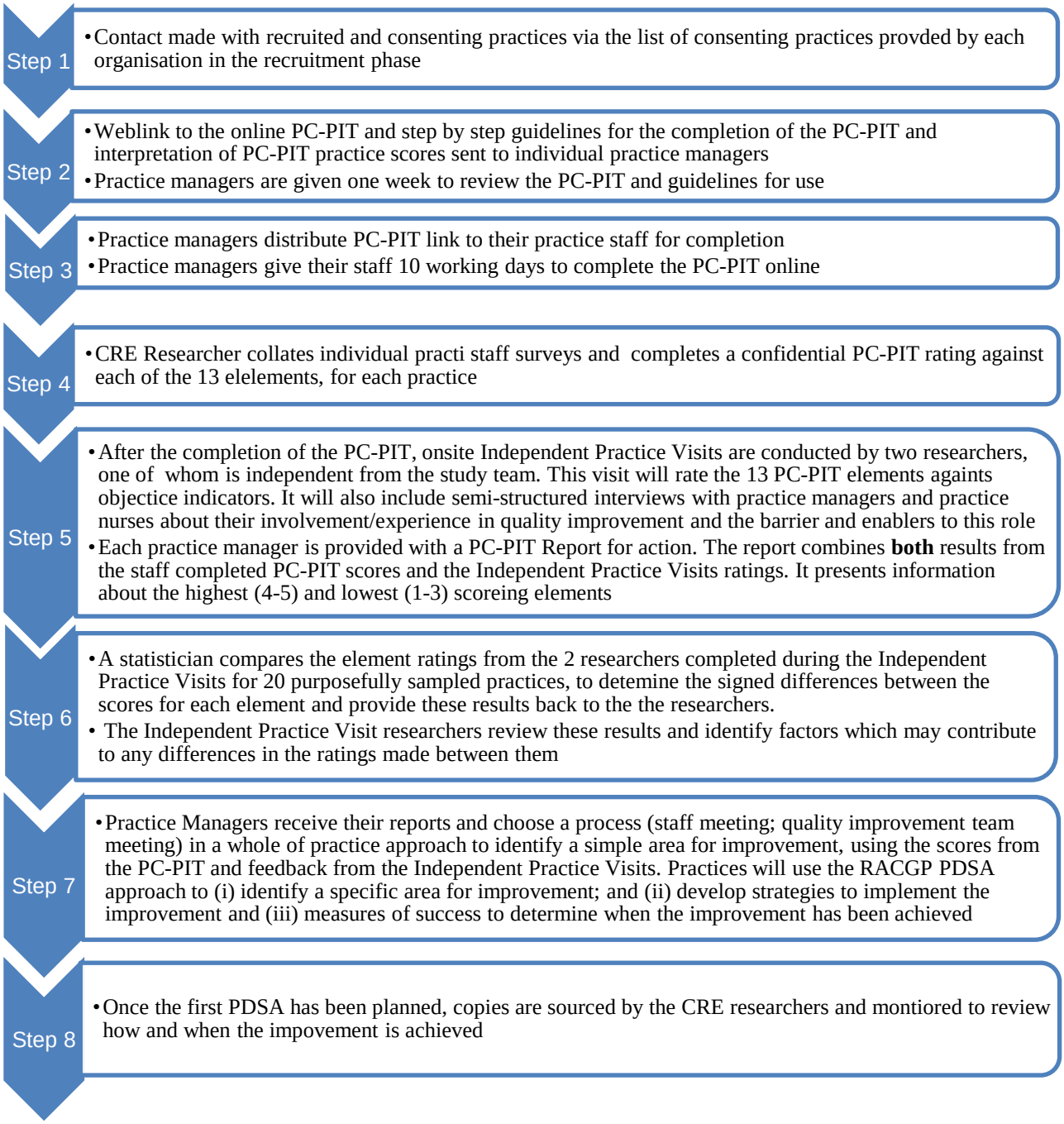
> Independent review of the PC-PIT elements by each researcher against defined objective indicators, in order to complete an overall ranking for each of the 13 PC-PIT elements, for each practice. This will be done using all relevant documentation and information such as protocols; guidelines; scheduled meetings (agendas and minutes) with the focus on quality improvement; other evidence of quality improvement work.

> Semi-structured interviews with practice manager s and practice nurses (as available) will aim to document the background (including previous professional training) and the personal experiences of practice managers in undertaking performance improvement and QI and the barriers and enablers to this. Interviews with practice managers and practice nurses will explore involvement o in QI activities, both internal and external to the practice. This will include internal practice QI activities (such as the use of Plan Do Study Act approaches) and improvements identified and achieved as well as involvement in (and experiences of) external QI activities and programs, such as participation in accreditation; the Collaboratives and/or programs and activities facilitated by Medicare Locals.

After the Independent Practice Visit has been conducted, the principal researcher will develop a confidential scored report for each practice, presenting the aggregated rankings from the PC-PIT staff surveys and the PC-PIT rankings from the Independent Practice Visit. This report will then be sent back to each practice manager for action. Practice managers will use these reports to facilitate discussions with staff in order to identify a key area for improvement, a strategy to achieve the improvement, a means of measuring when the improvement has been made and a timeframe for achieving the improvement. This will achieved by using the RACGP Plan Do Study Act (PDSA) approach. Practices will then undertake 1-2 PDSA cycles (using the RACGP Quality Improvement and Continuing Professional Development PDSA Form). Practice managers will act as the leaders and facilitators of the identified improvement. They will be responsible for encouraging and supporting staff to implement the improvement, using the PDSA cycles. PDSA cycles will be undertaken until the improvement has been achieved, as demonstrated by the key performance measures on the PDSA

form. It is anticipated that where simple areas for improvement are chosen, practices will be able to achieve these within one PDSA cycle; the more complicated the area for improvement (such as requiring multiple strategies and longer term out measures), the more likely practices will complete up to 2 PDSA cycles in order to achieve the improvement. Copies of the completed PDSAs will be sourced by the principal CRE researcher and reviewed and monitored to identify the specific improvement chosen, how and when it is achieved.

Figure 2 Trial Steps



Data collection and analysis

Measurement tools to be used

The Primary Care Practice Improvement Tool (PC-PIT)
PC-PIT Independent Practice Visit Evidence Assessment Form
Semi-structured interview proforma

How data will be collected

PC-PIT Independent Practice Visit:

- Twenty (20) consenting practices will be provided with the online PC-PIT link and all staff given one week to complete the tool.
- Completed PC-PITs from participating practices will be accessed and downloaded by the researcher online through the Qualtrics website and analysed.
- Onsite Independent Practice Visits will be conducted by two researchers, one of whom is independent to the study team. The researchers will use the following methods to determine how the practice meets each element on the PC-PIT:
  (i) Rate each elements of the PC-PIT against objective indictors.
  (ii) Review information and materials such as the existence and use of protocols; guidelines; scheduled meetings with the focus of discussing quality improvement; meeting minutes and other evidence of quality improvement work.
  (iii) Conduct semi-structured interviews with practice managers and practice nurses, as available.

When data collection will occur

Individual PC-PIT tools will be accessed and downloaded by the researcher.
Independent Practice Visits will be conducted once each practice has as staff completed the completed the PC-PIT within the 10 working days.

Procedures for rigour/validity

- Quantitative
  Statisticians have assisted in developing an appropriate trial protocol. Statisticians will assist in analysing Independent Practice Visit data recorded by each of the 2 researchers and assess the inter-rater reliability in relation to the PC-PIT objective indicators. A weighted Kappa will also be performed.

After inter-rater reliability has been completed for the 20 practices, the two researchers will review the results in order to identify any discrepancies. Where discrepancies in the ratings have occurred, they will compare their original ratings along with the evidence cited for the PC-PIT element in question in order to and identify and document the reason for the discrepancies.

> Qualitative

Well documented strategies to enhance trustworthiness and rigour are incorporated in the study design. [1, 2] The study will include primary care services from a range of business models, geographic locations and QI environments, i.e. both extensive and limited previous experience of, and involvement in, general practice based QI activities (both internal and external activities).

Data will be gathered from a variety of sources which will include interviews with practice managers and practice nurses, background materials and documented evidence which includes but is not limited to: meeting minutes; policy and procedure manuals and communications books. These will be cited independently by both the researchers undertaking the Independent Practice Visits. The Evidence Based Assessment Forms will also be completed independently by 2 researchers, one of whom will be independent from the study team. This will allow the triangulation of data sources and the review and also confirmation of findings. Following the interviews, participants will be provided with the opportunity to review and edit their interview responses. The CRE principal researcher in this study is an experienced interviewer and qualitative researcher, with over 17 years' experience in primary care research in Australia.

Data monitoring

Practices that drop out/discontinuation of data collection?

Practices who decide not to complete the PC-PIT pilot and take part in the feedback will be invited to undertake exit interviews. These interviews will gather basic information about the reasons why the practice chose not to continue with the PC-PIT trial. The key focus will be on difficulties in understanding, completing and/or using the online PC-PIT form and those issues to do with the role and expectations of the Practice Managers in facilitating the tool. Replacement practices of similar size in Queensland will be identified and invited to participate.

Statistical considerations and data analysis

PC-PIT Reports will be prepared using Qualtrics survey management program and Microsoft Excel to process data.

Interview recordings will be transcribed and analysed using inductive thematic approach, aided by NVivo (QSR software).

Independent Practice Visits will be undertaken with 20 practices in order to undertake the inter-rater reliability. Independent Practice Visit ratings for each element will be into Microsoft Excel spreadsheet. A statistician will compare the scoring between the 2 researchers undertaking Independent Practice Visit, for each of the 13 PC-PIT elements and determine where the rankings are the same between both assessors; where they differ by one point; by two points and so on.
A Kappa with 95% confidence intervals (CI) will be conducted. Concordance will be determined by a presentation of the distribution of signed differences (that is, rater one scores compared with rater two scores) for each of the 13 elements and also between each of the 20 practices.
Identified differences in ratings between the two researchers will be identified and discussed between the 2 researchers, in order to explore why these differences may have occurred.

Ethical considerations

Ethical clearance has been granted by the University of Queensland ethics committee.

Outcomes and significance

The 3 significant outcomes for this phase are:

(i) The trial of a tool to improve the quality, sustainability and integration of primary health care in Australia.

(ii) The identification and understanding of key factors influencing how the PC-PIT is used in practice and the role and validation of the Independent Practice Visit in the PC-PIT process.

(iii) Recommendations for the development of additional resources and supports, as identified by practice managers, to facilitate their role as QI leaders in primary care.

References

1. Patton, MQ. Qualitative Research and Evaluation Methods. 3rd edition, Sage Publications, USA 2002.
2. Golafshani, N. Understanding reliability and validity in qualitative research. *The Qualitative Report* 2003; 8:597-607.

Figure 3 Flow diagram of trial process