Author’s response to reviews

Title: Prescribing Data in General Practice Demonstration (PDGPD) Project - A cluster randomised controlled trial of a quality improvement intervention to achieve better prescribing for chronic heart failure and hypertension

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Abstract

**Background:** Research literature consistently documents that scientifically based therapeutic recommendations are not always followed in the hospital or in the primary care setting. Currently, there is evidence that some general practitioners in Australia are not prescribing appropriately for patients diagnosed with 1) hypertension (HT) and 2) chronic heart failure (CHF). The objectives of this study were to improve general practitioner’s drug treatment management of these patients through feedback on their own prescribing and small group discussions with peers and a trained group facilitator. The impact evaluation includes quantitative assessment of prescribing changes at 6, 9, 12 and 18 months after the intervention.

**Methods:** A pragmatic multi site cluster RCT began recruiting practices in October 2009 to evaluate the effects of a multi-faceted quality improvement (QI) intervention on prescribing practice among Australian general practitioners (GP) in relation to patients with CHF and HT. General practices were recruited nationally through General Practice Networks across Australia. Participating practices were randomly allocated to one of three groups: two groups received the QI intervention (the prescribing indicator feedback reports and small group discussion) with each group undertaking the clinical topics (CHF and HT) in reverse order to the other. The third group was waitlisted to receive the intervention 6 months later and acted as a “control” for the other two groups.

De-identified data on practice, doctor and patient characteristics and their treatment for CHF and HT are extracted at six-monthly intervals before and after the intervention. Post-test comparisons will be conducted between the intervention and control arms using intention to treat analysis and models that account for clustering of practices in a Network and clustering of patients within practices and GPs.

**Discussion:** This paper describes the study protocol for a project that will contribute to the development of acceptable and sustainable methods to promote QI activities.
within routine general practice, enhance prescribing practices and improve patient outcomes in the context of CHF and HT. Trial registration: Australian New Zealand Clinical Trials Registry (ANZCTR), Trial # 320870.
Background

Pharmacological management of hypertension (HT) reduces cardiac events, stroke, hospitalisations, health care costs and improves quality of life for hypertensive patients (HT).[1, 2] Appropriate treatment of chronic heart failure (CHF) with ACE inhibitors, angiotensin II receptor antagonists, beta-blockers and diuretics have also shown benefits in terms of survival and averted hospitalisations, irrespective of the underlying cause.[3, 4]

Australian [5, 6] and overseas studies report that treatment of HT [7-15] and heart failure [16-19] are not well aligned with evidence-based guidelines. For example, in Australia, fewer than 50 percent of heart failure patients admitted to any of three hospitals in Tasmania were being treated with target doses of the recommended drugs. [18] Among Australian patients attending general practice, under-prescribing for heart failure was found both in terms of the number receiving the recommended drugs and the dosage levels. [20, 21] A national Australian survey reported the prevalence of untreated HT at 15.2% [13] and four consecutive GP audits of self-reported prescribing practices concluded that there was room for improvement in the management of hypertensive patients with co-morbidities. [14]

The consequences of suboptimal care for these conditions include increased hospitalisation, higher mortality, [22, 23] greater symptom severity [23] and increased costs to the health care system. [22, 24-26] It is clear that best practice guidelines alone cannot secure improvements in practice.[5, 27-29]

Educational interventions and quality improvement (QI) activities can improve the quality of prescribing in general practice settings. [5, 30]. Multi-faceted interventions, particularly those involving interactive educational sessions for healthcare providers, and/or patient education are reported to be more effective than passive interventions.[10, 31-37] Multi-faceted interventions have shown modest
improvements in patient outcomes such as the proportion of patients meeting blood pressure targets [8, 23] and also changes in prescribing patterns such as the proportion CHF patients receiving a beta blocker or taking target doses of ACE inhibitors.[38]

In evaluating these types of complex QI interventions, pragmatic randomised controlled trials (RCTs) are emerging as a way of bridging the gap between traditional RCTs which have a good internal validity and observational studies, which have good external validity. [39-41]

The Prescribing Data in General Practice Demonstration (PDGPD) project uses a multifaceted complex intervention aimed to improve GP prescribing behaviour for patients with HT and CHF in alignment with clinical practice guidelines. This paper provides details of the intervention components and protocol, and methods and measurements used to evaluate the impact of the quality improvement initiative.

The project is a partnership between NPS: Better Choices, Better Health (formerly National Prescribing Service), an independent, evidence-based organisation delivering continuing education for health professionals to enable better decisions about medicines and medical tests, [42] and the Australian General Practice Network (AGPN), the body representing a network of 111 local general practice networks (henceforth referred to as Networks) which covers 90% of registered GPs in the country.[43]

The project governance included several external and internal groups that oversee various aspects of the project including the evaluation and the implementation. (Appendix 1).
Methods/Design

Aims of the intervention

The aim of the PDGPD intervention is to improve prescribing behaviour and clinical outcomes for patients with HT and CHF. These topics were chosen due to the existing gap between evidence and actual practice and the potential benefits resulting from changes in the management of patients. A list of terms used in clinical practice software to describe these two diagnoses can be found in Appendix 2. The quality improvement activity allows GPs to use their own prescribing data for ongoing review of patient management and for peer comparison.

The intervention

The intervention included facilitated discussion about these conditions within general practices recruited across Australia using feedback about their patient management extracted from practice clinical software. This multi-faceted intervention was designed to be implemented from June 2009 with follow-up until December 2011. We use a multifaceted intervention based upon recognised quality improvement strategies that are implemented over a 12 month time frame. The intervention in this project consisted of a series of quality improvement activities (Figure 1). Data cleaning and recording of relevant clinical information by practices was actively encouraged (step 1) to enable extraction of reliable information from relevant database fields. An initial facilitated group discussion (clinical meeting) was held by GPs within the practice with a trained project facilitator on treatment of CHF and HT (step 2). A data extraction and report tool supplied immediate feedback from the practice clinical software system regarding each GP’s own prescribing, as well as the results for the whole practice and the local GP network for peer comparisons for each clinical meeting.

Identification of patients suitable for clinical review occurred after the initial clinical meeting (step 3). A follow-up facilitated peer group clinical meeting was held around
two to three months after the first meeting (step 4) to check progress on the patients prioritised for review of therapy and any changes to the prescribing data feedback.

**Figure 1. Quality improvement intervention process**

**Preliminary Steps**
*Introductory meeting* with practice staff (practice managers and practice nurses and GPs in some instances) to fully explain the project, install and demonstrate the data extraction and reporting tool.

**Step 1. Improve data quality**
With the practice staff, examine data quality reports and baseline results and identify inactive or deceased patients. Find unrecorded cases and ensure conditions and BPs are coded in correct fields and current medication lists are accurate. Update medical records where necessary.

**Step 2. Assess data and plan actions**
At *initial clinical meeting*, review current clinical indicator results and compare with peers. Identify patients who will most benefit from review. Agree on number of patients to review and strategies for change.

**Step 3. Implement changes**
Practice to implement agreed strategies for change over the agreed time period between clinical meetings. Review patients identified by indicators reports and adjust treatment where appropriate.

**Step 4. Assess data and progress**
At the *follow-up clinical meeting*, assess current clinical indicator results progress against agreed planned compare with local and national aggregate clinical indicator results. Agree on next steps: additional patients to review and strategies for change.

**Step 5. Implement changes**
Practice to implement agreed strategies for change over the agreed time period. Review patients identified by indicators reports and adjust treatment where appropriate.

**Step 6. Continue the quality improvement activity**
Assess current data, reflect on progress and plan next quality improvement cycle.
**Aim of the evaluation**

The aim of the evaluation of the PDGPD project is to estimate the impact of the quality improvement intervention on prescribing practice and to measure short term changes in blood pressure in patients with HT and CHF. The evaluation uses a pragmatic randomised cluster controlled trial design.

**Study Groups and Randomisation**

Practices agreeing to participate were registered and randomly allocated automatically into one of the three study groups (either into one of the two intervention groups or into the wait-control group) using computer generated random numbers. Block randomisation was used to enable balanced representation of practices in each of the Networks. The randomisation determined the sequence of exposure to the intervention as follows (see Figure 2):

- **Group 1** received the intervention for the CHF topic in the first six months and the HT topic in the next six months. In the first six months, this group also acts as the topic control group for group 2.
- **Group 2** received the intervention for the HT topic in the first six months and the CHF in the next six months and also acts as topic control group for group 1 in the first six months.
- **Group 3** is a wait-control for groups 1 and 2 in the first six months and did not receive any intervention in the first six months. This group received the intervention after six months and implemented the 2 topics sequentially – the order of topics was left up to the practice involved to choose. This group acts as ‘true’ control for groups 1 and 2 in the first six months.

As it is well recognised with educational interventions delivered at the practice level,[40, 44] it was not feasible to blind participating general practitioners and
practices to the intervention because they had to be trained on the software installation and needed to be notified of their topic allocation in order to carry out the required quality improvement activity.

The expected time frame for the research was 2 years, including the recruitment and training time and 18 months of follow-up; data collection for baseline and six months are currently being analysed.
Figure 2. Evaluation using a cluster randomised controlled design. Group allocation and timeframes for data extraction and clinical meetings

General Practice Networks recruit practices

Cluster random allocation of practices to sequence of education interventions

Time -2m
Software installation & data cleaning

Group 1: CHF Topic
Software installation and data extraction

1st clinical meeting: CHF

2nd clinical meeting: CHF

HT Topic

1st clinical meeting: HT

2nd clinical meeting: HT

CHF Topic

1st clinical meeting: CHF

2nd clinical meeting: CHF

Data extraction for HT or CHF Topic

1st clinical meeting: HT or CHF

CHF or HT Topic

1st clinical meeting: CHF or HT

2nd clinical meeting: CHF or HT

Intervention Group 1

Intervention Group 2

Wait control Group 3

Time 0
Baseline data extraction for all groups

Time 3 m
data extraction for all groups

Time 6 m
data extraction for all groups

Time 9 m
data extraction for all groups

Time 12 m
data extraction for all groups

Time 15 m
data extraction for all groups

Time 18 m
data extraction for all groups

Time 9 m
data extraction for all groups

Time 15 m
data extraction for all groups

Time 18 m
data extraction for all groups
Outcome assessment

Clinical indicators of appropriate and safe prescribing behaviour were used as measures of impact at various stages of the intervention. This type of indicator is widely used in the medical literature, and Australian doctors are familiar with the concept from their exposure to locally relevant educational resources and interventions extracting data from their medical software for other quality improvement initiatives.[45-47]

The impact of the intervention is measured by two primary prescribing outcomes for each condition targeted by the intervention and five secondary prescribing outcomes relating to these two clinical topics. These were largely based on the prescribing indicators used in the feedback reports to the GPs. For details of the medicines covered see Appendix 3.

Primary prescribing indicators

Hypertension

1. Proportion of adult patients with a diagnosis of HT who have suboptimal control of blood pressure as follows:
   a. Proportion of adult patients with HT and using at least one antihypertensive drug, whose latest blood pressure is 140 / 90 mm Hg or higher
   b. Proportion of adult patients with HT and coronary heart disease, diabetes, chronic kidney disease, stroke or transient ischaemic attacks (TIA), whose latest blood pressure is 130 / 80 mm Hg or higher
### Chronic heart failure

1. Proportion of adult patients with chronic heart failure receiving appropriate treatment, ie:
   a. using an ACE inhibitor or angiotensin II-receptor antagonist
   b. using an ACE inhibitor or angiotensin II-receptor antagonist and using a heart-failure-specific beta blocker

### Secondary prescribing outcomes

#### Hypertension

1. Proportion of adult patients with HT using a prohypertensive drug whose latest blood pressure is 140 / 90 mm Hg or higher
2. Proportion of adult patients using an ACE inhibitor or angiotensin II-receptor antagonist, who are concurrently using a systemic nonsteroidal anti-inflammatory drug and a diuretic
3. Mean change in blood pressure at six-month intervals for patients with and without co-morbidities (i.e. diabetes, CHD, chronic kidney disease, stroke or TIA)

#### Chronic Heart Failure

1. Proportion of adult patients with chronic heart failure using an ACE inhibitor below the recommended dose
2. Proportion of adult patients with chronic heart failure using a drug that may exacerbate the disease

The clinical indicators used in this study were developed in consultation with clinical experts, GPs, pharmacists, consumers and policy makers via focus groups.
Refinement to ensure face validity was undertaken during a large workshop. Final selection of 9 indicators from a set of 82 potential clinical indicators was followed by field testing. The indicators were included in the study if there was evidence of their potential to improve patient care in the general practice setting, and they could be automatically extracted from general practice clinical software.

**Data collection for the impact evaluation**

The extraction tool enables de-identification of GP and patient data, encryption and transfer of information to a secure NPS file transfer site for the evaluation.

Data extracts to estimate indicators for evaluation by group allocation was planned to occur every three months after the initial clinical meeting.

**Sample Size estimations**

Sample sizes were calculated with an assumed intra-cluster correlation of 0.08 at the 80% power and 5% significance level using the University of Aberdeen sample size calculator, (version 1.0.2) which adjusts for the clustering of GPs and patients in practices. [48] Estimates for the ICC and other parameters were based on previous studies and analysis of data from a sample of general practices. [49] In order that the trial was powered to detect changes for the condition with lower prevalence in Australian general practice, we applied the CHF clinical indicators as the basis of the sample size calculations (estimated prevalence: 1%-4.1% for CHF vs. 10%-44% for HT) [50-52]. Data previously collected from an Australian GP panel source,[49] were used for the following calculations. Assuming each of the GPs saw at least half of their patient clientele in a year, it was estimated that around 3% of GPs patient population had CHF and that there are 7200 active adult patients in an average 3 GP practice, of which 86 patients with CHF were expected to visit the practice during the first 6 months of the study. For a three-arm study with ICC=0.08, the total number of
practices required to show this difference is 99. Further, based on previous
Australian and overseas experiences of GP or practice recruitment in trials and
surveys, [19, 53, 54] with an estimated drop out rate of 40-50% of all clusters
(practices), at least 180 practices were required to identify both sufficient cases of
chronic heart failure (the smaller patient group) and observable changes such as
10% absolute increase in prescribing of ACE inhibitors and 15% absolute increase in
prescribing of beta blockers.

**Eligibility criteria for Networks, practices and GPs**

To be eligible to participate, a Network had to agree to promote the study to their
practices and GPs, be able to recruit a minimum of 7 and a maximum of 15 general
practices, and have the capacity to appoint appropriate personnel (project facilitators
and other relevant staff) to support the quality improvement intervention. For
practices to be eligible, the practice principal GP had to consent to allow the
installation of the data software extraction tool and consent for the data to be
securely transferred for analysis. Consent was obtained from GPs participating in the
PDGPD activities.

**Incentives for GPs, practices and Networks**

GPs participating in two facilitated peer group clinical meetings and undertaking a
review of their patients are eligible for mandatory continuing professional
development points recognised by the Royal Australian College of General Practice
and the Australian College of Rural and Remote Medicine. This quality prescribing
initiative also makes the practice eligible for payment as part of a
Australian Government’s Practice Incentives Program. The funds provided to the
Networks to deliver the project were deliberately weighted to ensure Networks
recruited and retained the required minimum number of practices for the duration of the project. Networks were requested to provide $A500 to each practice to assist with data cleaning processes at the project start.

**Recruitment procedures**
Recruitment of GP practices occurred in two stages. In stage 1, Networks were recruited through a call for Expressions of Interest from NPS and AGPN to recruit practices and deliver the intervention. In stage 2, Networks recruited practices and GPs to participate in the study and employed project facilitators to deliver and coordinate the intervention in participating practices in their Network.

**Project facilitator training**
Two 2-day facilitator training workshops were delivered by NPS at the study start to give project facilitators a clear understanding of the Project, its aims, their roles and responsibilities and principles of research design, privacy issues and project implementation. Clinical knowledge of management of patients with HT and chronic heart failure was another important component. The focus then turned to developing skills in communication, negotiation and persuasion, group facilitation, problem solving, facilitating decision making, and change management. Data management skills covered demonstration of the software installation, data collection and cleaning, data transfer and storage and data interpretation as well as hands on use of the data extraction tool and practical examples on how to improve data quality. On-going monthly teleconferences with groups of facilitators were also established to support problems to support facilitators in the field.

**Data Extraction and data cleaning**
A third party software tool was used to extract prescribing data from general practices. The tool was developed to: (1) provide *clinical indicator reports* to measure
the clinical indicators; (2) provide *data quality reports* to identify missing or incorrect clinical data to ensure accurate calculation of clinical indicator reports; and (3) *evaluation data extracts* at baseline, and at regular intervals through the intervention, in order to evaluate changes in prescribing over the intervention period. The data extraction tool was developed over a period of 18 months and included functional specification development, software development, testing and piloting in general practice. The functional specifications included definitions for where data is stored in clinical software; how the data is coded or recorded, and the algorithms for calculating the clinical indicator.

A pre-intervention phase of two months included the installation of the data extraction software, training of practice staff in its use for data cleaning, upload and transfer (Appendix 4). Data quality reports obtained from the data software extraction tool allow the practice to *clean* their data by improving the quality of coding and completeness of fields in the practice clinical software during this first two months. Clinical indicator reports were collected from the GP clinical software just before the initial clinical meeting and every quarter. They were used within the practices to give individual GP and practice-level feedback, Evaluation data extracts to extract anonymised data for patients with relevant conditions. This complete data subset with intervention-relevant variables extracted was transferred to a secure data repository located at NPS for the impact evaluation.

**Data Analysis**

The unit of randomisation is the practice and unit of analysis is the patients accounting for clustering by practice (using *Proc surveyfreq* in SAS Enterprise Guide v4). The following analysis will be presented comparing the three groups:

a. Successive cross-sectional analyses at six-month intervals which include any practice with patient data available at each point. This will be to estimate point
prevalences of each indicator before and after the intervention. Comparisons of practice proportions of patients meeting the individual guideline-recommended indicators (with 95% confidence intervals) across intervention groups will be conducted using $\chi^2$ statistics.

b. Longitudinal (cohort) estimates of changes in indicators occurring between time points, based on data from patients who had at least one visit before baseline and at least one visit following the intervention.

c. Sequential indicators will be calculated where changes in prescribing behaviours are measured only for patients not meeting guideline-driven indicators in the preceding 6-12-month period (e.g. proportion of CHF patients using an ACE inhibitor or angiotensin II-receptor antagonist at 6 months, out of those not receiving this treatment at baseline). This approach will show whether the intervention modified prescribing behaviour using a denominator where patients have scope for improvement.

Changes in the proportion of patients appropriately prescribed target medicines before and after the intervention will also be presented, with $\chi^2$ statistics for categorical measures (e.g. on heart failure medication or not at each time point), and significance testing of before and after the intervention effects within intervention groups based on paired t tests for continuous measures (e.g. mean blood pressure change) within groups and with a p-level of $\leq 0.01$ considered to be statistically significant.

Supplementary regression analyses of the cohort will identify predictors of improved prescribing at 12 and 18 months after controlling for other possible confounders (determinants at the practice level) such as practice size, rural/urban location, socio-economic level of the area, percentage female doctors, mean years of GP
experience. Post-test comparisons will be conducted between the intervention and wait-control arms using intention to treat analysis [55] and models that account for the non-independence of observations due to the clustering of practices in a Network and clustering of patients within practices and GPs. Separate binary logistic regression models will be analysed for CHF and HT adjusting for clustering effects of practice and GP.[56] Stepwise regression techniques will be used. Odds ratios will be used as the common measure of the estimated effect of the intervention and the independent effect of explanatory variables. To account for chance imbalance across intervention groups,[57] explanatory variables for each model will include patient characteristics, practice characteristics, and location of the Network. The researchers analysing the impact of the intervention on study outcomes have no contact with Networks or practices involved and are blinded to allocation group code at the baseline analysis stage.

**Ethical Considerations**

The study obtained ethics approvals from the Royal Australian College of General Practitioners Human Research Ethics Committee (approval number RACGP 08/007).

Participation of GPs and practices was voluntary and subject to informed consent for participation by the practice and the GP prior to any whole-of-practice data extraction. Although patients are not direct participants in the study, their non-identifiable data is being used to evaluate the intervention with GPs. Patients are notified that the practice is participating in a quality improvement initiative and can opt out of the process of their de-identified information being sent to NPS for analysis by notifying their doctor. After recording withdrawal of consent, their data are removed and not extracted by the data extraction tool used to collect the evaluation data.
Members of the research and evaluation team analysing the data have access only to de-identified information for Networks, practices and patients. Staff involved in data decryption do not participate in the analysis and all staff are required to sign a confidentiality agreement.

**Discussion**

The challenges of implementing and evaluating real-world interventions to improve health and professional behaviours are well documented.[27, 30, 58-60] Participation of doctors in educational interventions and their willingness to accept evaluation audits rely on practice-based and doctor-based factors not often reported in the literature.[53, 54] A doctor’s prescribing behaviour also depends on personal characteristics, years of experience, motivation, marketing strategies used by pharmaceutical industries, demands from society and patients, knowledge of guidelines, confidence and regulatory actions.[34, 60-63]

There are methodological difficulties in designing sound evaluations to identify the impact that context can have on success of prescribing interventions.[54, 57, 64] For instance, GPs prescribe in apparent conflict with guidelines for reasons that are complex, and can vary from previous experience with medical misadventures, to patient-factors such as patient age, education, ethnicity, social class, likely compliance and lifestyle considerations. [62, 64] Uncertainty of intervention effectiveness is further compounded by the bias in reporting of studies and the inability to attribute success to individual intervention components. [23, 65]

The evaluation of PDGPD project uses a pragmatic cluster RCT design, where one of two interventions or control status is randomly assigned to individual practices. A pragmatic cluster-randomised trial is considered an appropriate research design in
public health and educational interventions as it allows more variability in the entry
criteria, reduces the impact of contamination within groups, and provides
administrative convenience for implementation. [39, 40, 57, 66] PDGPD will have
access to several data points to investigate immediate and mid-term impact of the
quality improvement initiative. However, several potential weaknesses in the design
of PDGPD are acknowledged: first, the voluntary nature of GP participation in the
cluster design where a practice [cluster] agreed to participate but not all GPs in the
practice received the intervention. This may lead to dilution of the intervention effect
when data from all patients seen by all GPs in the practice are analysed. The
intervention is designed to encourage GPs to communicate key messages with other
non-participating GPs in the practice and to welcome non-enrolled GPs to attend
clinical discussion meetings within the same intervention group; further, the impact of
participation rate by practice can be incorporated in the regression analysis model.
Second, the cross-over design (Figure 1) where the same facilitator delivers one
intervention after another in the same practice and one topic in one intervention
practice and the competing topic in another practice carries the risk of cross-
contamination; allocation of clinical topic order was done at random and facilitators
were trained at focusing on discrete messages of one topic at a time. Thirdly, the
wait-control group provides pre-intervention comparisons only for the first six months
of the trial; for practical reasons in non-research settings (i.e. need for an intervention
in exchange for participation) the control group received the intervention six months
later.

Results of this evaluation will document the impact of an intervention to align GP
prescribing behaviours with practice guidelines over time in Australia. Further, the
evaluation will report the extent to which practice characteristics (such as rural/urban
location and total number of active patients) and patient profile, (such as age, sex,
presence of co-morbidities and number of medications) may affect the likelihood of
adopting these prescribing changes. The ability to adopt or adapt evidence-based programs with fidelity in general practice is an important aspect to identify feasibility, acceptability and sustainability of such programs in the future. A comprehensive suite of qualitative studies have been developed for this project to assess such issues. Details on the qualitative evaluation components of the PDGPD will be described elsewhere.

Finally, the PDGPD project is expected to bring the following benefits:

- Improved care and outcomes for patients with heart failure and hypertension
- Acceptable and sustainable methods to promote quality improvement activities within general practice
- Purpose-built extraction and feedback tools that can calculate complex indicators useful to monitor prescribing behaviour, promote change and enable evaluation of educational interventions
- Opportunity to refine clinical indicators to better reflect quality of clinical care and outcomes of prescribing behaviour

**Competing interests**

The authors declare that they have no competing interests. Staff from the NPS Research and Development team had a role in project design and data analysis independently of the NPS health professional staff and decision support staff who designed the quality improvement activity, delivered the project facilitator training on the two clinical topics and managed the program implementation and data coordination. AGPN played an advisory role on the practicalities of working with, and in the recruitment of general practice networks, and had no involvement in data analysis or interpretation. The government funding body (Commonwealth Department of Health and Ageing) had no role in the conception or development of
the study design, the writing of the manuscript or the decision to submit it for publication. This study has not received any funding from commercial organisations.

**Author’s contributions**

MW conceived and developed the design of the study, developed ethics application and obtained ethics approval, conducted literature searches, undertook and supervised data quality assurance, led the first draft and revised this manuscript and commented on subsequent versions. MCM conducted literature searches, contributed to the definitions of prescribing indicators to measure impact, produced data specifications and analysis plan for the impact analysis plan and led subsequent drafts of the manuscript to completion. JDE contributed to indicator development, project design, project implementation, data coordination, and revision of the manuscript versions. JM provided input into project design, indicator development, clinical considerations and day-to-day strategic decisions on project direction. NS, JG and JE made intellectual contributions into trial design and project implementation issues and commented on drafts of the manuscript. All authors read and approved the final manuscript.

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Appendix 1: PDGPD Study Governance membership and functions

The overall structure of the governance of the PDGPD Project illustrated below consisted of several groups with complementary functions.

The PDGPD External Steering Committee provided the overall strategic direction for the PDGPD Project and AGPN as our collaborating partner was represented on this group, as well as representation from the Networks and GPs with an interest in this area.

The NPS Internal Steering Committee (formerly known as the Internal Governance Group) consisted of the Project Sponsor, project manager and managers from the Health Professional, Decision Support, R&D, Data Management and IT teams. The role of the Group was to provide overall management and corporate accountability for the project, ensuring proper governance.

The Project Implementation Group consisted of members from AGPN and NPS and was used as a forum to discuss stakeholder issues, including selection of
Networks for the expressions of interest process, discussion and agreement of the roles and responsibilities of both parties, formulation of a communications plan and managing Network and practice relationships.

**The Clinical Reference Group** consisted of GPs with a knowledge of Australian Primary Care Collaboratives methodology and experience of extractable clinical indicators and whose function was to provide clinical knowledge, feedback on the definition, suitability and usability of the data extraction software and input into the intervention design.

**The Study Guidance Group**’s main function was to provide advice and direction for the development, conduct, analysis and reporting of evaluation of the project.

**Software Governance Group** was an internal group providing direction and final decisions for the development and testing of data extraction software tools.
Appendix 2: Scope of CHF and HT definitions

<table>
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<th>Include patients:</th>
<th>Terms used in the indicator specifications to describe hypertension in the clinical software</th>
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<td>Hypertension</td>
<td>Essential hypertension</td>
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<td>High blood pressure</td>
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<td>Labile Hypertension</td>
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<tr>
<td></td>
<td>Malignant hypertension</td>
</tr>
<tr>
<td></td>
<td>Primary hypertension</td>
</tr>
<tr>
<td></td>
<td>Renal Hypertension</td>
</tr>
<tr>
<td></td>
<td>Reno-vascular Hypertension</td>
</tr>
<tr>
<td></td>
<td>Severe refractory hypertension</td>
</tr>
<tr>
<td></td>
<td>Blood Pressure Labile</td>
</tr>
<tr>
<td></td>
<td>BP Labile</td>
</tr>
<tr>
<td></td>
<td>BP Unstable</td>
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<tr>
<td></td>
<td>Labile BP</td>
</tr>
<tr>
<td></td>
<td>Labile Blood Pressure</td>
</tr>
<tr>
<td></td>
<td>Excludes</td>
</tr>
<tr>
<td></td>
<td>Possible hypertension</td>
</tr>
<tr>
<td></td>
<td>White coat HT</td>
</tr>
<tr>
<td></td>
<td>HT-pregnancy</td>
</tr>
<tr>
<td></td>
<td>HT-borderline</td>
</tr>
<tr>
<td></td>
<td>HT-stress related</td>
</tr>
<tr>
<td></td>
<td>HT investigation</td>
</tr>
<tr>
<td></td>
<td>HT-one reading</td>
</tr>
<tr>
<td></td>
<td>Anxiety provoked HT</td>
</tr>
<tr>
<td></td>
<td>HT- lifestyle</td>
</tr>
<tr>
<td></td>
<td>management</td>
</tr>
<tr>
<td></td>
<td>HT-preventive care</td>
</tr>
<tr>
<td></td>
<td>Hypertensive heart failure</td>
</tr>
<tr>
<td></td>
<td>? hypertension</td>
</tr>
<tr>
<td></td>
<td>Excludes</td>
</tr>
<tr>
<td></td>
<td>Acute heart failure</td>
</tr>
<tr>
<td></td>
<td>Diastolic heart failure</td>
</tr>
<tr>
<td></td>
<td>Possible CHF</td>
</tr>
<tr>
<td></td>
<td>? heart failure</td>
</tr>
<tr>
<td></td>
<td>CHF investigation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Include patients:</th>
<th>Terms used in the indicator specifications to describe chronic heart failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic heart failure or left ventricular dysfunction</td>
<td>Cardiac failure</td>
</tr>
<tr>
<td></td>
<td>CCF</td>
</tr>
<tr>
<td></td>
<td>Congestive Cardiac Failure</td>
</tr>
<tr>
<td></td>
<td>Congestive Heart Failure</td>
</tr>
<tr>
<td></td>
<td>Heart failure - Biventricular</td>
</tr>
<tr>
<td></td>
<td>Heart failure - High output</td>
</tr>
<tr>
<td></td>
<td>Heart failure - Left</td>
</tr>
<tr>
<td></td>
<td>Heart failure - Right</td>
</tr>
<tr>
<td></td>
<td>High output cardiac failure</td>
</tr>
<tr>
<td></td>
<td>High output heart failure</td>
</tr>
<tr>
<td></td>
<td>Hypertensive heart failure</td>
</tr>
<tr>
<td></td>
<td>Left Ventricular Failure</td>
</tr>
<tr>
<td></td>
<td>LHF (Left Heart Failure)</td>
</tr>
<tr>
<td></td>
<td>LVF (Left ventricular failure)</td>
</tr>
<tr>
<td></td>
<td>Pulmonary oedema</td>
</tr>
<tr>
<td></td>
<td>RHF (Right heart failure)</td>
</tr>
<tr>
<td></td>
<td>Right ventricular failure</td>
</tr>
<tr>
<td></td>
<td>RVF (Right ventricular failure)</td>
</tr>
<tr>
<td></td>
<td>Left Ventricular Dysfunction</td>
</tr>
<tr>
<td></td>
<td>Ventricular dysfunction – left</td>
</tr>
<tr>
<td></td>
<td>Poor left ventricular function</td>
</tr>
<tr>
<td></td>
<td>Cor pulmonale</td>
</tr>
<tr>
<td></td>
<td>Excludes</td>
</tr>
<tr>
<td></td>
<td>Acute heart failure</td>
</tr>
<tr>
<td></td>
<td>Diastolic heart failure</td>
</tr>
<tr>
<td></td>
<td>Possible CHF</td>
</tr>
<tr>
<td></td>
<td>? heart failure</td>
</tr>
<tr>
<td></td>
<td>CHF investigation</td>
</tr>
</tbody>
</table>
### Appendix 3: Medicines relevant to the intervention

#### ANTI-HYPERTENSIVES

<table>
<thead>
<tr>
<th>Category</th>
<th>Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Centrally-acting antihypertensives (A)</strong></td>
<td>Clonidine, Methyldopa, Moxonidine</td>
</tr>
<tr>
<td><strong>ACE inhibitors (B)</strong></td>
<td>Captopril, Enalapril or enalapril maleate, Fosinopril or fosinopril sodium, Lisinopril, Perindopril or perindopril arginine or perindopril erbumine, Quinapril or quinapril hydrochloride, Ramipril, Trandolapril</td>
</tr>
<tr>
<td><strong>Thiazide or thiazide-like Diuretics (C)</strong></td>
<td>Hydrochlorothiazide, Chlorthalidone, Indapamide</td>
</tr>
<tr>
<td><strong>ACE inhibitor plus thiazide or thiazide-like diuretic (B+C)</strong></td>
<td>Enalapril/hydrochlorothiazide, Fosinopril/hydrochlorothiazide, Perindopril/indapamide, Quinapril/hydrochlorothiazide</td>
</tr>
<tr>
<td><strong>Calcium-channel blockers (D)</strong></td>
<td>Amlodipine or amlodipine besylate or amlodipine maleate, Felodipine, Lercanidipine or lercanidipine hydrochloride, Nifedipine, Diltiazem (controlled delivery) or diltiazem hydrochloride (controlled delivery), Verapamil or verapamil hydrochloride</td>
</tr>
<tr>
<td><strong>ACE inhibitor plus calcium channel blocker (B+D)</strong></td>
<td>Enalapril/lercanidipine hydrochloride, Ramipril/felodipine, Trandolapril/verapamil or trandolapril/verapamil hydrochloride, Perindopril/Amlodipine</td>
</tr>
<tr>
<td><strong>Angiotensin II-receptor antagonists (E)</strong></td>
<td>Candesartan or candesartan cilexetil, Eprosartan or eprosartan mesylate, Irbesartan, Losartan or losartan potassium, Olmesartan or olmesartan medoxomil, Telmisartan, Valsartan</td>
</tr>
<tr>
<td><strong>Calcium channel blocker plus statin (D)</strong></td>
<td>Amlodipine/atorvastatin or amlodipine besylate/atorvastatin calcium</td>
</tr>
</tbody>
</table>
| **Angiotensin II-receptor antagonist plus thiazide diuretic (E+C)** | Candesartan/hydrochlorothiazide or candesartan cilexetil/hydrochlorothiazide  
Eprosartan/hydrochlorothiazide or eprosartan mesylate/hydrochlorothiazide  
Irbesartan/hydrochlorothiazide  
Olmesartan/hydrochlorothiazide or olmesartan medoxomil/hydrochlorothiazide  
Telmisartan/hydrochlorothiazide  
Valsartan/hydrochlorothiazide |
| **Angiotensin II-receptor antagonist plus calcium channel blocker (E+D)** | Amlodipine/valsartan or amlodipine besylate/valsartan  
Amlodipine/olmesartan |
| **Beta blockers (F)** | Atenolol  
Bisoprolol or bisoprolol fumarate  
Carvedilol  
Esmolol  
Labetalol or labetolol hydrochloride  
Metoprolol or metoprolol succinate or metoprolol tartrate  
Oxprenolol or oxprenolol hydrochloride  
Pindolol  
Propranolol or propranolol hydrochloride |
| **Potassium-sparing diuretic (G)** | Amiloride  
Triamterene |
| **Thiazide plus potassium-sparing diuretic (C+G)** | Hydrochlorothiazide/amiloride  
Hydrochlorothiazide/triamterene |
| **Alpha-blockers (selective) (H)** | Prazosin or prazosin hydrochloride  
Terazosin or terazosin hydrochloride |
| **Vasodilators (I)** | Hydralazine or hydralazine hydrochloride  
Minoxidil |
| **PRO-HYPERTENSIVES** | **Corticosteroid-Glucocorticoid.**  
Corticosteroid – Glucocorticoid class – include all  
Corticosteroid – Mineralocorticoid class – include all |
| **Hormone replacement therapy (HRT) and oral contraceptives** | Hormone Replacement Therapy (HRT) class – include all  
Hormone Replacement Therapy (HRT) Oestrogen only class – exclude topical oestrogens  
Oestrogen/Progestogen Combinations as OCs class – include all  
Progestogen/Oestrogen Combinations as OCs class – include all  
Oral Contraceptives – Combined class – include all  
Contraceptive - Oral Combined class – include all  
Oestrogenic/Progestogenic Combinations as HRT class – include all  
Progestogenic/Oestrogenic Combinations as HRT class – include all |
### Systemic Nonsteroidal anti-inflammatory agents (NSAIDs)

- 'NSAIDs Systemic', 'Nonsteroidal anti-inflammatory agents Systemic', 'Systemic NSAIDs' including:
  - Diclofenac or diclofenac sodium or diclofenac potassium
  - Ibuprofen or ibuprofen lysine
  - Ibuprofen/pseudoephedrine hydrochloride
  - Indomethacin
  - Ketoprofen
  - Ketorolac or ketorolac trometamol
  - Mefenamic acid
  - Naproxen or naproxen sodium
  - Piroxicam
  - Sulindac
  - Tiaprofenic acid
  - Diclofenac sodium/misoprostol
  - Ibuprofen/codeine phosphate

  Do not include: glucosamine, glucosamine sulfate, glucosamine hydrochloride, glucosamine hydrochloride/chondroitin sulfate, glucosamine sulfate/potassium chloride, chondroitin, chondroitin sulphate, methylsulfonylmethane/glucosamine hydrochloride/chondroitin sulfate sodium/ascorbic acid/citrus
  - Bioflavonoids/zinc/manganese/copper/boron, tricosanthes kirilowii/prunella vulgaris/clematis sinensis – exclude topical NSAIDs

### Anti-androgen and other hormones

- Cyproterone Acetate/Ethinyloestradiol
- Dienogest/Oestradiol Valerate
- Nomegestrol Acetate/Oestradiol

### Cyclooxygenase 2 COX 2) inhibitors

- Include all
  - Celecoxib
  - Meloxicam
  - Parecoxib or parecoxib sodium
  - Etoricoxib

### MAO inhibitors

- Include all
  - Phenelzine
  - Tranylcypromine

### Decongestant – Systemic

- Include drugs with ephedrine and pseudoephedrine and/or phenylephrine (alone or in combination products)

### Sympathomimetics

- Adrenaline or adrenaline hydrochloride, Noradrenaline

### Generic drug names (no applicable classes available)

- Bromocriptine, bromocriptine (as mesylate), clozapine, cyclosporine, darbepoetin, darbepoetin alfa, epoetin, epoetin alfa, epoetin beta, leflunomide, moclobemide, nicotine, sibutramine, sibutramine hydrochloride, phentermine, tacrolimus, reboxetine, reboxetine mesilate, venlafaxine, venlafaxine hydrochloride, dehydro-epi-androsteron (DHEA), melatonin, hypericum, hypericum perforatum, hypericum perforatum standardised, St. John's wort, hypericum perforatum/L-tyrosine/L-glutamine/magnesium, hypericum perforatum (St. John's wort) dried flower herb top, hypericum perforatum/passion flower/gotu kola/gingko biloba/green tea, hypericum/eleutherococcus/vitamins
<table>
<thead>
<tr>
<th>DRUGS THAT EXACERBATE CHF</th>
<th>MD drug generic name or brand name in ‘ ’</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antiarrhythmic class I</strong></td>
<td>Antiarrhythmic class I – include all</td>
</tr>
<tr>
<td></td>
<td>Disopyramide</td>
</tr>
<tr>
<td></td>
<td>Flecainide or flecainide acetate</td>
</tr>
<tr>
<td></td>
<td>Lignocaine hydrochloride, but only brand name</td>
</tr>
<tr>
<td></td>
<td>‘Xylocard 500 infusion’</td>
</tr>
<tr>
<td></td>
<td>Mexiletine or mexiletine hydrochloride</td>
</tr>
<tr>
<td><strong>Antiarrhythmic class III</strong></td>
<td>Antiarrhythmic class III – include only</td>
</tr>
<tr>
<td></td>
<td>Sotalol or sotalol hydrochloride</td>
</tr>
<tr>
<td><strong>Non dihydropyridine calcium channel blockers</strong></td>
<td>Verapamil or verapamil hydrochloride</td>
</tr>
<tr>
<td><strong>(These two drugs are a subset of</strong></td>
<td>Diltiazem or diltiazem hydrochloride or diltiazem hydrochloride (controlled delivery)</td>
</tr>
<tr>
<td>The calcium channel blocker class)</td>
<td></td>
</tr>
<tr>
<td><strong>Tricyclic Antidepressants</strong></td>
<td>Amitriptyline or amitriptyline hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Clomipramine or clomipramine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Dothiepin or dothiepin hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Doxepin or doxepin hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Imipramine or imipramine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Nortriptyline or nortriptyline hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Trimipramine or trimipramine maleate</td>
</tr>
<tr>
<td><strong>Systemic Nonsteroidal anti-inflammatory agents (NSAIDs)</strong></td>
<td>Include the following from the Systemic NSAIDs class</td>
</tr>
<tr>
<td></td>
<td>Diclofenac or diclofenac sodium or diclofenac potassium</td>
</tr>
<tr>
<td></td>
<td>Ibuprofen or ibuprofen lysine</td>
</tr>
<tr>
<td></td>
<td>Ibuprofen/pseudoephedrine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Indomethacin</td>
</tr>
<tr>
<td></td>
<td>Ketoprofen</td>
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<tr>
<td></td>
<td>Ketorolac or ketorolac trometamol</td>
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<tr>
<td></td>
<td>Mefenamic acid</td>
</tr>
<tr>
<td></td>
<td>Naproxen or naproxen sodium</td>
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<tr>
<td></td>
<td>Piroxicam</td>
</tr>
<tr>
<td></td>
<td>Sulindac</td>
</tr>
<tr>
<td></td>
<td>Tiaprofenic acid</td>
</tr>
<tr>
<td></td>
<td>Diclofenac sodium/misoprostol</td>
</tr>
<tr>
<td></td>
<td>Ibuprofen/codeine phosphate</td>
</tr>
<tr>
<td><strong>Do not include:</strong></td>
<td>Glucosamine or glucosamine sulphate or glucosamine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Glucosamine hydrochloride/chondroitin sulfate</td>
</tr>
<tr>
<td></td>
<td>Glucosamine sulfate/potassium chloride</td>
</tr>
<tr>
<td></td>
<td>Chondroitin or chondroitin sulphate</td>
</tr>
<tr>
<td></td>
<td>Methylsulfonylmethane/glucosamine</td>
</tr>
<tr>
<td></td>
<td>hydrochloride/chondroitin sulfate sodium/ascorbic acid/citrus</td>
</tr>
<tr>
<td></td>
<td>bioflavonoids/zinc/manganese/copper/boron</td>
</tr>
<tr>
<td></td>
<td>Triclosanthes kirilowii/prunella vulgaris/clematis sinensis</td>
</tr>
</tbody>
</table>
| **COX 2 inhibitors** | Includes all from Cyclooxygenase 2 inhibitors class  
Celecoxib  
Meloxicam  
Parecoxib or parecoxib sodium  
Etoricoxib |
|----------------------|-----------------------------------------------------------------|
| **Glitazones**       | Pioglitazone or pioglitazone hydrochloride  
Rosiglitazone  
Rosiglitazone/metformin |
| (Drugs from the antidiabetic agents class) | |
| **Corticosteroid-Glucocorticoid class** | Betamethasone or betamethasone acetate or betamethasone sodium phosphate  
Budesonide (oral capsules only – brand name ‘Entocort’)  
Cortisone or cortisone acetate  
Dexamethasone  
Fludrocortisone or fludrocortisone acetate  
Hydrocortisone or hydrocortisone acetate or hydrocortisone sodium succinate  
Methylprednisolone or methylprednisolone acetate or methylprednisolone sodium succinate  
Prednisolone or prednisolone sodium phosphate  
Prednisone  
Triamcinolone or triamcinolone acetonide |
| **Tumour Necrosis Factor Receptor Blockers** | Adalimumab  
Etanercept  
Infliximab |
Appendix 4: Key Data Management and Data Cleaning Activities Undertaken by Facilitators or Practice Staff

- Archive deceased patients and those who have not been in contact with the practice for over two years and reactivate patients if they return to the practice at a later date
- Clean recall lists and outstanding action lists. Identify patients to be recalled and check BP records for recalled patients
- Update current medication list deleting old scripts, entering over-the-counter and complementary medicines, changing doses when relevant, flagging medications prescribed elsewhere and completing reason for prescribing
- Ensure diagnoses are updated and entered in the relevant field or removed if no longer applicable. Use maintenance program to convert old diagnosis text into a searchable diagnosis codes (history codes)
- Convert blood pressure readings into values in the relevant fields
- Run data extractions and save results at each extraction date
- Print data quality reports for practice and GPs
- Print patient lists for data quality reports
- Respond to data quality queries from NPS by clarifying missing or conflicting data and update records before next extraction date