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TITLE PAGE

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ABSTRACT

Introduction

Chronic diseases are the leading cause of illness, disability and death in Australia. The prevalence and associated health expenditure are projected to soar. There is no 'whole system' approach to healthcare in Australia. To overcome this fragmentation, the Gold Coast Hospital and Health Service (GCHHS) is developing a new model known as Gold Coast Integrated Care (GCIC). To evaluate GCIC a four-year pilot trial commenced in March 2015. This protocol paper describes the evaluation of GCIC.

Methods and analysis

A pragmatic non-randomised controlled clinical trial will be conducted to test the hypothesis that GCIC will result in improved health and well-being at no additional cost to the healthcare system. Using a mixed methods approach, impact, outcome, and process evaluations will be undertaken to assess the effectiveness and acceptability, including the balance of costs between primary and public secondary care sectors, staff and training requirements, clinical service delivery, and trial implementation.

Fifteen general practices have agreed to deliver GCIC. One thousand five hundred of their adult patients with treated chronic diseases, high risk of hospitalisation or healthcare utilisation will be recruited to the intervention arm. Approximately 3,000 patients not associated with the participating general practices will be matched as controls providing service utilisation and disease data for usual care.

Baseline data and follow-up observations will be collected every 3-12 months until the end of 2018. Quantitative analyses will use a range of advanced statistical techniques, and qualitative analyses will focus on experiences, satisfaction, engagement and implementation.

Ethics and dissemination

Approval received from the GCHHS on the 16th March 2015, and from Griffith University on the 16th April 2015. The study is registered with the Australian New Zealand Clinical Trial Registry (ACTRN12616000821493). Findings will be communicated via yearly reports to funding bodies and scientific publications.

Strengths and limitations of this study

- The considerable number of participating patients in the GCIC program is expected to yield meaningful information to inform future health service planning;
- The three to four year follow-up period which is longer than most clinical trials should give an adequate indication of the longer-term effectiveness of the GCIC program;
- A potential limitation includes self-selection bias from both participating general practices and patients who may represent a more engaged and motivated health provider and patient group;
- Patient choice should also be considered as a limitation as all patients are free to decide where to seek health care and are permitted to change their general practitioner to one who is not in the program.

INTRODUCTION

Chronic diseases were the leading cause of illness, disability and death in Australia in 2011 [1 2], and their relative burden on the health system increases over time. For example, health expenditure on the most prevalent chronic condition (type 2 diabetes) is projected to increase 520% from a 2002-03 level by 2032-33, while the increase in total health expenditure is expected to be 189% over the same period, mainly due to two demographic growth factors: population ageing and the increase in population [3]. The majority of chronic disease health dollars are allocated to hospital service for admitted patients, out-of-hospital services, medications and dental services [1]. A major problem in managing chronic disease services is the fragmentation of the Australian health care system, attributed to the complex interplay of health funding and division of responsibilities between the federal, state and local governments for both private and public health services [4].

In Australia, there are numerous national and state initiatives and programs aimed at linking sectors of the healthcare system; however, no consistent 'whole-system' approach to integrating services between primary health care and other health care services exists [5]. A national agreement between all Australian federal, state and territory governments in 2012 supported an integrated approach to promote healthy lifestyles, prevention of illness and injury, and diagnosis and treatment across the continuum of care, as a means to improve health outcomes for all Australians and the sustainability of the Australian health system [6]. These improvements are particularly relevant for the Gold Coast (Queensland, Australia) population, where almost one-third of the population will be over 55 years of age, and the number of people aged over 85 years will nearly double by 2021 compared to the 2006 level [7]. In the context of this national agreement and growing burden of disease, the Gold Coast Hospital and Health Service (GCHHS) and the Gold Coast Primary Health Network (GCPHN) and Queensland Health in partnership with Griffith University (GU), led the development of a new model of care. To evaluate this new model of service delivery a four-year pilot trial, referred to as Gold Coast Integrated Care (GCIC), commenced in March 2015 with the establishment of a coordination centre to coordinate health services linking the patient and general practice with all other relevant health and hospital services. Significant funding was secured from Queensland Health and the GCHHS, with a contribution from the GCPHN. Additional funds were received from the Australian Government Department of Health to perform this evaluation study. None of the funding bodies had or will have an input in the design and management of the study, in the analysis and interpretation of data, or in the writing and submission of reports and publications. The GCHHS and the GCPHN are providing administrative data for analysis for the evaluation.

The design principles of GCIC are based on that of large-scale whole system models such as Kaiser Permanente [8] and Intermountain Healthcare [9] in the USA. A review of these American models

highlights the merits of integrated care programs that focus on high-impact health conditions whilst situating primary care at the centre of chronic illness management, making it "*accessible, continuous, comprehensive, coordinated, and delivered in the context of family and the community*" [8 10-13].

Common attributes of successful integrated care programs targeting individuals with chronic and complex conditions include the ability to stratify and target high-cost, high need individuals, fostering effective interactions with patients providing self-management support, and multidisciplinary care pathways organised through a single point-of-entry whilst creating an environment for successful leadership at all levels [12 14]. The patient-centred medical home described by Jaén et al is an example of this type of approach which acts as a coordination centre for patients and their families, providing easy access to first-contact and comprehensive care where the patient is an active participant in their own health and well-being [15]. A two year evaluation of this model in the USA showed improvements across both patient and health service outcomes with improved patient experience, quality, fewer emergency department and hospital visits, and lower costs [16].

In the United Kingdom (UK), health leaders, policy makers and researchers have a long established interest in integrated care with the decentralised capitated health service model rather than the fee for service framework in Australia. Lessons from UK programs including the Integrated Care Pilots and Trafford highlight the importance of strong leadership and collective governance with co-location of multidisciplinary teams within an integrated care framework [17-21]. Additionally, researchers emphasise the need for communication, exploiting linked data sets including general practice data, and shared information technology and health record systems [18 22].

The GCIC program is founded on the notion that care coordination, planning and patient advocacy is best achieved in collaboration with general practitioners (GPs), supported by specialists, multidisciplinary teams, non-government organisations and private allied health providers, so that patients get the care they need, when they need it, in ways that are user friendly, achieve the desired results and provide value for money [23]. The overarching goal of GCIC is to proactively manage patients with chronic and complex conditions, in close collaboration with GPs, to reduce presentations to emergency departments, improve the capacity of specialist hospital outpatient departments, and decrease planned and unplanned hospital admission rates, all of which should be cost effective for the GCHHS. This protocol paper describes the evaluation of the GCIC program, guided by the SPIRIT recommendations [24].

METHODS AND ANALYSIS

Study design

The evaluation study is a pragmatic non-randomised controlled clinical trial to test the primary hypothesis that GCIC will result in improved health and well-being at no additional cost to the healthcare system. The primary unit of analysis will be the individual, while the general practices and healthcare work force will be the secondary units of analysis.

Using a mixed methods approach; impact, outcome, and process evaluations will be undertaken to assess the overall effectiveness and acceptability of GCIC. The evaluation includes two components: a core evaluation of high risk patients and a population health outcomes component. The following research questions were defined. *Primary question.* Did GCIC reduce overall costs of delivering health care services to the GCHHS and improve health outcomes for high risk patients with complex needs? *Outcome evaluations*. (a) Did GCIC change the proportion of costs shared by the primary and secondary care sectors? (b) Did GCIC reduce potentially avoidable hospital admissions, emergency presentations and length of stay? (c) To what extent did GCIC improve experiences and satisfaction with care for both patients and clinicians? (d) What was the relationship between patient outcomes and clinical and demographic characteristics? (e) What was the cost effectiveness of GCIC? *Impact evaluation.* a) What are the costs and benefits of generalising the GCIC model to other parts of Australia? (b) What are the projected changes in numbers of hospital admissions, emergency presentations, general practice visits and other healthcare utilisation? (c) What is the staffing requirement (including training needs) and displacement from generalising GCIC? *Process evaluation*. (a) Did GCIC improve clinical service delivery according to guidelines? (b) To what extent was GCIC implemented as intended? (c) Which elements of GCIC were seen to be most useful by staff and patients respectively? (d) To what extent did GCIC improve continuity of care?

Governance arrangements for GCIC include a managing director and a senior management team referred to as the *Executive Management Team*, which provides strategic leadership and management of the overall processes and business operations as well as strategy, budget, program structure, and administration. A *Strategic and Clinical Advisory Committee* has been appointed for the purpose of providing clinical oversight and strategic direction. An *Evaluation Steering Committee* acts as the peak advisory body for the evaluation study, providing oversight and advice to the team to ensure the continued quality and credibility of evaluation activities. Individuals responsible for the design and implementation of GCIC are employees of the GCHHS and other organisations (excluding the GU). GU provides an independent team based at the School of Medicine to perform trial data management, data monitoring, analyses, interpretation and reporting.

Participants and recruitment

An expression of interest was sent to all general practices on the Gold Coast (n=165) to invite them to participate in GCIC. General practices that indicated an interest received a visit from representatives of the program and the GCPHN. As a result, 15 general practices have signed on to deliver the proposed integrated model of care as part of GCIC (referred to as network general practices). The GCIC program will also engage at least another 15 general practices to provide usual care (referred to as non-network general practices); their involvement in GCIC will be limited to provision of aggregate (de-identified) service utilisation and clinical metrics data, which will be used for research questions within the population health outcomes component.

The network general practices have a total active (i.e., attended the practice three or more times in the past 2 years [25]) population of approximately 92,000 patients (about 17% of the Gold Coast population). Literature indicates that approximately 3 to 5% of the general practice population are complex 'high risk' patients having multiple chronic conditions with the highest risk of hospitalisation, and 10% to 15% are 'diagnosed but stable' with a known chronic condition and at medium risk of hospitalisation [26 27]. The following six processes are being used to identify high risk patients into the intervention group: (a) a manual trawl of hospital and general practice records to identify patients who in the past 12 months had ≥ 1 inpatient admissions in the past 3 years, ≥ 1 emergency department presentations in the past 3 years, ≥ 5 current medications, ≥ 20 general practice visits, and have a coded diagnosis of diabetes, chronic heart disease, chronic obstructive pulmonary disease, or chronic kidney disease [28], (b) purposely designed risk of hospitalisation score, (c) disease registers using risk of hospitalisation score plus clinical metrics beyond normal range, (d) medical registrar reviews of patients' records when admitted to hospital from network practices, (e) GP referrals for patients who were not captured in the manual risk stratification process, (f) direct referral by family members of patients requesting to be part of the program and who were assessed as amenable. For evaluation purposes eligibility will be restricted to the adult (≥ 18 years of age) high risk population living at a private home at the time of enrolment. Exclusion criteria include those with non-chronic conditions, maternity patients, residents of aged care facilities, residents of areas other than the Gold Coast, children < 18 years at the time of recruitment. Approximately 1,500 patients were recruited to form the intervention arm of GCIC between March 2015 and September 2016. Participants gave written informed consent to participate in GCIC, and separate consents to access their hospital, Medicare and pharmaceutical records (see Supplement A, B, and C).

Approximately 3,000 patients will be allocated to a matched control group (1:2 = intervention:control). These participants will be shortlisted in the GCHHS database, using the

following criteria: at least one hospital admission between July 2012 and June 2015, aged ≥ 18 years, resident of the Gold Coast area, not a patient of network general practices (i.e., not a participant of the intervention arm), not requiring an interpreter, not a resident of an aged care or nursing facility, and alive in June 2015. Following this initial identification, participants for the control group will be selected through propensity score matching on a range of demographic and chronic health characteristics. The control group will receive usual care. Participants of the control group will be contacted with an invitation to join the sub-group referred to as the active control group. The size of the active control group will be approximately 20% of the size of the control group, but allowing for some deaths and losses (by over-sampling by 25%) recruitment into the active control group will continue up to n = 750. These participants will provide informed written consent to allow access to their Medicare and pharmaceutical records, and will complete follow-up questionnaires.

Patients within the network general practices who have been diagnosed with at least one chronic condition and do not meet the 'high risk' criteria will be categorised as 'diagnosed but stable', and will be proactively managed through 'live' general practice based disease registers. These patients may transfer into the 'high risk' category and thus be eligible for holistic assessment, depending on the status of their condition.

Intervention

A key element of the GCIC program is the proactive management of participating patients. Participating patients will undertake a comprehensive holistic assessment which includes a review of previous medical information, identification of current service providers, and health assessments to develop a detailed summary of their social needs for building a jointly agreed and flexible shared care plan. The holistic assessment incorporates a health profile which determines the need for further medical, nursing, pharmacy and allied health assessments to identify relevant clinical metrics for on-going monitoring and exacerbation management. The care delivery team is centred on the GP as the primary care provider with assistance provided from both clinical and non-clinical staff depending on the patients requirements and care plan. The care plan is developed collaboratively by the GP and members of the multidisciplinary team at the GCIC coordination centre. A shared care record accessible by the patient and members of their nominated health care team is central to facilitating timely communication of care needs between multiple health care providers and to accommodate patients' needs and preferences for care.

Major features of GCIC include: (a) participant identification through risk stratification, (b) joint clinical governance between the GCHHS, primary care practitioners, and the social and community services sector to develop individual, flexible shared care agreements and plans, (c) proactive care

managed through general practice patient registers, to ensure all people requiring care receive it, not just those who seek it, (d) care aimed at assessing and treating the whole patient, not just one condition, through the operation of integrated care clinics staffed by multidisciplinary health professionals, (e) a single contact phone number for general practice staff, patients, families and carers (i.e. the coordination centre), (f) rapid access to additional home services, specialist teams within the GCHHS or other participating clinics, (g) enhanced information and communication systems between all services including shared electronic patient records to allow the care team to assist in the timely coordination of care, (h) care supported by protocols, clinical guidelines, care pathways, discharge and referral guidelines, (i) shared decision making between patient and health care team with family and carer involvement as required, (j) register of patients maintained and accessible to the Medical Assessment Units at GCHHS, (k) direct admission to the Medical Assessment Units or inpatient wards for selected complex patients.

Study data

Data for the evaluation will be collected from a number of sources, including general practices, GCHHS, Medicare, surveys and focus groups. Baseline data will be collected at recruitment, and follow-up observations will be collected at every 3-12 months until the end of 2018 (see Table 1 and Supplement D). An incentive (gift cards) will be introduced to mitigate the potential risk of low response rates from active control patients. Discontinuations are anticipated to be due to losses to follow-up (e.g., admission into a residential aged care facility, or moving out of area), and deaths. Data on deaths will be obtained from the GCHHS and the Queensland Government death register. Administrative data on losses to follow-up will continue to be collected through the GCHHS and GCPHN for discontinuations accessing local healthcare services. Identifiable participant information used for evaluation purposes [or for the evaluation] will be managed separately from de-identified observations, and stored in locked filing cabinets or password protected in GU's secure research data storage. A research review committee (MC, AMcM, PS) will have ultimate authority on access to the data and agreements. Any complaints or spontaneously reported adverse events will be reported to the primary contacts for the evaluation (PS, LW) and to the ethics committee.

Table 1. Data collection plan

Core evaluation of high risk patients

- characteristics (age, sex, home post code, health insurance status) at baseline [A,B,C]
- additional characteristics (education, income, employment, living arrangement, smoking, etc.) at baseline and 12 monthly follow-ups [A,B]
- surveys (quality of life using AQoL-4D [29], capability using ICECAP-O [30], social support using LSNS [31], assessment of care using PACIC-20 [32], satisfaction using SAPS [33]) at baseline and at 12 monthly follow-up intervals [A,B]
- qualitative data (service acceptability, etc.) at 12 month intervals (intervention patients), at 24 months (control patients), at 6 months, 18 months and completion (intervention staff) [D]
- qualitative data (implementation, acceptability, etc.) at baseline and 12 month intervals[E]
- hospital inpatient details (medical classifications, length of stay, cost) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- emergency presentations (priority, diagnoses, length of stay, cost, etc.) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- hospital outpatient visits (specialty, cost, etc.) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- hospital investigations (test type, cost, etc.) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- medications prescribed (type, class, cost, etc.) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- general practice visits (number, Medicare item numbers) [A]
- tests e.g., weight, HbA_{1c}, blood pressure, total cholesterol, etc. (result and date) [A]
- Medicare claim details (item numbers, date, cost, etc.) over 1 year prior to enrolment and 12 monthly follow-ups [A,B]
- PBS claim details (item numbers, date, cost, etc.) over 1 year prior to enrolment and 12 monthly follow-ups [A,B]
- mortality at 12 monthly follow-ups [A,B,C]
- staff cost at 12 monthly follow-ups
- population projections (age, sex, region, size, healthcare utilisation, staffing, etc.) for a time period of 2015-2018

Evaluation of population outcomes

- diabetes care and prevalence details (HbA_{1c}, foot, eye, blood pressure, lipid examinations, vaccinations, etc.) at baseline and 3 monthly follow-ups [F]
- chronic obstructive pulmonary disease care details (spirometry, vaccinations, etc.) at baseline and 3 monthly follow-ups [F]
- chronic kidney disease care details (eGFR, blood pressure, lipid examinations, vaccinations, medications, adherence to guidelines, etc.) at baseline and 3 monthly follow-ups [F]
- heart disease care details (blood pressure, lipid examinations, vaccinations, medications, adherence to guidelines, etc.) at baseline and 3 monthly follow-ups [F]
- survey of chronic illness care provision at baseline and at trial completion [G]

Trial evaluation at completion

- risk stratification, holistic assessment, services accessed, patient records and disease registries, governance and organisational arrangements, training and skills, etc.

A = intervention group; B = active control group; C = passive control group; D = focus group; E = general practice staff surveys; F = patients of all network and non-network general practices; G = network general practices; HbA_{1c} = glycated haemoglobin; PBS = Pharmaceutical Benefit Scheme; eGFR = estimated Glomerular Filtration Rate;

Power, detectable difference and sample size

The detectable difference in total healthcare cost per patient will be calculated based on: (a) the average number of intervention arm participants enrolled at each of the 15 network general practices (clusters) is approximately 107, (b) 15 non-network general practices are also clusters, (c) mean cost per participant (in the control group) over two years of AU$10,000 (Australian Dollars in 2015; standard deviation: AU$4,000), (d) coefficient of variance within each cluster of 0.47, (e) an intra-cluster correlation of 0.01, resulting in a difference of $644 at the 0.05 significance level which can be detected with 80% power. This approach is a simplification as there is no formula for clusters of unequal size or different number of clusters in the arms. Nevertheless, given the 1:2 ratio smaller differences could be detected.

A second detectable difference calculation will be undertaken at the participant level, assuming 78% hospitalisation rate per year in the control group and 20% of participants lost to follow-up in both groups: at the level of 90% power and 0.05 significance there will be adequate sample size to detect a 5% reduction in hospitalisation rates between the study groups.

For the analysis of health outcomes and patient satisfaction, 215 control participants will be sufficient to identify a mean difference in quality of life (measured using the AQoL-4D scored with utility weights from an Australian population on a scale of 0 to 1 [29]) of 0.05 compared to intervention arm participants with 80% power at the 0.05 level of significance. This calculation is based on a standard deviation of 0.20 for the intervention arm participants and 0.25 for the active control group participants. This active control group sample size allows for factors such as 55% attrition.

Quantitative analyses

An economic evaluation of GCIC will be undertaken from the perspective of the Queensland and Australian governments (i.e., the healthcare funders). This will present the additional cost per quality-adjusted life year gained. In addition, separate analyses will be undertaken around costs to the GCHHS and the Commonwealth Government to identify additional costs and cost-savings in the different sectors. Generalised linear models will be developed to allow us to model clinical and economic outcome factors, with dependent variables that follow a distribution that is Poisson (e.g., number of emergency department visits), exponential (e.g., length of hospital stay), normal or binomial. The functional form chosen for the analysis will be driven by the distributions of the data. Data will be analysed taking into account the time-series nature of the data. A series of regressions will be undertaken, with dependent variables of volume of services used, mortality, quality-adjusted life years, total costs to the health system and net health benefits. Where the dependent variable contains zeros, alternative forms of generalised linear models will be used such as Poisson,

negative-binomial or zero-inflated regression approaches. Diagnostics of regression models will be examined, e.g., residuals, influential values, etc. The incremental cost per quality-adjusted life-year gained (incremental cost-effectiveness ratio) will be calculated. Forward estimates (up to five years following the end of GCIC) will be undertaken to identify the likely costs and cost-offsets from generalising GCIC. The budget impact will be presented as annual budget costs for up to five years for the GCHHS and primary care sectors, for the Gold Coast, Queensland and the Australian population. Deterministic sensitivity analyses will be undertaken around key parameters with the greatest uncertainty.

Qualitative analyses

Qualitative evaluation data will be collected and analysed around the following topics: (a) patient experiences of care, (b) level of satisfaction with GCIC, (c) influences on continuity of care throughout the patient journey, (d) overall staff experience and level of satisfaction, (e) staff member engagement in change management, (f) strategy implementation, (g) most useful elements in achieving optimal patient outcomes, (h) modifications to GCIC to achieve process improvements to meet goals, (i) team culture influencing outcomes, and (j) change management. Data will be collected via focus groups and surveys: (a) intervention patient focus groups held at every 12 months, to gauge satisfaction and discuss recommendations, including randomly selected patients 60 minute group sessions, open ended questions, discussion of experiences and perceptions of GCIC, (b) control patient focus groups held at 24 months to examine experiences of 'usual care', including randomly selected patients from the active control group, (c) staff focus groups held at 6 months, 18 months and completion, to gauge satisfaction and discuss recommendations, including staff from each work group, 60 minute group sessions, and open-ended questions, (d) general practice staff surveys at baseline and 12 month intervals, (e) ongoing staff feedback through confidential online surveys, with monthly feedback reports, (f) historical documents analysis (to track program development), and (g) stakeholder feedback (through membership on *Strategic and Clinical Advisory Committee*). The focus group sessions will be recorded, transcribed and interpreted using content analysis. Qualitative data will be categorised for comparison with the quantitative findings to identify areas of congruence or issues to be addressed in the evaluation.

Strengths and limitations

While a strength of GCIC is the substantial number of participating patients, indicating that the evaluation will yield meaningful information to inform future service planning, GCIC is limited by the fact that it is currently a three year 'proof of concept' endeavour in one geographic location, and its expansion to other local health and hospital services will depend on the results of the economic evaluation. Additionally, there may be selection bias from (a) general practices who responded to

the letter of invitation to participate, with insufficient feedback to ascertain the reasons for non-participation, and (b) from the active control group who actively opt-in. Limitations in terms of patient choice should also be considered as all patients have a choice about where to seek health care as well as the fact that a chronic disease health population such as those enrolled in GCIC are closer to death than another population. Finally, duration of follow up may be a study limitation, however the three to four year follow up period is more than most clinical trials, and should give a good indication of the longer-term effectiveness of GCIC.

ETHICS AND DISSEMINATION

Ethics approval from GCHHS Human Research Ethics Committee (HREC) was received on 16th March 2015 as well as Griffith University HREC on 16th April 2015. The study is registered with the Australian New Zealand Clinical Trial Registry (registration number: ACTRN12616000821493) as a non-randomised controlled intervention study. Amendments to the protocol will be passed by the HREC and noted in resulting publications.

The results will be disseminated via yearly interim reports including a final report to the Commonwealth Department of Health and GCHHS board and executive as well as the wider GCHHS staff, and GU team members. It is expected that there will be several publications and conference presentations from this study. We anticipate that the evaluation findings will augment the evidence pertaining to the value of a whole-system integrated model of care in Australia.

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Authors' contributions

PS, GM, AMcM, MC conceived of the study, PS, GM, LW, AMcM, MC participated in design and coordination. PS, GM, LW, AMcM, MC participated in the preparation of the study protocol. All authors read and approved the final manuscript.

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Competing interests

None declared.

REFERENCES

1. Australia's health 2014. Canberra: Australian Institute of Health and Welfare, 2014.
2. Cottrill A. The need for an integrated approach to chronic disease management in Australia. Health Voices 2015(17):28-29.
3. Goss J. Projection of Australian health care expenditure by disease, 2003 to 2033. Canberra: Australian Institute of Health and Welfare, 2008.
4. *OECD Reviews of Health Care Quality: Australia 2015*. Paris: OECD Publishing, 2015.
5. Bywood PT, Jackson-Bowers E, Muecke S. Initiatives to integrate primary and acute health care, including ambulatory care services. Adelaide: Primary Health Care Research & Information Service, 2011.
6. National Healthcare Agreement 2012. Canberra: Council of Australian Governments, 2012.
7. The Reality of Life on the Gold Coast: Gold Coast Primary Care Partnership Council, 2009.
8. McCarthy D, Mueller K, Wrenn J. Kaiser Permanente: Bridging the Quality Divide with Integrated Practice, Group Accountability, and Health Information Technology. New York: The Commonwealth Fund, 2009.
9. Silow-Carroll S, Edwards JN. Intermountain Healthcare's McKay-Dee Hospital Center: Driving Down Readmissions by Caring for Patients the "Right Way". New York: The Commonwealth Fund, 2011.
10. Bodenheimer T. Coordinating Care - A Perilous Journey through the Health Care System. The New England Journal of Medicine 2008;**358**(10):1064-71.
11. Bodenheimer T, Berry-Millett R. Follow the Money - Controlling Expenditures by Improving Care for Patients Needing Costly Services. The New England Journal of Medicine 2009;**361**(16):1521-23.
12. Minkman MMN. The current state of integrated care: an overview. Journal of Integrated Care 2012;**20**(6):346-58.
13. Reiss-Brennan B, Briot PC, Savitz LA, et al. Cost and quality impact of intermountain's mental health integration program. Journal of Healthcare Management 2010;**55**(2):97-113.
14. Anderson GF, Ballreich J, Bleich S, et al. Attributes Common to Programs That Successfully Treat High-Need, High-Cost Individuals. American Journal of Managed Care 2015;**21**(11):E597-E600.
15. Jaén CR. Methods for evaluating practice change toward a patient-centered medical home. Annals of family medicine 2010;**8**(Suppl 1):S9-S92.
16. Reid RJ, Coleman K, Johnson EA, et al. The Group Health Medical Home At Year Two: Cost Savings, Higher Patient Satisfaction, And Less Burnout For Providers. Health Affairs 2010;**29**(5):835-43.
17. Alderwick H, Ham C, Buck D. Population health systems: Going beyond integrated care. London: The King's Fund, 2015.
18. Bramwell D, Checkland K, Allen P, et al. Moving Services out of hospital: Joining up General Practice and community services? London: Policy Research Unit in Commissioning and the Healthcare System, 2015.
19. Connor M, Kissen G. Tackling Whole-Systems Change: The Trafford Framework for Integrated Services. Journal of Integrated Care 2010;**18**(3):4-14.
20. Curry N, Ham C. Clinical and service integration: The route to improved outcomes. London: The King's Fund, 2010.
21. Fillingham D, Weir B. System leadership: Lessons and learning from AQuA's Integrated Care Discovery Communities. London: The King's Fund, 2014.
22. Bardsley M, Steventon A, Smith J, et al. Evaluating integrated and community-based care: How do we know what works? London: Nuffield Trust, 2013.
23. Integrated Health Services - What and Why? Geneva: World Health Organization, 2008.
24. Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ (Clinical research ed) 2013;**346**:e7586.

25. Standards for general practices (4th edition). East Melbourne: The Royal Australian College of General Practitioners, 2015.
26. Applications of the ACG System in the UK (White Paper): The Johns Hopkins University, 2014.
27. Singh D, Ham C. Improving Care for People with Long-Term Conditions: A Review of UK and International Frameworks. Birmingham: University of Birmingham, 2006.
28. Connor M, Day GE, Meston D. Successful linking of patient records between hospital services and general practice to facilitate integrated care in a hospital and health service in south-east Queensland. Australian health review : a publication of the Australian Hospital Association 2015;**40**(1):78-81.
29. Hawthorne G, Korn S, Richardson J. Population norms for the AQoL derived from the 2007 Australian National Survey of Mental Health and Wellbeing. Australian and New Zealand Journal of Public Health 2013;**37**(1):7-16.
30. Coast J, Flynn TN, Natarajan L, et al. Valuing the ICECAP capability index for older people. Social Science & Medicine 2008;**67**(5):874-82.
31. Lubben J, Blozik E, Gillmann G, et al. Performance of an Abbreviated Version of the Lubben Social Network Scale among Three European Community-Dwelling Older Adult Populations. The Gerontologist 2006;**46**(3):503.
32. Glasgow RE, Wagner EH, Schaefer J, et al. Development and Validation of the Patient Assessment of Chronic Illness Care (PACIC). Medical Care 2005;**43**(5):436-44.
33. Hawthorne G, Sansoni J, Hayes L, et al. Measuring patient satisfaction with health care treatment using the Short Assessment of Patient Satisfaction measure delivered superior and robust satisfaction estimates. Journal of Clinical Epidemiology 2014;**67**(5):527-37.

Griffith UNIVERSITY Gold Coast Health

Gold Coast Integrated Care Program Evaluation: Information sheet

A

26 May 2016

Good Afternoon,

At Gold Coast Hospital and Health Service and Griffith University, we are interested in YOUR health and wellbeing. A group of leading edge researchers are studying how your health condition is managed and how we can provide recommendations to the health community to ensure you and others suffering long term conditions can receive the best service possible. Could you read the information below and see whether you would be able to fill out some of this information to help us ensure that Gold Coast Hospital Health services are world class. We also have a little reward for you if you are able to participate.

If you do decide to become part of our study and send us your responses **within a fortnight of receiving this invitation**, you will go into a draw to win one of 250 **$20 gift card**s (redeemable at Coles, Myer, Coles Express, Target, Kmart, Liquorland, Vintage Cellars, 1st Choice Liquor Superstores and Officeworks). If you decide to complete the next round of surveys over the next 3 years, we will put your name in three further draws for Coles/Myer gift cards for **$100** (at 1 year), **$500** (at 2 years) and **$1,000** (at 3 years).

Please turn over the page to see what the study involves and the assurances we have put in place to guarantee your privacy as well as how to contact us for further information.

Sincerely

Professor Paul Scuffham

Principal Investigator

Gold Coast Integrated Care Program Evaluation

WHY IS THIS RESEARCH/EVALUATION BEING CONDUCTED?

The Gold Coast Hospital and Health Service and Griffith University researchers are undertaking a project to evaluate alternative models of health care provision. Your experiences with health care is important to us in understanding how to design the most effective health care for the elderly and those with chronic and complex conditions such as diabetes, chronic obstructive pulmonary disease, renal and cardiac disease.

The research/evaluation will evaluate Gold Coast Hospital and Health Service activities to determine the impact, quality and effectiveness of models of care provided by Gold Coast Health Services. First, we will determine whether the Gold Coast Health Service model of care reduces overall costs to the Gold Coast Hospital and Health Service for chronic and complex health conditions.

The secondary aims of this evaluation/research are to evaluate whether the model of care:

- reduces unplanned admissions to emergency departments, and hospital inpatient episodes;
- improves clinical service quality including process and outcomes for high risk patients;
- improves patient experience and satisfaction with care;
- improves staff experience and satisfaction with care.

WHAT INFORMATION ABOUT YOU WILL BE COLLECTED?

We are asking you to consent to us accessing two types of information. The first is routine data collected and stored in the Gold Coast Hospital and Health Service records. The second is to consent to us accessing your Medicare (MBS) and pharmaceutical (PBS) claims data (form C) from the Commonwealth Government Department of Human Services. The list below outlines the information we would like to evaluate:

- Number of hospital and emergency department admissions, diagnosis, length of stay in hospital, number of specialty visits – collected 3 years retrospectively and for the duration of the evaluation (from March 2015 – December 2018) from Gold Coast Hospital and Health Service records;
- MBS and PBS claims information collected by the Commonwealth Government Department of Human Services.

  - For MBS claims, this includes: claim details (date of service, the Medicare item number, item description), costs (the charge by the provider, the schedule fee, benefit paid, patient out-of-pocket cost, whether the service was bulk-billed), service provider information (date of referral, your GP's provider number, your GP's postcode, hospital indicator for hospital services billed to Medicare). Data collected excludes information on the purpose of the visit to a GP or any medical condition you may have;

  - For PBS claims, this includes: claim details (item description, date of supply, date of prescribing, item code and description), costs (patient category, patient contribution, net benefit) and prescribing details (prescriber number, class of medicine).
- Health outcomes including quality of life collected upon commencement into the program through a short survey (form D), and again at 12 month intervals until December 2018;
- Patient satisfaction – assessed by a survey (form D) upon commencement into the program, and then again at 12 month intervals until December 2018;
- Costs – collected from Gold Coast Hospital and Health Service records, which include the number of hospital and emergency department admissions.

WHAT WILL YOU BE ASKED TO DO?

You will be asked to fill out a consent form authorising the study access to your complete MBS and PBS data as outlined on the back of the consent (form C).

Medicare collects information on your doctor and specialists visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds this information confidentially.

You will also be requested to complete a written survey (Form D) – one now, and then three more will be posted to you in the mail for you to complete and return in a reply paid self-addressed envelope at 12, 24 and 36 month intervals. Each survey will take approximately 10-15 minutes to complete. If you require any assistance in completing the questionnaire, please contact a member of the research team Lauren Ward on 1300 004 242 for assistance.

WHAT ARE THE EXPECTED BENEFITS OF THIS EVALUATION?

It is expected that this research will increase clinicians' and policy makers' understanding of how best to coordinate care for people with complex and chronic conditions, so as to provide the most effective healthcare. Information and data will be used to provide evidence of the impact of the care activities and provide an informed basis for review and future planning of services.

HOW WILL THE CONFIDENTIALITY OF MY INFORMATION BE KEPT?

The research team will gather information from Gold Coast Hospital and Health Services records, and MBS/PBS data from the Commonwealth Government Department of Human Services. Your personal information such as address, telephone number and date of birth, as well as questionnaire responses will be stored in a locked filing cabinet in a secure facility at Griffith University. Your information will not be shared with a third party unless informed consent is given. The collected information will be entered into a computerised database which will be protected by password. No identification of individuals will be published. Consent forms will be kept securely in a locked cabinet at Griffith University for seven years and then destroyed.

ARE THERE ANY RISKS TO ME?

There are no significant risks associated with participation in the evaluation/research project. All information will be de-identified and your identity will not be revealed to other parties.

YOUR PARTICIPATION IS VOLUNTARY

Involvement in this evaluation/research project is voluntary. If you choose not to participate it will not disadvantage you in any way and will not affect your relationship with the Gold Coast Hospital and Health Service, any health staff, your GP or the care provided to you. At any point you are free to withdraw from the study by contacting the research team (Lauren Ward on 1300 004 242 or *l.ward@griffith.edu.au*) and completing a *Revocation of Consent* form.

THE ETHICAL CONDUCT OF THIS RESEARCH

Gold Coast Hospital and Health Service and *Griffith University* conduct research in accordance with the *National Statement on Ethical Conduct in Human Research*. If potential participants have any concerns or complaints about the ethical conduct of the research project they should contact the Research Ethics Coordinator on (07) 5687 3879 or email *GCHEthics@health.qld.gov.au*.

FEEDBACK TO YOU

At the completion of the study it is anticipated that the findings may be published in a research journal and presented at scientific conferences. Any publications and presentations would include de-identified data only and in no way identify individuals. A summary of the findings of the evaluation will be made available to you upon request.

Griffith UNIVERSITY Gold Coast Health

Gold Coast Integrated Care Program Evaluation: Information sheet

A

PRIVACY STATEMENT

The information collected is confidential and will not be disclosed to third parties. Any information collected will be used for this project only. Anonymity will at all times be safeguarded. For further information consult the University's Privacy Plan at *http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan* or telephone (07) 3735 5585.

PRINCIPAL INVESTIGATORS

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Griffith University and
Gold Coast Hospital and Health Service
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QUESTIONS/FURTHER INFORMATION

Should you have any questions or comments about this evaluation at any point in time, please contact the following evaluation project representative: Lauren Ward at *l.ward@griffith.edu.au* or 1300 004 242.

PLEASE FILL OUT, SIGN AND RETURN FORMS B, C AND D IN THE REPLY-PAID ENVELOPE PROVIDED.

THANK YOU.

Please complete this form and return

Griffith UNIVERSITY Gold Coast Health

Gold Coast Integrated Care Program Evaluation: Consent form

B

PARTICIPANT CONSENT FORM

I have read and understood the information sheet on the evaluation project. I have had the opportunity to ask any questions I need to understand the project and agree to participate, and received satisfactory answers to my questions. I understand that taking part in the consultations is voluntary and that I can withdraw at any time without disadvantaging me or affecting my relationship with the Gold Coast Hospital and Health Service, health staff and or my GP (refer to *Revocation of Consent* form). I understand that if I decide to withdraw for any reason, I will be withdrawing only from the research, and will still be provided care for my condition through the Gold Coast Hospital and Health Service. I understand that individuals' health information and contributions will not be identified in any report or publication. I understand that if I have any questions relating to the collection of my health information, surveys, and/or interviews/focus groups I may contact Lauren Ward at *l.ward@griffith.edu.au* or 1300 004 242. Alternatively I can contact the Research Ethics Coordinator at Gold Coast Hospital and Health Service on (07) 5687 3879 or email *GCHEthics@health.qld.gov.au*.

I, _____ agree to take part in this study on health condition management.

Signature _____ **Date** _____

People often move address and sometimes it is difficult for the study researchers to make contact again. In this case the following friend or relative of mine who lives at a different location can be contacted:

Name/relationship/phone: _____

Signed on behalf of participant by (full name and signature) _____

Date: _____ Circle where appropriate: *Power of attorney* / *Guardianship order* / *Statutory Health Attorney*. Please also attach supporting evidence.

Please complete this form and return

Griffith UNIVERSITY

Gold Coast Health

Gold Coast Integrated Care Program Evaluation: MBS/PBS consent

C

PARTICIPANT CONSENT FORM

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the Gold Coast Integrated Care Program Evaluation Study.

Important information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the Gold Coast Integrated Care Program Evaluation Study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth (DD/MM/YYYY): ☐☐☐☐**1 9**☐☐

2. Medicare card number: ☐☐☐☐ ☐☐☐☐☐ ☐

Individual Reference Number: ☐

3. Permanent address:

_____

Postal address (if different to above):

_____

☐☐☐☐☐☐

SURVEY C

Griffith UNIVERSITY Gold Coast Health

Gold Coast Integrated Care Program Evaluation: MBS/PBS consent

C

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

- ☐ Medicare claims history, OR
- ☐ PBS claims history, OR
- ☐ Medicare & PBS claims history

for the period* 01/01/2014 to 31/12/2024 to the Gold Coast Integrated Care Program Evaluation Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), therefore the consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature)

Dated: _____ OR

6. Signed on behalf of participant by _____ (full name)

_____ (signature)

Dated: _____

- ☐ Parent (where the participant is under the age of 14 years old*)
- ☐ Legal guardian** (where the participant is under 14 years old*)
- ☐ Power of attorney**
- ☐ Guardianship order**

* Once a young person has turned 14 years old they must consent to their own information being released.

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Date of Processing	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	03/05/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	23/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	999999A		2300		N	1
999999A	999999A	20/04/09	2300	2302	N	2

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999	2530

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.
** Under co-payments can now be provided for data after 1 June 2012

SUPPLEMENT A - Data collection and sampling plan

Objective	Research question	Outcome measure	Data source	Schedule
Reduced overall costs to the GCHHS for high risk complex and comorbid conditions	1. Does the program reduce overall costs of delivering health care services for patients with complex needs? 2. What is the cost effectiveness of the GCIC program?	MBS costs: - benefit paid - patient contribution	Commonwealth Government, Department of Human Services	data range: 01/01/2014 to 31/12/2018
		PBS costs (for each class of medication): - patient contribution - net benefit		
		Emergency Department costs per episode	GCHHS	3 years retrospective and 12 monthly
		Inpatient costs per episode (based on AR-DRGs and costed using the National Efficient Price weights)		
		Outpatient visit costs (using the Tier 2 weights from the National Efficient Price)		
		Investigation costs incl. radiology and pathology		
		Quality of life (AQOL-4D)	holistic assessment	baseline and 12 monthly
		GCIC staff costs	GCIC human resources	annually
Improved health outcomes	1. Does the program improve health outcomes for high risk patients with complex needs? 2. What is the relationship between patient outcomes and clinical and demographic characteristics?	Quality of life (AQOL-4D)	patient questionnaire	baseline and 12 monthly
		Mortality	GCIC/GCHHS	annually
		Capability/wellness (ICECAP-O-5)	patient questionnaire	baseline and 12 monthly
		Social support (LSNS-6)		
		Number of falls		
		Blood pressure, Body Mass Index, smoking status and history, condition specific indicators (e.g. HbA1c, lipids) (intervention group only)	holistic assessment, GPr and GCIC data (Shared Care Record, Pencat)	baseline and 12 monthly
	Does the program change the proportion of costs shared by the	Number of Emergency Department attendances	GCHHS	3 years retrospective and 12 monthly
		Number of inpatient admissions (unplanned / emergency)		
		Number of GP visits	GPr data (Pencat)	

Objective	Research question	Outcome measure	Data source	Schedule
	primary and secondary care sectors?	Number of outpatient visits by specialty (new and review)	GCHHS	
		Analysis of MBS/PBS data according to primary and secondary care	Commonwealth Government, Department of Human Services	data range: 01/01/2014 to 31/12/2018
Reduced number of potentially avoidable hospital admissions	Does the program reduce potentially avoidable hospital admissions and or presentations and length of stay?	Number of Emergency Department attendances	GCHHS	3 years retrospective and 12 monthly
		Number of inpatient admissions (unplanned / emergency)		
		Hospital inpatient length of stay		
		Number of outpatient visits by specialty (new and review)		
		Number and type of investigations e.g. radiology, pathology		
Improved patient satisfaction	Does the program improve patient experiences and satisfaction with care?	Patient satisfaction (SAPS-7)	questionnaire	baseline and 12 monthly
		Assessment of chronic illness care (PACIC-20)		
		Specifically designed open-ended questions (incl. acceptability of services) (qualitative method)	Focus Groups	12 month intervals(intervention group); at 24 months (control group)
Improved staff satisfaction	Does the program improve clinician experience and satisfaction?	Specifically designed GPr staff questions (incl. referral processes, communication with service providers) (intervention group only)	surveys (GPr nurse, GP, Practice Manager)	baseline and 12 monthly
		Specifically designed open ended questions (incl. barriers & enablers to implementation, change management strategies, acceptability of program, confidence) (qualitative method) (GCIC staff only)	Focus Groups	6 months, 18 months, completion
To provide projected estimates of health service utilisation from generalising the program for	What are the projected changes in future numbers of admissions, emergency attendances, GP visits and other healthcare	Population projections: - age - gender - region	Australian Bureau of Statistics population trends	data range: 01/01/2014 to 31/12/2018
		Differences in rates of healthcare utilisation between intervention and control groups: - Emergency Department attendances	GCIC	

Objective	Research question	Outcome measure	Data source	Schedule
the Gold Coast and other metropolitan areas of Australia	utilisation based on generalising the GCIC program for the Gold Coast and other metropolitan areas of Australia for patients with complex needs over the five years from the end of the pilot?	- inpatient admissions - GP visits - outpatient attendances		
To provide financial estimates for health budgets from generalising the program for the Gold Coast and other metropolitan areas of Australia	What are the forward estimates for the GCIC program for the Gold Coast, and expected costs of adapting the GCIC program to other metropolitan areas of Australia for patients with complex needs?	Population projections: - age - gender - region	Australian Bureau of Statistics population trends	data range: 01/01/2014 to 31/12/2018
To estimate any changes in the mix of the healthcare workforce required to provide integrated care should it be rolled out across the Gold Coast,	What are the additional types of staff requirements (including training needs) and staff displaced from generalising the intervention across the Gold Coast and other metropolitan areas of Australia?	- potential target population size - staffing ratios per participant - changes in healthcare utilisation across the different sectors and services	- Australian Bureau of Statistics population trends - GCIC - intervention staff needs assessment - estimates of changes in hospital and primary care services	data range: 01/01/2014 to 31/12/2018

Objective	Research question	Outcome measure	Data source	Schedule
Queensland and/or Australia				
Improved clinical service delivery according to guidelines	To what extent does the program improve clinical service delivery according to guidelines?	Measures relating to diabetes annual cycle of care. Process outcomes: - proportion of patient population with HbA_{1c} tests completed - proportion of patient population with foot exams completed - proportion of patient population with eye examinations completed - proportion of patient population with blood pressure recorded - proportion of patient population with lipids tests completed - proportion of patient population with microalbuminuria tests completed - proportion of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded. Clinical outcomes: - proportion of patient population with $HbA_{1c} \leq 7\%$ - proportion of patient population with blood pressure <130/80 - proportion of patient population with total cholesterol <4mmol/L - proportion of patient population with LDL cholesterol <2mmol/L - proportion of patient population with microalbuminuria <2.5/3.5 mg/mmol (men/women)	GPr & GCIC data (Shared Care Record, Pencat)	3 month intervals
		Measures relating to chronic obstructive pulmonary disease. Process outcomes: - proportion of population with spirometry completed - proportions of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded - proportion of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded.		

Objective	Research question	Outcome measure	Data source	Schedule
		Clinical outcomes: - proportion of patient population with current influenza vaccination - proportions of patient population with current pneumococcal vaccination - proportion of patients whom are non-smokers.		
		Measures relating to chronic kidney disease best practice guidelines. Process outcomes: - proportion of patient population with blood pressure recorded - proportion of patient population with eGFR recorded - proportion of patients with ARB or ACE medication prescribed - proportion of population with ACR recorded - proportion of patient population with lipids tested - proportion of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded. Clinical outcomes: - proportion of patient population with blood pressure ≤140/90 mmHg - proportion of patient population with lipids <4.0 mmol/L total, <2.5 mmol/L LDL		
		Measures relating to heart disease best practice guidelines. Process outcomes: - proportion of patient population with lipid lowering medication prescribed - proportion of patient population with anti-hypertensive medication prescribed - proportion of patient population with blood pressure recorded - proportion of patient population with lipids tested - proportion of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded. Clinical outcomes:		

Objective	Research question	Outcome measure	Data source	Schedule
		- proportion of patient population with blood pressure ≤140/90 - proportion of patient population with LDL cholesterol <2mmol/L		
		Measures relating to service delivery (process outcomes): - number of GP management plans and reviews - number of Team Care Arrangements and reviews		
		Assessment of chronic illness care (ACIC-28) (intervention group only)	GP surveys	Baseline and completion
To examine implementation fidelity	1. To what extent was the program implemented as intended? 2. How successfully were the strategies of the program implemented and conducted as planned?	Completion of risk stratification of patients: - method of patient identification (collaboration with GP, algorithm tool). Holistic assessments: - number completed - model of holistic assessment (incl. completed by whom) - type of risk assessment tools completed.	- risk stratification point criteria - review of GCIC protocols and manuals - holistic assessment monitoring database (daily reports) - GCIC quality audits	
To examine implementation determinants	1. What were the factors that facilitated and / or impeded program implementation? 2. Which elements of the program were seen to be most useful by staff and patients which contributed to outcomes?	Risk stratification: - number of patients identified - patient characteristics (incl. demographics). Services accessed: - number and type of services used e.g., allied health, home care, brokered services, hospital services. Holistic assessment outputs: - number of patient goals created - number of referrals - number of actions - number of live care plans. Shared Care Record: - number and type of consumer views on acceptability, usefulness, efficiency (client, GP, specialist). Disease registries: - number of disease registries implemented in GPrs	- administrative records - daily reports - holistic assessment monitoring database (daily reports) - staff focus groups - staff surveys and diaries - administrative data for use of components (revealed preferences)	

Objective	Research question	Outcome measure	Data source	Schedule
		- number of patients on disease registry. Governance arrangements: - leadership stability - organisational capacity - adequacy of infrastructure, staff arrangement, partnerships, resources. Change management strategies Staff and skills training: - GCIC staff - GPr staff - other care providers. Program reach: - numbers and timeframe of GPr on-boarding - number of patients enrolled.		
Improved continuity of care	To what extent does the program improve continuity of care?	ACIC survey on management of chronic conditions in relation to the chronic disease model (network GPrs only)	questionnaire	baseline and at program completion
		Patients perspectives on continuity and coordination of care (qualitative method)	Focus Groups	12 month intervals (intervention group), 24 months (control group)

GCHHS = Gold Coast Hospital and Health Service; GCIC = Gold Coast Integrated Care; MBS = Medicare Benefits Schedule; PBS = Pharmaceutical Benefits Scheme; AR-DRG = Australian Refined Diagnosis Related Groups; AQOL-4D = Assessment of Quality of Life questionnaire; ICECAP-O-5 = Index of Capability for older people; LSNS-6 = Lubben Social Network Scale; GP = general practitioner; GPr = general practice; Pencat = Classic Clinical Audit Tool; SAPS-7 = Short Assessment of Patient Satisfaction questionnaire; PACIC-20 = Patient-Assessed Chronic Illness Care questionnaire; HbA_{1c} = glycated haemoglobin; LDL = low-density lipoprotein; eGFR = estimated glomerular filtration rate; ARB = angiotensin II receptor blocker; ACE = angiotensin converting enzyme; ACR = albumin-to-creatinine ratio; ACIC-28 = Assessment of Chronic Illness Care; [a] out of pocket costs are reported for MBS/PBS data only, and calculations exclude private health insurance, travel costs, loss of income and other non-healthcare costs;

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 10
	2b	All items from the World Health Organization Trial Registration Data Set	Title page, pages 2-4, 7, 8, 10
Protocol version	3	Date and version identifier	Title page
Funding	4	Sources and types of financial, material, and other support	Page 10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page, page 10
	5b	Name and contact information for the trial sponsor	Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 1
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Page 3
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 1

	6b	Explanation for choice of comparators	Page 4-5
Objectives	7	Specific objectives or hypotheses	Page 3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 2-3
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 5
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 6
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 5
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 5
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 3, Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 6
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 4
Methods: Assignment of interventions (for controlled trials)			

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Table 1
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 6
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	-
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 8
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 8
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	-

Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 3
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 10
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 6
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	-
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 10
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 4
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 6
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 10
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 6

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 10
	31b	Authorship eligibility guidelines and any intended use of professional writers	-
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	-
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary Files
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Evaluation of Gold Coast Integrated Care for patients with chronic disease or high-risk of hospitalisation through a non-randomised controlled clinical trial: a pilot study protocol.

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TITLE PAGE

Title of the article

Evaluation of Gold Coast Integrated Care for patients with chronic disease or high-risk of hospitalisation through a non-randomised controlled clinical trial: a pilot study protocol.

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ABSTRACT

Introduction

Chronic diseases are the leading cause of illness, disability and death in Australia. The prevalence and associated health expenditure are projected to soar. There is no 'whole system' approach to healthcare in Australia. To overcome this fragmentation, the Gold Coast Hospital and Health Service (GCHHS) is developing a new model known as Gold Coast Integrated Care (GCIC). To evaluate GCIC a four-year pilot trial commenced in March 2015. This protocol paper describes the evaluation of GCIC.

Methods and analysis

A pragmatic non-randomised controlled clinical trial is conducted to test the hypothesis that GCIC will result in improved health and well-being at no additional cost to the healthcare system. Using a mixed methods approach, impact, outcome, and process evaluations will be undertaken to assess the effectiveness and acceptability, including the balance of costs between primary and public secondary care sectors, staff and training requirements, clinical service delivery, and trial implementation.

Fifteen general practices have agreed to deliver GCIC. One thousand five hundred of their adult patients with treated chronic diseases, high-risk of hospitalisation or healthcare utilisation were recruited to the intervention arm. Approximately 3,000 patients not associated with the participating general practices were identified as controls using propensity matching which will provide service utilisation and disease data for usual care.

Baseline data and follow-up observations are collected annually until the end of 2018. Quantitative analyses will measure patient health care costs, utilisation of health services, and health outcomes, and general practice clinical service delivery according to clinical guidelines (number of foot exams, HbA1c tests). Qualitative analyses will focus on patient and staff experiences, satisfaction, engagement and implementation of the program as planned.

Ethics and dissemination

Approval received from the GCHHS on the 16th March 2015, and from Griffith University on the 16th April 2015. The study is registered with the Australian New Zealand Clinical Trial Registry (ACTRN12616000821493). Findings will be communicated via yearly reports to funding bodies and scientific publications.

INTRODUCTION

Chronic diseases were the leading cause of illness, disability and death in Australia in 2011 (1, 2), and their relative burden on the health system increases over time. For example, health expenditure on the most prevalent chronic condition (type 2 diabetes) is projected to increase 520% from a 2002-03 level by 2032-33, while the increase in total health expenditure is expected to be 189% over the same period, mainly due to two demographic growth factors: population ageing and the increase in population (3). The majority of chronic disease health dollars are allocated to hospital service for admitted patients, out-of-hospital services, medications and dental services (1). A major problem in managing chronic disease services is the fragmentation of the Australian health care system, attributed to the complex interplay of health funding and division of responsibilities between the federal, state and local governments for both private and public health services. Fragmentation is also pervasive between general practice and acute care, creating discontinuities in service provision (4, 5).

In Australia, there are numerous national and state initiatives and programs aimed at linking sectors of the healthcare system; however, no consistent 'whole-system' approach to integrating services between primary health care and other health care services exists (6). A national agreement between all Australian federal, state and territory governments in 2012 supported an integrated approach to promote healthy lifestyles, prevention of illness and injury, and diagnosis and treatment across the continuum of care, as a means to improve health outcomes for all Australians and the sustainability of the Australian health system (7). These improvements are particularly relevant for the Gold Coast (Queensland, Australia) population, where almost one-third of the population will be over 55 years of age, and the number of people aged over 85 years will nearly double by 2021 compared to the 2006 level (8). In the context of this national agreement and growing burden of disease, the Gold Coast Hospital and Health Service (GCHHS) and the Gold Coast Primary Health Network (GCPHN) and Queensland Health in partnership with Griffith University (GU), led the development of a new model of care. To evaluate this new model of service delivery a four-year pilot trial, referred to as Gold Coast Integrated Care (GCIC), commenced in March 2015 with the establishment of a coordination centre to coordinate health services linking the patient and general practice with all other relevant health and hospital services. Significant funding was secured from Queensland Health and the GCHHS, with a contribution from the GCPHN. Additional funds were received from the Australian Government Department of Health to perform this evaluation study. None of the funding bodies had or will have an input in the design and management of the study, in the analysis and interpretation of data, or in the writing and submission of reports and publications. The GCHHS and the GCPHN are providing administrative data for analysis for the evaluation.

The design principles of GCIC are based on that of large-scale whole system models such as Kaiser Permanente (8) and Intermountain Healthcare (9) in the USA. A review of these American models highlights the merits of integrated care programs that focus on high-impact health conditions whilst situating primary care at the centre of chronic illness management, making it "*accessible, continuous, comprehensive, coordinated, and delivered in the context of family and the community*" (8, 10-13).

Common attributes of successful integrated care programs targeting individuals with chronic and complex conditions include the ability to stratify and target high-cost, high need individuals, fostering effective interactions with patients providing self-management support, and multidisciplinary care pathways organised through a single point-of-entry whilst creating an environment for successful leadership at all levels (12, 14). The patient-centred medical home described by Jaén et al is an example of this type of approach which acts as a coordination centre for patients and their families, providing easy access to first-contact and comprehensive care where the patient is an active participant in their own health and well-being (15). A two year evaluation of this model in the USA showed improvements across both patient and health service outcomes with improved patient experience, quality, fewer emergency department and hospital visits, and lower costs (16).

In the United Kingdom (UK), health leaders, policy makers and researchers have a long established interest in integrated care with the decentralised capitated health service model rather than the fee for service framework in Australia. Lessons from UK programs including the Integrated Care Pilots and Trafford highlight the importance of strong leadership and collective governance with co-location of multidisciplinary teams within an integrated care framework (17-21). Additionally, researchers emphasise the need for communication, exploiting linked data sets including general practice data, and shared information technology and health record systems (18, 22).

The GCIC program was founded on the notion that care coordination, planning and patient advocacy is best achieved in collaboration with general practitioners (GPs), supported by specialists, multidisciplinary teams, non-government organisations and private allied health providers, so that patients get the care they need, when they need it, in ways that are user friendly, achieve the desired results and provide value for money (23). The overarching goal of GCIC is to proactively manage patients with chronic and complex conditions, in close collaboration with GPs, to reduce presentations to emergency departments, improve the capacity of specialist hospital outpatient departments, and decrease planned and unplanned hospital admission rates, all of which should be cost effective for the GCHHS. This protocol paper describes the evaluation of the GCIC program, a four year pilot program, guided by the SPIRIT recommendations (24).

METHODS AND ANALYSIS

Study design

The evaluation study is a pragmatic non-randomised controlled clinical trial to test the primary hypothesis that the GCIC will result in improved health and well-being at no additional cost to the healthcare system. The primary unit of analysis will be the individual, while the general practices and healthcare work force will be the secondary units of analysis.

Using a mixed methods approach; impact, outcome, and process evaluations will be undertaken to assess the overall effectiveness and acceptability of GCIC. The evaluation includes two components: a core evaluation of high-risk patients and a population health outcomes component. The following research questions were defined. *Co-Primary questions:* 1. Did the GCIC reduce overall costs of delivering health care services to the GCHHS for high-risk patients with complex needs compared to usual care? 2. Did the GCIC improve health outcomes for high-risk patients with complex needs compared with usual care? *Outcome evaluations*. (a) Did GCIC change the proportion of costs shared by the primary and secondary care sectors? (b) Did GCIC reduce potentially avoidable hospital admissions, emergency presentations and length of stay? (c) To what extent did GCIC improve experiences and satisfaction with care for both patients and clinicians? (d) What was the relationship between patient outcomes and clinical and demographic characteristics? (e) What was the cost effectiveness of GCIC? *Impact evaluation.* a) What are the costs and benefits of generalising the GCIC model to other parts of Australia? (b) What are the projected changes in numbers of hospital admissions, emergency presentations, general practice visits and other healthcare utilisation? (c) What is the staffing requirement (including training needs) and displacement from generalising GCIC? *Process evaluation*. (a) Did GCIC improve clinical service delivery according to guidelines? (b) To what extent was GCIC implemented as intended? (c) Which elements of GCIC were seen to be most useful by staff and patients respectively? (d) To what extent did GCIC improve continuity of care?

Governance arrangements for GCIC include a managing director and a senior management team referred to as the *Executive Management Team*, which provides strategic leadership and management of the overall processes and business operations as well as strategy, budget, program structure, and administration. A *Strategic and Clinical Advisory Committee* has been appointed for providing clinical oversight and strategic direction. An *Evaluation Steering Committee* acts as the peak advisory body for the evaluation study, providing oversight and advice to the team to ensure the continued quality and credibility of evaluation activities including facilitating access to administrative data and ensuring the evaluation is on track. Individuals responsible for the design and implementation of GCIC are employees of the GCHHS and other organisations (excluding the

GU). GU provides an independent team based at the School of Medicine to perform trial data management, analyses, interpretation and reporting.

Participants and recruitment

An expression of interest was sent to all general practices on the Gold Coast (n=165) to invite them to participate in GCIC. General practices that indicated an interest received a visit from representatives of the program and the GCPHN. As a result, 15 general practices have signed on to deliver the proposed integrated model of care as part of GCIC (referred to as network general practices). The GCIC program has also engaged the 23 Gold Coast general practices that had a data sharing arrangement with the PHN, and were available to act as practice controls. These 'non-network' practices were approached in person, and invited to provide written consent to be involved in the study. Their involvement in GCIC is limited to providing aggregate (de-identified) service utilisation and clinical metrics data, which will be used to compare population health outcomes with the network practices. The larger sample size of non-network practices is an attempt to overcome the potential bias due to systematic differences between practices, including PHN chronic disease interventions.

The network general practices have a total active (i.e., attended the practice 3 or more times in the past 2 years (25)) population of approximately 92,000 patients (about 17% of the Gold Coast population). Literature indicates that approximately 3 to 5% of the general practice population are complex high-risk patients having multiple chronic conditions with the highest risk of hospitalisation, and 10% to 15% are 'diagnosed but stable' with a known chronic condition and at medium risk of hospitalisation (26, 27). Eligibility for the program included GCHHS patients at high-risk of hospitalisation identified through the following six processes: (a) a manual trawl of hospital and general practice records to identify patients who in the past 12 months had ≥ 1 inpatient admissions in the past 3 years, ≥ 1 emergency department presentations in the past 3 years, ≥ 5 current medications, ≥ 20 general practice visits, and have a coded diagnosis of diabetes, chronic heart disease, chronic obstructive pulmonary disease, or chronic kidney disease (28), (b) purposely designed risk of hospitalisation (RoH) score within the next 12 months based on 58 predictor variables covering medical history, demographics and prior healthcare utilisation from both general practice and hospital data. Patients with a RoH score of 70% and higher were identified and their details sent to the GP to consider for enrolment to the program, (c) disease registers using risk of hospitalisation score plus clinical metrics beyond normal range, (d) medical registrar reviews of patients' records when admitted to hospital from network practices, (e) GP referrals for patients who were not captured in the manual risk stratification process, (f) direct referral by family members of patients requesting to be part of the program and who were assessed

as amenable. For evaluation purposes eligibility was restricted to the adult (≥ 18 years of age) high-risk population at the time of enrolment. Exclusion criteria include those with non-chronic conditions, maternity patients, residents of aged care facilities, residents of areas other than the Gold Coast, children < 18 years at the time of recruitment. Approximately 1,500 patients were recruited to form the intervention arm of GCIC between March 2015 and September 2016. Participants gave written informed consent to participate in GCIC, and separate consents to access their hospital, Medicare and pharmaceutical (MBS/PBS) claims records (see Supplement A, B, and C). Patients within the network general practices who have been diagnosed with at least one chronic condition and do not meet the high-risk criteria are categorised as 'diagnosed but stable', and are proactively managed through 'live' general practice based disease registers. These patients may transfer into the high-risk category and thus be eligible for holistic assessment, depending on the status of their condition.

Approximately 3,000 patients with similar characteristics at baseline to patients in the intervention group have been allocated to a matched control group (1:2 = intervention:control) through a two-step process: initial identification and propensity score matching. The aim was to achieve the best possible match, however, restriction to patient level hospital data has limited the evaluation team's ability to match on all criteria used for identifying the intervention group. Initial identification of potential control group members was completed according to the following hospital criteria:

- Diagnosis of at least one ICD-10 block (n = 108) marked as primary or secondary reason for admission
- Any occasion of service at GCHHS between 01/07/2012 – 30/06/2015
- Aged ≥ 18 years
- Resident of the Gold Coast region
- Not a patient of network general practices
- Not requiring an interpreter
- Not a resident of an aged care or nursing facility
- Alive in June 2015

Following the initial identification, the research team identified and selected control group participants through *propensity matching*, for inclusion in the evaluation study.

Propensity scores were calculated using a probit model, where the covariates included age, gender, number of outpatient appointments, number of emergency presentations, number of hospitalisations, length of stay at emergency, length of stay in hospital, and a number of binary hospitalisation history variables (to indicate where the primary reason of admission was one of 108 predetermined ICD-10 blocks of interest). Matching on propensity scores was completed using the 1:1 nearest neighbour matching without replacement method.

Participants of the control group have been contacted with an invitation to join the sub-group referred to as the active control group. The size of the active control group is approximately 20% of the size of the control group, but allowing for some deaths and losses (by over-sampling by 25%) recruitment into the active control group reached n = 750. These participants have provided informed written consent to allow access to their MBS/PBS claims records, and will complete follow-up surveys annually. Patients who did not consent to participate as an active control have been allocated to a passive control group with the purpose of tracking hospital utilisation data only. Figure 1 presents the total recruited cohort numbers. Public Health Act approval (RD005624) was received from the Queensland Government Department of Health for access to confidential health information to undertake the matching process and data analysis.

[Figure 1 about here]

Intervention

A key element of the GCIC program is the proactive management of participating patients. Participating patients undertook a comprehensive holistic assessment which included a review of previous medical information, identification of current service providers, and health assessments to develop a detailed summary of their social needs for building a jointly agreed and flexible shared care plan. The holistic assessment incorporates a health profile which determines the need for further medical, nursing, pharmacy and allied health assessments to identify relevant clinical metrics for on-going monitoring and exacerbation management. The care delivery team is centred on the GP as the primary care provider with assistance provided from both clinical and non-clinical staff depending on the patients requirements and care plan. The care plan is developed collaboratively by the GP and members of the multidisciplinary team at the GCIC coordination centre. A shared care record accessible by the patient and members of their nominated health care team is central to facilitating timely communication of care needs between multiple health care providers and to accommodate patients' needs and preferences for care.

Major features of GCIC include: (a) participant identification through risk stratification, (b) joint clinical governance between the GCHHS, primary care practitioners, and the social and community services sector to develop individual, flexible shared care agreements and plans, (c) proactive care managed through general practice patient registers, to ensure all people requiring care receive it, not just those who seek it, (d) care aimed at assessing and treating the whole patient, not just one condition, through the operation of integrated care clinics staffed by multidisciplinary health professionals, (e) a single contact phone number for general practice staff, patients, families and carers (i.e. the coordination centre), (f) rapid access to additional home services, specialist teams within the GCHHS or other participating clinics, (g) enhanced information and communication systems between all services including shared electronic patient records to allow the care team to assist in the timely coordination of care, (h) care supported by protocols, clinical guidelines, care pathways, discharge and referral guidelines, (i) shared decision making between patient and health care team with family and carer involvement as required, (j) register of patients maintained and accessible to the Medical Assessment Units at GCHHS, (k) direct admission to the Medical Assessment Units or inpatient wards for selected complex patients.

Study data

Data for the evaluation are being collected from a number of sources, including general practices, GCHHS, Medicare, surveys and focus groups. Baseline data were collected at recruitment, and follow-up observations are being collected at every 3-12 months until the end of 2018 (see Table 1 and Supplement D). An incentive (gift cards) was introduced to mitigate the potential risk of low response rates from active control patients. Discontinuations are anticipated to be due to losses to follow-up (e.g., admission into a residential aged care facility, or moving out of area), and deaths. Data on deaths is obtained from the GCHHS and the Queensland Government death register. Administrative data on losses to follow-up are collected through the GCHHS and GCPHN for discontinuations accessing local healthcare services. Identifiable participant information used for evaluation is managed separately from de-identified observations, and stored in locked filing cabinets or password protected in GU's secure research data storage. A research review committee (MC, AMcM, PS) has ultimate authority on access to the data and agreements. Any complaints or spontaneously reported adverse events are reported to the primary contacts for the evaluation (PS, LW) and to the ethics committee.

Table 1. Data collection plan

Core evaluation of high-risk patients

- characteristics (age, sex, home post code, health insurance status) at baseline [A,B,C]
- additional characteristics (education, income, employment, living arrangement, smoking, etc.) at baseline and 12 monthly follow-ups [A,B]
- surveys (quality of life using AQoL-4D (29), capability using ICECAP-O (30), social support using LSNS (31), assessment of care using PACIC-20 (32), satisfaction using SAPS (33)) at baseline and at 12 monthly follow-up intervals [A,B]
- qualitative data (service acceptability, etc.) at 12 month intervals (intervention patients), at 24 months (control patients), at 6 months, 18 months and completion (intervention staff) [D]
- qualitative data (implementation, acceptability, etc.) at baseline and 12 month intervals[E]
- hospital inpatient details (medical classifications, length of stay, cost) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- emergency presentations (priority, diagnoses, length of stay, cost, etc.) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- hospital outpatient visits (specialty, cost, etc.) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- hospital investigations (test type, cost, etc.) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- medications prescribed (type, class, cost, etc.) over 3 years prior to enrolment and 6 monthly follow-ups [A,B,C]
- general practice visits (number, Medicare item numbers) [A]
- tests e.g., weight, HbA_{1c}, blood pressure, total cholesterol, etc. (result and date) [A]
- Medicare claim details (item numbers, date, cost, etc.) over 1 year prior to enrolment and 12 monthly follow-ups [A,B]
- PBS claim details (item numbers, date, cost, etc.) over 1 year prior to enrolment and 12 monthly follow-ups [A,B]
- mortality at 12 monthly follow-ups [A,B,C]
- staff cost at 12 monthly follow-ups
- population projections (age, sex, region, size, healthcare utilisation, staffing, etc.) for a time period of 2015-2018

Evaluation of population outcomes

- diabetes care and prevalence details (HbA_{1c}, foot, eye, blood pressure, lipid examinations, vaccinations, etc.) at baseline and 3 monthly follow-ups [F]
- chronic obstructive pulmonary disease care details (spirometry, vaccinations, etc.) at baseline and 3 monthly follow-ups [F]
- chronic kidney disease care details (eGFR, blood pressure, lipid examinations, vaccinations, medications, adherence to guidelines, etc.) at baseline and 3 monthly follow-ups [F]
- heart disease care details (blood pressure, lipid examinations, vaccinations, medications, adherence to guidelines, etc.) at baseline and 3 monthly follow-ups [F]
- survey of chronic illness care provision at baseline and at trial completion [G]

Trial evaluation at completion

- risk stratification, holistic assessment, services accessed, patient records and disease registries, governance and organisational arrangements, training and skills, etc.

A = intervention group; B = active control group; C = passive control group; D = focus group; E = general practice staff surveys; F = patients of all network and non-network general practices; G = network general practices; HbA_{1c} = glycated haemoglobin; PBS = Pharmaceutical Benefit Scheme; eGFR = estimated Glomerular Filtration Rate; Instrument reliability: internal consistency of AQoL-4D is (Cronbach's) α=0.81 (34), LSNS-6 α=0.83 (31) and SAPS α=0.86 (33), ICECAP-O is not fully validated (35, 36), test-retest reliability of PACIC-20 is r=0.58 (37);

Power, detectable difference and sample size

The detectable difference in total healthcare cost per patient was calculated based on: (a) assuming 15 general practices (clusters) per study group, (b) the number of participants enrolled at each of the clusters is reasonably balanced with an average of approximately 100, (c) mean costs for hospitalisations per participant (in the control group) over two years of AU$10,000 (Australian Dollars in 2015; standard deviation: AU$4,000(38), (d) a 6% reduction in hospital admissions (39) (e) a coefficient of variance within each cluster of 0.47, (f) an intra-cluster correlation of 0.01, resulting in a difference of $630 at the 0.05 significance level which can be detected with 80% power. Given the 1:2 ratio, smaller differences could be detected.

A second detectable difference calculation was undertaken at the participant level, assuming 78% hospitalisation rate per year in the control group and 20% of participants lost to follow-up in both groups: at the level of 90% power and 0.05 significance there will be adequate sample size to detect a 5% reduction in hospitalisation rates between the study groups. The Group Health Cooperative reported a 6% difference in hospitalisations from their Integrated Care model (39).

For the analysis of health outcomes and patient satisfaction, 215 control participants are sufficient to identify a mean difference in quality of life (measured using the AQoL-4D scored with utility weights from an Australian population on a scale of 0 to 1 (29)) of 0.05 compared to intervention arm participants with 80% power at the 0.05 level of significance. This calculation was based on a standard deviation of 0.20 for the intervention arm participants and 0.25 for the active control group participants. This active control group sample size allowed for factors such as 55% attrition.

Quantitative analyses

An economic evaluation of GCIC will be undertaken from the perspective of the Queensland and Australian governments (i.e., the healthcare funders). This will present the additional cost per quality-adjusted life year gained. In addition, separate analyses will be undertaken around costs to the GCHHS and the Commonwealth Government to identify additional costs and cost-savings in the different sectors. Generalised linear models will be developed to allow us to model clinical and economic outcome factors, with dependent variables that follow a distribution that is Poisson (e.g., number of emergency department visits), exponential (e.g., length of hospital stay), normal or binomial. The functional form chosen for the analysis will be driven by the distributions of the data. Data will be analysed taking into account the time-series nature of the data. A series of regressions will be undertaken, with dependent variables of volume of services used, mortality, quality-adjusted life years, total costs to the health system and net health benefits. Where the dependent variable contains zeros, alternative forms of generalised linear models will be used such as Poisson, negative-binomial or zero-inflated regression approaches. Diagnostics of regression models will be

examined, e.g., residuals, influential values, etc. The incremental cost per quality-adjusted life-year gained (incremental cost-effectiveness ratio) will be calculated. Forward estimates (up to five years following the end of GCIC) will be undertaken to identify the likely costs and cost-offsets from generalising GCIC. The budget impact will be presented as annual budget costs for up to five years for the GCHHS and primary care sectors, for the Gold Coast, Queensland and the Australian population. Deterministic sensitivity analyses will be undertaken around key parameters with the greatest uncertainty.

Qualitative analyses

Qualitative evaluation data will be collected and analysed around the following topics: (a) patient experiences of care, (b) level of satisfaction with GCIC, (c) influences on continuity of care throughout the patient journey, (d) overall staff experience and level of satisfaction, (e) staff member engagement in change management, (f) strategy implementation, (g) most useful elements in achieving optimal patient outcomes, (h) modifications to GCIC to achieve process improvements to meet goals, (i) team culture influencing outcomes, and (j) change management. Data will be collected via focus groups and surveys: (a) intervention patient focus groups: four, 60 minute groups of 10-12 randomly selected patients every 12 months, to gauge satisfaction and discuss recommendations, , open ended questions, discussion of experiences and perceptions of GCIC, (b) control patient focus groups: four, 60 minute groups of 10-12 randomly selected patients from the active control group held at 24 months to examine experiences of 'usual care', , (c) incremental 60 minute staff focus groups held at 6 months, 18 months and completion, to gauge satisfaction and discuss recommendations, with all GCIC staff (d) general practice staff surveys at baseline and 12 month intervals, (e) ongoing staff feedback through confidential online surveys, with monthly feedback reports, (f) historical documents analysis (to track program development), and (g) stakeholder feedback (through membership on *Strategic and Clinical Advisory Committee*). The focus group sessions will be recorded, transcribed and interpreted using Braun & Clark's (40) method of content analysis. Qualitative data will be categorised for comparison with the quantitative findings to identify areas of congruence or issues to be addressed in the evaluation.

Strengths and limitations

While a strength of GCIC is the substantial number of participating patients, indicating that the evaluation will yield meaningful information to inform future service planning, GCIC is limited by the fact that it is currently a three year 'proof of concept' endeavour in one geographic location, and its expansion to other local health and hospital services will depend on the results of the economic evaluation. The lack of randomisation in patient recruitment to the program may present a potential selection bias. Additionally, there may be selection bias from (a) general practices who responded

to the letter of invitation to participate, with insufficient feedback to ascertain the reasons for non-participation, and (b) from the active control group who actively opt-in. A potential confounding factor may be an inability to detect significant differences between groups due to competing interventions occurring in the control practices. Quarterly reports from the PHN will provide details of programs/interventions implemented in each practice to identify any contextual elements affecting the findings. Limitations in terms of patient choice should also be considered as all patients have a choice about where to seek health care as well as the fact that a chronic disease health population such as those enrolled in GCIC are closer to death than another population. Studies in the UK(41-43) and evaluation of the chronic disease management plans in Australia(5) have also reported a potential confounding factor because of regression to the mean. This occurs because those with high-risk of hospitalisation have shown natural reductions in hospital use over time, with subsequent rates of hospitalisation being statistically less likely to be as high, even in the absence of intervention. We are attempting to overcome this situation by using propensity matching with a retrospective valid control group from routinely collected, computerised, patient-level health and health services data(41, 43). Another potential confounding factor cautions us against drawing conclusions about patient outcomes linked exclusively to the model of care rather than the broader health system(44) . Further, as reported in previous evaluations(45) the general practices who volunteered to participate may have had both the will and resources for quality improvement so our controls have been selected from non-participating practices. Finally, duration of follow up may be a study limitation, however the three to four year follow up period is more than most clinical trials, and should give a good indication of the longer-term effectiveness of GCIC.

ETHICS AND DISSEMINATION

Ethics approval from GCHHS Human Research Ethics Committee (HREC) was received on 16th March 2015 as well as Griffith University HREC on 16th April 2015. The study is registered with the Australian New Zealand Clinical Trial Registry (registration number: ACTRN12616000821493) as a non-randomised controlled intervention study. Amendments to the protocol will be passed by the HREC and noted in resulting publications.

The results will be disseminated via yearly interim reports including a final report to the Commonwealth Department of Health and GCHHS board and executive. Summary reports will be disseminated to the wider GCHHS staff, GU team members, the PHN, the general practices and participating patients. It is expected that there will be several publications and conference presentations from this study. We anticipate that the evaluation findings will augment the evidence pertaining to the value of a whole-system integrated model of care in Australia.

ACKNOWLEDGEMENTS

Authors' contributions

PS, AMcM, MC conceived of the study. PS, GM, LW, AMcM, MC participated in design and coordination, and in the preparation of the study protocol. All authors read and approved the final manuscript.

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Competing interests

None declared.

REFERENCES

1. Australia's health 2014. Canberra: Australian Institute of Health and Welfare; 2014.
2. Cottrill A. The need for an integrated approach to chronic disease management in Australia. Health Voices. 2015(17):28-9.
3. Goss J. Projection of Australian health care expenditure by disease, 2003 to 2033. Canberra: Australian Institute of Health and Welfare; 2008.
4. OECD Reviews of Health Care Quality: Australia 2015. Paris: OECD Publishing; 2015.
5. Billot L, Corcoran K, McDonald A, Powell-Davies G, Feyer AM. Impact Evaluation of a System-Wide Chronic Disease Management Program on Health Service Utilisation: A Propensity-Matched Cohort Study. PLoS Med. 2016;13(6):e1002035.
6. Bywood PT, Jackson-Bowers E, Muecke S. Initiatives to integrate primary and acute health care, including ambulatory care services. Adelaide: Primary Health Care Research & Information Service; 2011.
7. National Healthcare Agreement 2012. Canberra: Council of Australian Governments; 2012.
8. McCarthy D, Mueller K, Wrenn J. Kaiser Permanente: Bridging the Quality Divide with Integrated Practice, Group Accountability, and Health Information Technology. New York: The Commonwealth Fund; 2009.
9. Silow-Carroll S, Edwards JN. Intermountain Healthcare's McKay-Dee Hospital Center: Driving Down Readmissions by Caring for Patients the "Right Way". New York: The Commonwealth Fund; 2011.
10. Bodenheimer T. Coordinating care - A perilous journey through the health care system. N Engl J Med. 2008;358(10):1064-71.
11. Bodenheimer T, Berry-Millett R. Follow the money--controlling expenditures by improving care for patients needing costly services. N Engl J Med. 2009;361(16):1521-3.
12. Minkman MMN. The current state of integrated care: an overview. J Integr Care (Brighton). 2012;20(6):346-58.
13. Reiss-Brennan B, Briot PC, Savitz LA, Cannon W, Staheli R. Cost and quality impact of Intermountain's mental health integration program. J Healthc Manag. 2010;55(2):97-113; discussion -4.
14. Anderson GF, Ballreich J, Bleich S, Boyd C, DuGoff E, Leff B, et al. Attributes Common to Programs That Successfully Treat High-Need, High-Cost Individuals. Am J Manag Care. 2015;21(11):E597-E600.
15. Jaen CR, Crabtree BF, Palmer RF, Ferrer RL, Nutting PA, Miller WL, et al. Methods for evaluating practice change toward a patient-centered medical home. Ann Fam Med. 2010;8 Suppl 1(Suppl 1):S9-20; S92.
16. Reid RJ, Coleman K, Johnson EA, Fishman PA, Hsu C, Soman MP, et al. The Group Health Medical Home At Year Two: Cost Savings, Higher Patient Satisfaction, And Less Burnout For Providers. Health Affair. 2010;29(5):835-43.
17. Alderwick H, Ham C, Buck D. Population health systems: Going beyond integrated care. London: The King's Fund; 2015.
18. Bramwell D, Checkland K, Allen P, Peckham S. Moving Services out of hospital: Joining up General Practice and community services? London: Policy Research Unit in Commissioning and the Healthcare System; 2015.
19. Connor M, Kissen G. Tackling Whole-Systems Change: The Trafford Framework for Integrated Services. J Integr Care (Brighton). 2010;18(3):4-14.
20. Curry N, Ham C. Clinical and service integration: The route to improved outcomes. London: The King's Fund; 2010.
21. Fillingham D, Weir B. System leadership: Lessons and learning from AQuA's Integrated Care Discovery Communities. London: The King's Fund; 2014.
22. Bardsley M, Steventon A, Smith J, Dixon J. Evaluating integrated and community-based care: How do we know what works? London: Nuffield Trust; 2013.

23. Integrated Health Services - What and Why? Geneva: World Health Organization; 2008.
24. Chan AW, Tetzlaff JM, Gotzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346:e7586.
25. Standards for general practices (4th edition). East Melbourne: The Royal Australian College of General Practitioners; 2015.
26. Applications of the ACG System in the UK (White Paper). The Johns Hopkins University; 2014.
27. Singh D, Ham C. Improving Care for People with Long-Term Conditions: A Review of UK and International Frameworks. Birmingham: University of Birmingham; 2006.
28. Connor M, Day GE, Meston D. Successful linking of patient records between hospital services and general practice to facilitate integrated care in a hospital and health service in south-east Queensland. Aust Health Rev. 2015;40(1):78-81.
29. Hawthorne G, Korn S, Richardson J. Population norms for the AQoL derived from the 2007 Australian National Survey of Mental Health and Wellbeing. Aust N Z J Public Health. 2013;37(1):7-16.
30. Coast J, Flynn TN, Natarajan L, Sproston K, Lewis J, Louviere JJ, et al. Valuing the ICECAP capability index for older people. Soc Sci Med. 2008;67(5):874-82.
31. Lubben J, Blozik E, Gillmann G, Iliffe S, Kruse WV, Beck JC, et al. Performance of an abbreviated version of the Lubben Social Network Scale among three European community-dwelling older adult populations. Gerontologist. 2006;46(4):503-13.
32. Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). Med Care. 2005;43(5):436-44.
33. Hawthorne G, Sansoni J, Hayes L, Marosszeky N, Sansoni E. Measuring patient satisfaction with health care treatment using the Short Assessment of Patient Satisfaction measure delivered superior and robust satisfaction estimates. J Clin Epidemiol. 2014;67(5):527-37.
34. Hawthorne G, Richardson J, Osborne R. The Assessment of Quality of Life (AQoL) instrument: a psychometric measure of health-related quality of life. Qual Life Res. 1999;8(3):209-24.
35. Couzner L, Ratcliffe J, Lester L, Flynn T, Crotty M. Measuring and valuing quality of life for public health research: application of the ICECAP-O capability index in the Australian general population. Int J Public Health. 2013;58(3):367-76.
36. Makai P, Brouwer WB, Koopmanschap MA, Stolk EA, Nieboer AP. Quality of life instruments for economic evaluations in health and social care for older people: a systematic review. Soc Sci Med. 2014;102:83-93.
37. Russell EG, Edward HW, Judith S, Lisa DM, Robert JR, Sarah MG. Development and Validation of the Patient Assessment of Chronic Illness Care (PACIC). Med Care. 2005;43(5):436-44.
38. Australian Public Hospitals Cost Report 2013-2014 Round 18. Independent Hospital Pricing Authority; 2016.
39. Vijayaraghavan V, Beasley G. Group Health Cooperative: A case study series on disruptive innovations within integrated health systems. A Health Care Case Study.: Innosight Institute, Inc.; 2011.
40. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77-101.
41. Davies AA, Cono; Georghiou, Theo; Bardsley, Martin. Evaluation of complex health and care interventions using retrospective matched control methods. Report. UK: Nuffield Trust; August 2015 6 August 2015.
42. Greaves F, Pappas Y, Bardsley M, Harris M, Curry N, Holder H, et al. Evaluation of complex integrated care programmes: the approach in North West London. Int J Integr Care. 2013;13(1):e006.

43. Steventon A, Bardsley M, Billings J, Georghiou T, Lewis GH. The role of matched controls in building an evidence base for hospital-avoidance schemes: a retrospective evaluation. Health Serv Res. 2012;47(4):1679-98.
44. Mitchell GK, Burridge L, Zhang J, Donald M, Scott IA, Dart J, et al. Systematic review of integrated models of health care delivered at the primary–secondary interface: how effective is it and what determines effectiveness? Aust J Prim Health. 2015;21(4):391-408.
45. Cretin S, Shortell SM, Keeler EB. An evaluation of collaborative interventions to improve chronic illness care. Framework and study design. Eval Rev. 2004;28(1):28-51.

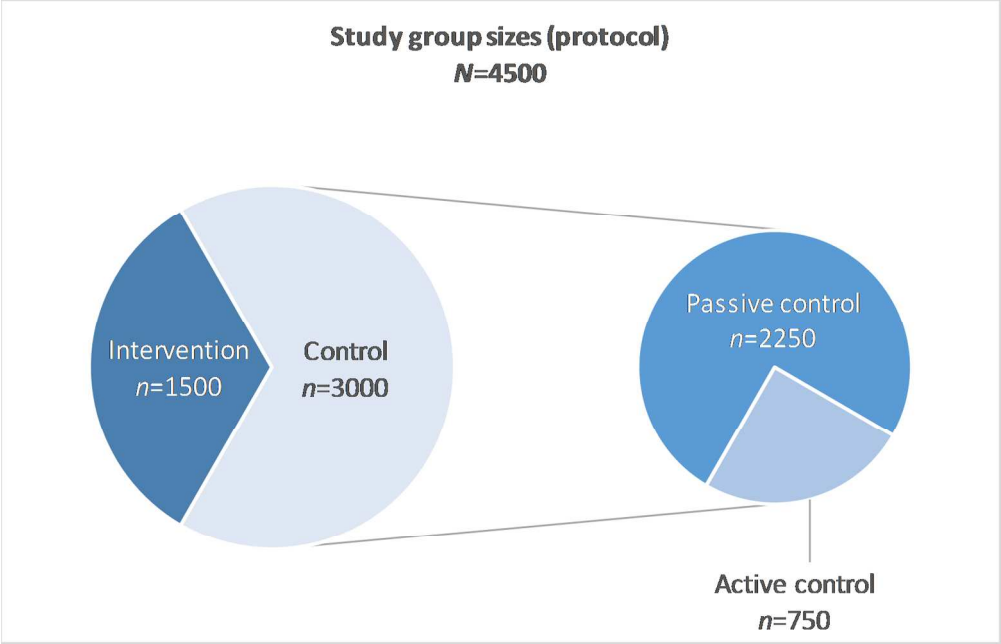

Figure 1. Study group sizes (protocol)

146x94mm (300 x 300 DPI)

Griffith UNIVERSITY Gold Coast Health

Gold Coast Integrated Care Program Evaluation: Information sheet **A**

26 May 2016

Good Afternoon,

At Gold Coast Hospital and Health Service and Griffith University, we are interested in YOUR health and wellbeing. A group of leading edge researchers are studying how your health condition is managed and how we can provide recommendations to the health community to ensure you and others suffering long term conditions can receive the best service possible. Could you read the information below and see whether you would be able to fill out some of this information to help us ensure that Gold Coast Hospital Health services are world class. We also have a little reward for you if you are able to participate.

If you do decide to become part of our study and send us your responses **within a fortnight of receiving this invitation**, you will go into a draw to win one of 250 **$20 gift card**s (redeemable at Coles, Myer, Coles Express, Target, Kmart, Liquorland, Vintage Cellars, 1st Choice Liquor Superstores and Officeworks). If you decide to complete the next round of surveys over the next 3 years, we will put your name in three further draws for Coles/Myer gift cards for **$100** (at 1 year), **$500** (at 2 years) and **$1,000** (at 3 years).

Please turn over the page to see what the study involves and the assurances we have put in place to guarantee your privacy as well as how to contact us for further information.

Sincerely

Professor Paul Scuffham
Principal Investigator
Gold Coast Integrated Care Program Evaluation

WHY IS THIS RESEARCH/EVALUATION BEING CONDUCTED?

The Gold Coast Hospital and Health Service and Griffith University researchers are undertaking a project to evaluate alternative models of health care provision. Your experiences with health care is important to us in understanding how to design the most effective health care for the elderly and those with chronic and complex conditions such as diabetes, chronic obstructive pulmonary disease, renal and cardiac disease.

The research/evaluation will evaluate Gold Coast Hospital and Health Service activities to determine the impact, quality and effectiveness of models of care provided by Gold Coast Health Services. First, we will determine whether the Gold Coast Health Service model of care reduces overall costs to the Gold Coast Hospital and Health Service for chronic and complex health conditions.

The secondary aims of this evaluation/research are to evaluate whether the model of care:

- reduces unplanned admissions to emergency departments, and hospital inpatient episodes;
- improves clinical service quality including process and outcomes for high risk patients;
- improves patient experience and satisfaction with care;
- improves staff experience and satisfaction with care.

WHAT INFORMATION ABOUT YOU WILL BE COLLECTED?

We are asking you to consent to us accessing two types of information. The first is routine data collected and stored in the Gold Coast Hospital and Health Service records. The second is to consent to us accessing your Medicare (MBS) and pharmaceutical (PBS) claims data (form C) from the Commonwealth Government Department of Human Services. The list below outlines the information we would like to evaluate:

- Number of hospital and emergency department admissions, diagnosis, length of stay in hospital, number of specialty visits – collected 3 years retrospectively and for the duration of the evaluation (from March 2015 – December 2018) from Gold Coast Hospital and Health Service records;
- MBS and PBS claims information collected by the Commonwealth Government Department of Human Services.

  - For MBS claims, this includes: claim details (date of service, the Medicare item number, item description), costs (the charge by the provider, the schedule fee, benefit paid, patient out-of-pocket cost, whether the service was bulk-billed), service provider information (date of referral, your GP's provider number, your GP's postcode, hospital indicator for hospital services billed to Medicare). Data collected excludes information on the purpose of the visit to a GP or any medical condition you may have;

  - For PBS claims, this includes: claim details (item description, date of supply, date of prescribing, item code and description), costs (patient category, patient contribution, net benefit) and prescribing details (prescriber number, class of medicine).
- Health outcomes including quality of life collected upon commencement into the program through a short survey (form D), and again at 12 month intervals until December 2018;
- Patient satisfaction – assessed by a survey (form D) upon commencement into the program, and then again at 12 month intervals until December 2018;
- Costs – collected from Gold Coast Hospital and Health Service records, which include the number of hospital and emergency department admissions.

WHAT WILL YOU BE ASKED TO DO?

You will be asked to fill out a consent form authorising the study access to your complete MBS and PBS data as outlined on the back of the consent (form C).

Medicare collects information on your doctor and specialists visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds this information confidentially.

You will also be requested to complete a written survey (Form D) – one now, and then three more will be posted to you in the mail for you to complete and return in a reply paid self-addressed envelope at 12, 24 and 36 month intervals. Each survey will take approximately 10-15 minutes to complete. If you require any assistance in completing the questionnaire, please contact a member of the research team Lauren Ward on 1300 004 242 for assistance.

WHAT ARE THE EXPECTED BENEFITS OF THIS EVALUATION?

It is expected that this research will increase clinicians' and policy makers' understanding of how best to coordinate care for people with complex and chronic conditions, so as to provide the most effective healthcare. Information and data will be used to provide evidence of the impact of the care activities and provide an informed basis for review and future planning of services.

HOW WILL THE CONFIDENTIALITY OF MY INFORMATION BE KEPT?

The research team will gather information from Gold Coast Hospital and Health Services records, and MBS/PBS data from the Commonwealth Government Department of Human Services. Your personal information such as address, telephone number and date of birth, as well as questionnaire responses will be stored in a locked filing cabinet in a secure facility at Griffith University. Your information will not be shared with a third party unless informed consent is given. The collected information will be entered into a computerised database which will be protected by password. No identification of individuals will be published. Consent forms will be kept securely in a locked cabinet at Griffith University for seven years and then destroyed.

ARE THERE ANY RISKS TO ME?

There are no significant risks associated with participation in the evaluation/research project. All information will be de-identified and your identity will not be revealed to other parties.

YOUR PARTICIPATION IS VOLUNTARY

Involvement in this evaluation/research project is voluntary. If you choose not to participate it will not disadvantage you in any way and will not affect your relationship with the Gold Coast Hospital and Health Service, any health staff, your GP or the care provided to you. At any point you are free to withdraw from the study by contacting the research team (Lauren Ward on 1300 004 242 or *l.ward@griffith.edu.au*) and completing a *Revocation of Consent* form.

THE ETHICAL CONDUCT OF THIS RESEARCH

Gold Coast Hospital and Health Service and *Griffith University* conduct research in accordance with the *National Statement on Ethical Conduct in Human Research*. If potential participants have any concerns or complaints about the ethical conduct of the research project they should contact the Research Ethics Coordinator on (07) 5687 3879 or email *GCHEthics@health.qld.gov.au*.

FEEDBACK TO YOU

At the completion of the study it is anticipated that the findings may be published in a research journal and presented at scientific conferences. Any publications and presentations would include de-identified data only and in no way identify individuals. A summary of the findings of the evaluation will be made available to you upon request.

Griffith UNIVERSITY Gold Coast Health

Gold Coast Integrated Care Program Evaluation: Information sheet

A

PRIVACY STATEMENT

The information collected is confidential and will not be disclosed to third parties. Any information collected will be used for this project only. Anonymity will at all times be safeguarded. For further information consult the University's Privacy Plan at *http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan* or telephone (07) 3735 5585.

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QUESTIONS/FURTHER INFORMATION

Should you have any questions or comments about this evaluation at any point in time, please contact the following evaluation project representative: Lauren Ward at *l.ward@griffith.edu.au* or 1300 004 242.

PLEASE FILL OUT, SIGN AND RETURN FORMS B, C AND D IN THE REPLY-PAID ENVELOPE PROVIDED.

THANK YOU.

Please complete this form and return

Griffith UNIVERSITY Gold Coast Health

Gold Coast Integrated Care Program Evaluation: Consent form

B

PARTICIPANT CONSENT FORM

I have read and understood the information sheet on the evaluation project. I have had the opportunity to ask any questions I need to understand the project and agree to participate, and received satisfactory answers to my questions. I understand that taking part in the consultations is voluntary and that I can withdraw at any time without disadvantaging me or affecting my relationship with the Gold Coast Hospital and Health Service, health staff and or my GP (refer to *Revocation of Consent* form). I understand that if I decide to withdraw for any reason, I will be withdrawing only from the research, and will still be provided care for my condition through the Gold Coast Hospital and Health Service. I understand that individuals' health information and contributions will not be identified in any report or publication. I understand that if I have any questions relating to the collection of my health information, surveys, and/or interviews/focus groups I may contact Lauren Ward at *l.ward@griffith.edu.au* or 1300 004 242. Alternatively I can contact the Research Ethics Coordinator at Gold Coast Hospital and Health Service on (07) 5687 3879 or email *GCHEthics@health.qld.gov.au*.

I, _____ agree to take part in this study on health condition management.

Signature _____ **Date** _____

People often move address and sometimes it is difficult for the study researchers to make contact again. In this case the following friend or relative of mine who lives at a different location can be contacted:

Name/relationship/phone: _____

Signed on behalf of participant by (full name and signature) _____

Date: _____ Circle where appropriate: *Power of attorney* / *Guardianship order* / *Statutory Health Attorney*. Please also attach supporting evidence.

Please complete this form and return

Griffith UNIVERSITY

Gold Coast Health

Gold Coast Integrated Care Program Evaluation: MBS/PBS consent

C

PARTICIPANT CONSENT FORM

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the Gold Coast Integrated Care Program Evaluation Study.

Important information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the Gold Coast Integrated Care Program Evaluation Study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth (DD/MM/YYYY): ☐☐☐☐**1**☐**9**☐☐

2. Medicare card number: ☐☐☐☐ ☐☐☐☐☐ ☐

Individual Reference Number: ☐

3. Permanent address:

_____

Postal address (if different to above):

_____

☐☐☐☐☐☐

SURVEY C

Please complete this form and return

Griffith UNIVERSITY Gold Coast Health

Gold Coast Integrated Care Program Evaluation: MBS/PBS consent

C

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

- ☐ Medicare claims history, OR
- ☐ PBS claims history, OR
- ☐ Medicare & PBS claims history

for the period* 01/01/2014 to 31/12/2024 to the Gold Coast Integrated Care Program Evaluation Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), therefore the consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature)

Dated: _____ OR

6. Signed on behalf of participant by _____ (full name)

_____ (signature)

Dated: _____

- ☐ Parent (where the participant is under the age of 14 years old*)
- ☐ Legal guardian** (where the participant is under 14 years old*)
- ☐ Power of attorney**
- ☐ Guardianship order**

* Once a young person has turned 14 years old they must consent to their own information being released.

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Date of Processing	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	03/05/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	23/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	999999A		2300		N	1
999999A	999999A	20/04/09	2300	2302	N	2

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999	2530

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.
** Under co-payments can now be provided for data after 1 June 2012

SUPPLEMENT A - Data collection and sampling plan

Objective	Research question	Outcome measure	Data source	Schedule
Reduced overall costs to the GCHHS for high risk complex and comorbid conditions	1. Does the program reduce overall costs of delivering health care services for patients with complex needs? 2. What is the cost effectiveness of the GCIC program?	MBS costs: - benefit paid - patient contribution	Commonwealth Government, Department of Human Services	data range: 01/01/2014 to 31/12/2018
		PBS costs (for each class of medication): - patient contribution - net benefit		
		Emergency Department costs per episode	GCHHS	3 years retrospective and 12 monthly
		Inpatient costs per episode (based on AR-DRGs and costed using the National Efficient Price weights)		
		Outpatient visit costs (using the Tier 2 weights from the National Efficient Price)		
		Investigation costs incl. radiology and pathology		
		Quality of life (AQOL-4D)	holistic assessment	baseline and 12 monthly
		GCIC staff costs	GCIC human resources	annually
Improved health outcomes	1. Does the program improve health outcomes for high risk patients with complex needs? 2. What is the relationship between patient outcomes and clinical and demographic characteristics?	Quality of life (AQOL-4D)	patient questionnaire	baseline and 12 monthly
		Mortality	GCIC/GCHHS	annually
		Capability/wellness (ICECAP-O-5)	patient questionnaire	baseline and 12 monthly
		Social support (LSNS-6)		
		Number of falls		
		Blood pressure, Body Mass Index, smoking status and history, condition specific indicators (e.g. HbA1c, lipids) (intervention group only)	holistic assessment, GPr and GCIC data (Shared Care Record, Pencat)	baseline and 12 monthly
	Does the program change the proportion of costs shared by the	Number of Emergency Department attendances	GCHHS	3 years retrospective and 12 monthly
		Number of inpatient admissions (unplanned / emergency)		
		Number of GP visits	GPr data (Pencat)	

Objective	Research question	Outcome measure	Data source	Schedule
	primary and secondary care sectors?	Number of outpatient visits by specialty (new and review)	GCHHS	
		Analysis of MBS/PBS data according to primary and secondary care	Commonwealth Government, Department of Human Services	data range: 01/01/2014 to 31/12/2018
Reduced number of potentially avoidable hospital admissions	Does the program reduce potentially avoidable hospital admissions and or presentations and length of stay?	Number of Emergency Department attendances	GCHHS	3 years retrospective and 12 monthly
		Number of inpatient admissions (unplanned / emergency)		
		Hospital inpatient length of stay		
		Number of outpatient visits by specialty (new and review)		
		Number and type of investigations e.g. radiology, pathology		
Improved patient satisfaction	Does the program improve patient experiences and satisfaction with care?	Patient satisfaction (SAPS-7)	questionnaire	baseline and 12 monthly
		Assessment of chronic illness care (PACIC-20)		
		Specifically designed open-ended questions (incl. acceptability of services) (qualitative method)	Focus Groups	12 month intervals(intervention group); at 24 months (control group)
Improved staff satisfaction	Does the program improve clinician experience and satisfaction?	Specifically designed GPr staff questions (incl. referral processes, communication with service providers) (intervention group only)	surveys (GPr nurse, GP, Practice Manager)	baseline and 12 monthly
		Specifically designed open ended questions (incl. barriers & enablers to implementation, change management strategies, acceptability of program, confidence) (qualitative method) (GCIC staff only)	Focus Groups	6 months, 18 months, completion
To provide projected estimates of health service utilisation from generalising the program for	What are the projected changes in future numbers of admissions, emergency attendances, GP visits and other healthcare	Population projections: - age - gender - region	Australian Bureau of Statistics population trends	data range: 01/01/2014 to 31/12/2018
		Differences in rates of healthcare utilisation between intervention and control groups: - Emergency Department attendances	GCIC	

Objective	Research question	Outcome measure	Data source	Schedule
the Gold Coast and other metropolitan areas of Australia	utilisation based on generalising the GCIC program for the Gold Coast and other metropolitan areas of Australia for patients with complex needs over the five years from the end of the pilot?	- inpatient admissions - GP visits - outpatient attendances		
To provide financial estimates for health budgets from generalising the program for the Gold Coast and other metropolitan areas of Australia	What are the forward estimates for the GCIC program for the Gold Coast, and expected costs of adapting the GCIC program to other metropolitan areas of Australia for patients with complex needs?	Population projections: - age - gender - region	Australian Bureau of Statistics population trends	data range: 01/01/2014 to 31/12/2018
To estimate any changes in the mix of the healthcare workforce required to provide integrated care should it be rolled out across the Gold Coast,	What are the additional types of staff requirements (including training needs) and staff displaced from generalising the intervention across the Gold Coast and other metropolitan areas of Australia?	- potential target population size - staffing ratios per participant - changes in healthcare utilisation across the different sectors and services	- Australian Bureau of Statistics population trends - GCIC - intervention staff needs assessment - estimates of changes in hospital and primary care services	data range: 01/01/2014 to 31/12/2018

Objective	Research question	Outcome measure	Data source	Schedule
Queensland and/or Australia				
Improved clinical service delivery according to guidelines	To what extent does the program improve clinical service delivery according to guidelines?	Measures relating to diabetes annual cycle of care. Process outcomes: - proportion of patient population with HbA_{1c} tests completed - proportion of patient population with foot exams completed - proportion of patient population with eye examinations completed - proportion of patient population with blood pressure recorded - proportion of patient population with lipids tests completed - proportion of patient population with microalbuminuria tests completed - proportion of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded. Clinical outcomes: - proportion of patient population with $HbA_{1c} \leq 7\%$ - proportion of patient population with blood pressure <130/80 - proportion of patient population with total cholesterol <4mmol/L - proportion of patient population with LDL cholesterol <2mmol/L - proportion of patient population with microalbuminuria <2.5/3.5 mg/mmol (men/women)	GPr & GCIC data (Shared Care Record, Pencat)	3 month intervals
		Measures relating to chronic obstructive pulmonary disease. Process outcomes: - proportion of population with spirometry completed - proportions of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded - proportion of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded.		

Objective	Research question	Outcome measure	Data source	Schedule
		Clinical outcomes: - proportion of patient population with current influenza vaccination - proportions of patient population with current pneumococcal vaccination - proportion of patients whom are non-smokers.		
		Measures relating to chronic kidney disease best practice guidelines. Process outcomes: - proportion of patient population with blood pressure recorded - proportion of patient population with eGFR recorded - proportion of patients with ARB or ACE medication prescribed - proportion of population with ACR recorded - proportion of patient population with lipids tested - proportion of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded. Clinical outcomes: - proportion of patient population with blood pressure ≤140/90 mmHg - proportion of patient population with lipids <4.0 mmol/L total, <2.5 mmol/L LDL		
		Measures relating to heart disease best practice guidelines. Process outcomes: - proportion of patient population with lipid lowering medication prescribed - proportion of patient population with anti-hypertensive medication prescribed - proportion of patient population with blood pressure recorded - proportion of patient population with lipids tested - proportion of patient population with vaccinations completed in accordance with schedule - proportion of patients with smoking status recorded. Clinical outcomes:		

Objective	Research question	Outcome measure	Data source	Schedule
		- proportion of patient population with blood pressure ≤140/90 - proportion of patient population with LDL cholesterol <2mmol/L		
		Measures relating to service delivery (process outcomes): - number of GP management plans and reviews - number of Team Care Arrangements and reviews		
		Assessment of chronic illness care (ACIC-28) (intervention group only)	GP surveys	Baseline and completion
To examine implementation fidelity	1. To what extent was the program implemented as intended? 2. How successfully were the strategies of the program implemented and conducted as planned?	Completion of risk stratification of patients: - method of patient identification (collaboration with GP, algorithm tool). Holistic assessments: - number completed - model of holistic assessment (incl. completed by whom) - type of risk assessment tools completed.	- risk stratification point criteria - review of GCIC protocols and manuals - holistic assessment monitoring database (daily reports) - GCIC quality audits	
To examine implementation determinants	1. What were the factors that facilitated and / or impeded program implementation? 2. Which elements of the program were seen to be most useful by staff and patients which contributed to outcomes?	Risk stratification: - number of patients identified - patient characteristics (incl. demographics). Services accessed: - number and type of services used e.g., allied health, home care, brokered services, hospital services. Holistic assessment outputs: - number of patient goals created - number of referrals - number of actions - number of live care plans. Shared Care Record: - number and type of consumer views on acceptability, usefulness, efficiency (client, GP, specialist). Disease registries: - number of disease registries implemented in GPrs	- administrative records - daily reports - holistic assessment monitoring database (daily reports) - staff focus groups - staff surveys and diaries - administrative data for use of components (revealed preferences)	

Objective	Research question	Outcome measure	Data source	Schedule
		- number of patients on disease registry. Governance arrangements: - leadership stability - organisational capacity - adequacy of infrastructure, staff arrangement, partnerships, resources. Change management strategies Staff and skills training: - GCIC staff - GPr staff - other care providers. Program reach: - numbers and timeframe of GPr on-boarding - number of patients enrolled.		
Improved continuity of care	To what extent does the program improve continuity of care?	ACIC survey on management of chronic conditions in relation to the chronic disease model (network GPrs only)	questionnaire	baseline and at program completion
		Patients perspectives on continuity and coordination of care (qualitative method)	Focus Groups	12 month intervals (intervention group), 24 months (control group)

GCHHS = Gold Coast Hospital and Health Service; GCIC = Gold Coast Integrated Care; MBS = Medicare Benefits Schedule; PBS = Pharmaceutical Benefits Scheme; AR-DRG = Australian Refined Diagnosis Related Groups; AQOL-4D = Assessment of Quality of Life questionnaire; ICECAP-O-5 = Index of Capability for older people; LSNS-6 = Lubben Social Network Scale; GP = general practitioner; GPr = general practice; Pencat = Classic Clinical Audit Tool; SAPS-7 = Short Assessment of Patient Satisfaction questionnaire; PACIC-20 = Patient-Assessed Chronic Illness Care questionnaire; HbA_{1c} = glycated haemoglobin; LDL = low-density lipoprotein; eGFR = estimated glomerular filtration rate; ARB = angiotensin II receptor blocker; ACE = angiotensin converting enzyme; ACR = albumin-to-creatinine ratio; ACIC-28 = Assessment of Chronic Illness Care; [a] out of pocket costs are reported for MBS/PBS data only, and calculations exclude private health insurance, travel costs, loss of income and other non-healthcare costs;

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 10
	2b	All items from the World Health Organization Trial Registration Data Set	Title page, pages 2-4, 7, 8, 10
Protocol version	3	Date and version identifier	Title page
Funding	4	Sources and types of financial, material, and other support	Page 10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page, page 10
	5b	Name and contact information for the trial sponsor	Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 1
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Page 3
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 1

	6b	Explanation for choice of comparators	Page 4-5
Objectives	7	Specific objectives or hypotheses	Page 3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 2-3
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 5
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 6
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 5
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 5
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 3, Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 6
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 4
Methods: Assignment of interventions (for controlled trials)			

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Table 1
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 6
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	-
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 8
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 8
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	-

Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 3
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 10
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 6
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	-
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 10
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 4
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 6
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 10
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 6

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 10
	31b	Authorship eligibility guidelines and any intended use of professional writers	-
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	-
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary Files
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.