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Personalised Health Care
Proof of Concept Pilot Study

VERSION 1.4 - 02/09/2013

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Synopsis

Study Rationale

Personalised Health Care Proof of Concept Pilot Study

TITLE OF STUDY	**Personalised Health Care Proof of Concept Pilot Study**
PROTOCOL NUMBER	13/14
SPONSOR/FUNDING BODY	Victorian Department of Health \ Barwon Health
PROJECT PHASE/TYPE	Proof of concept pilot study
PRIMARY OBJECTIVE	To evaluate the effects of the personalised health care program, which includes care plans, escalation processes and tele-health.
CRITERIA FOR EVALUATION	• ED admissions • Acute Admissions • LOS on acute admission • Self-reported GP appointments To explore the patient experience of participation in a home tele-monitoring program that aims to support the self-management of their chronic disease. • To understand the effects of a model of care on health literacy and self-management • To understand the effect on various clinical measures • To assess appropriate outcome measures for a fully powered randomised controlled trial • To assess the variability of outcome measures to aid in sample size calculation for a fully powered randomised controlled trial • Recruitment and retention rates • Compliance with self-reporting
STUDY DESIGN	Randomised Control Methodology – proof of concept pilot study Post implementation • Qualitative interview using constant comparative

	thematic analysis • Survey
STUDY DURATION	Screening: Rolling enrolment of 6 months On Study: 12 months
NUMBER OF PARTICIPANTS	400 participants will be selected for the pilot study. This includes: 400 participants for the randomised pilot study Participants will be allocated to : • 200 in the intervention 'usual care plus Personalised Health Care' group • 200 in the control "usual care" group
NUMBER OF CENTRES	One
INCLUSION CRITERIA	1. Diagnoses of COPD or Diabetes (Type I and Type II) 2. PRaDA "likelihood of admission in the next 12 months" value of 0.5-0.8 3. Lives in own home 4. Over 18 years of age 5. Ability \ dexterity to enter and submit own data via a computer or similar device. 6. English speaking or carer who is English speaking 7. Willingness and ability to take own vital signs and biometric readings via appropriate selected device (e.g) a glucose meter or live with a carer who can.
EXCLUSION CRITERIA	1. Pregnancy 2. Vision impairment or hearing impairment which impacts ability to use the telehealth device or complete biometric readings. 3. Poor 12 month prognosis 4. Severe cognitive impairment as determined by clinical assessment 5. Sub-optimal management of mental illness as per clinical assessment 6. Current enrolment in Hospital Admission Reduction Program (HARP) 7. Active palliative care patient 8. Drug or alcohol dependency
STATISTICAL ANALYSES	This study is a pilot intended to gather information surrounding the efficacy and feasibility of the intervention. Due to the pilot nature of the study, analysis of study data will not follow a hypothesis testing framework. Further detail on statistical analysis can be found in the statistical analyses section of this document.

EXECUTIVE SUMMARY

Type of Study

A randomised controlled "proof of concept" pilot study and post intervention evaluation qualitative

interview and survey.

Study Plan
400 adults identified to be at a higher risk of readmission to hospital within the next 12 months who agree to participate will be randomised to either the intervention "usual care plus Personalised Health Care" group or the "usual care" control group. Patients in the intervention and control groups will be asked to participate for 12 months. Measures of hospital utilization and health literacy \ self-management will be measured at baseline and after 12 months of the intervention to determine if hospital utilization has decreased and if health literacy has increased for the intervention group.

Usual Care control group - Patient manages health condition as directed by usual and existing medical services, no limitations on care type that can be newly administered during the 12 months. Measures of Hospital Utilization, Health Literacy, self-management QOL at 0 and 12 months.

Usual Care plus "Personalised Health Care" Intervention group
Telehealth patient monitoring with phone access to specialised nursing team, personalised escalation and care plans. Patient can still access all existing modes of care and emergency services. Measures of Hospital Utilization, Health Literacy, self-management QOL at 0 and 12 months.

Please also refer to Appendix A –Project Flow chart

In similar models of care operating, one nurse monitors approximately 100 patients. In line with this, our proposed service model aims to provide proof of concept for a service at this scale. The funding provided by the Department of health to operate the pilot model of care, is specified for 200 patients. Therefore the "intervention group" sample size will be a maximum of 200. The control group will also be 200 in order to monitor comparative changes.

Intervention
The intervention is an additional monitoring service on top of a patients "usual care". There are three core aspects to the intervention; daily nurse monitored telehealth, personalised care plans and access to personalised advice from nurse team 24 hours a day which will provide a team of nurses and specialists the ability to respond early to the patient's needs. Patients will have the ability to have contact with a nurse at any time. Research suggests that these aspects individually can improve the consumer's understanding and ability to manage their own health conditions. This proof of concept pilot aims to demonstrate that a combination of these core aspects leads to decreased hospital utilisation as well as increases in health literacy and an improved ability to self-manage their health conditions.

Please Note:
Clients will be advised and reminded/reinforced throughput the pilot study period that at any time they feel they require emergency care they should follow their usual practice (e.g call 000, ambulance, present to ED).

1. RATIONALE/BACKGROUND

The Barwon Health Personalised Health Care Model would be a joint venture between Barwon Health and the Victorian Department of Health. A joint advisory committee will ensure the development and implementation model aligns with contemporary health policy and creates a basis that can be considered for capitation models of care. The implementation will be delivered by Barwon Health and reported to the advisory group.

Barwon Health has an opportunity to demonstrate a proof of concept for a model of care, which will create the final piece of the integrated-care continuum-framework for community-based service provision. The organisation has the opportunity to embed an innovative process of health practice that will improve consumer outcomes by integrating the lessons from current models, with self-care and health literacy practices. It is anticipated that this will free up the acute health services for those that require them most. This model will also enable Barwon Health to meet its Key Performance Indicators in an ever-growing service demand environment. It will provide a leading opportunity to utilise data to accurately predict which patients are more than likely to be readmitted, before it happens, thus being able to intervene and prevent admission.

The increasing prevalence of chronic disease amongst an ageing population is a worldwide challenge. Chronic diseases are associated with high use of healthcare services which contribute to major funding pressures for governments and health services. The growing use of telehealth is seen as one possible approach to alleviate acute bed pressures in health services by providing patients with the ability to access medical services where they otherwise may have chosen to attend a hospital.

The Victorian Department of Health has agreed to provide funding to Barwon Health to run a pilot program to deliver a trial of telehealth for patients with Chronic Obstructive Airway Disease and Diabetes due to the high prevalence of these diseases among Australians and the high rates of hospital utilisation among patients with these diseases. Deakin University's Pattern Recognition and Data Analytics (PRaDA) team will also collaborate in the project.

Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease is a common, burdensome and underdiagnosed condition in Australia. Multidisciplinary care plans and individual self-management plans may help to prevent or manage crises. Chronic obstructive pulmonary disease (COPD) is the third leading cause of disease burden in Australia. The Australian Lung Foundation has conservatively estimated the annual direct costs to exceed $900 million. However, COPD was only the tenth most commonly managed chronic condition in general practice in 2003-04.

- COPD is a lung disease that affects almost 13% or one in seven Australians 40 or over. [1]
- 7.5% of Australians 40 or over have COPD that has progressed sufficiently to where symptoms may already be present and affecting daily life. Half of these people will not

know they have it.[1]

- COPD is the second leading cause of avoidable hospital admissions.[2]
- In 2008-09 the median length of hospital stay for COPD was 5 days among people aged 55-69 years, rising to 6 days for those aged 85 years and over.[19]
- Despite falling death rates, COPD is still a leading cause of death and disease burden after heart disease, stroke and cancer.[3]
- While there is no cure for COPD, there is strong medical evidence to show that early diagnosis, combined with disease management programs at the early stages of the disease could reduce the burden of COPD, improving quality of life, slowing disease progression, reducing mortality and keeping people out of hospital.[4]
- In 2008, the total economic impact of COPD was estimated to be $98.2 billion of which $8.8 billion was attributed to financial costs and $89.4 billion to the loss of wellbeing.[10]

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Diabetes

Diabetes is the fastest growing chronic disease worldwide, and in Australia where it is estimated to affect in excess of 1.5 million people. It is a progressive, unrelenting and challenging disease with serious complications which can reduce both quality of life and life expectancy. By 2023, Type 2

diabetes is projected to become the leading specific cause of disease burden for men and the second leading cause for women. The number of Australians diagnosed with diabetes is expected to grow to 3.5 million by 2033.

Several key initiatives have particular value in generating across-the-board benefits by contributing to effective prevention, detection, risk-reduction and disease management. For example, measures must be designed and implemented to improve health literacy. This will help ensure that more people understand what diabetes is, how to prevent it and how to manage it, as well as how to navigate the health care system.

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Health Literacy \ Self-management \ Quality of Life

People with low levels of health literacy report poorer health status and experience poorer health outcomes compared to those with good health literacy.1.2 Poor health literacy is most prevalent in socio-economically disadvantaged populations, which are often in greater need of health care to manage complex conditions.3

Health literacy is defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”4 It is also seen as an outcome of health education; and improving health literacy may be one way of addressing the social determinants of health.

In the past, the concept of ‘health literacy’ has focused primarily on the ability to read labels, fill in forms and follow instructions; more recently, it has extended to the ability to access health information and use it critically and effectively;5 to navigate the health care system; and to communicate effectively about health relevant matters.9

Recent evidence shows that limited health literacy is associated with poorer overall health status and being less likely to have recently attended a doctor.8 It is also related to poor health outcomes, including: increased hospitalisation, greater use of emergency care, lower rates of mammography, lower use of influenza vaccine, higher risk of mortality for seniors, incorrect use of medications and poor medication compliance.1

Health literacy and illness self-management are Inextricably linked.18 The capacity to seek, access, comprehend and use health information and services influences participation in the treatment of conditions.19 People with lower health literacy are more likely to have chronic conditions and less able to manage their conditions.13; 18 Improved self-management may help compensate for lower levels of health literacy and improve health-related behaviours.20

Poor health literacy is associated with social disadvantage;8 and is prevalent among people from

lower socioeconomic backgrounds,2 the elderly, culturally and linguistically diverse populations (CALD)13 and Indigenous Australians.14 Given that the incidence of chronic conditions increases with age,15 and poor health literacy is common in the elderly,16 older Australians are a particularly vulnerable group.

Given the association between low health literacy and poor health outcomes, and the high prevalence of both factors among disadvantaged populations, interventions to improve health literacy are an important factor in reducing health disparities.

The Assessment of Quality of Life Tool (AQoL) has been selected after consultation with BH Health literacy experts as the most appropriate measure of health literacy, self-management and quality of life for this pilot study. The 8D version will be used. The AQoL has the ability to pick up nuanced differences in QoL- in areas such as mental health or health states with a major impact upon handicap (as distinct from impairment)
the AQoL provides:

- utility scores before and after intervention for use in economic evaluation studies;
- utility scores that are descriptive (epidemiological) in a study of different populations;
- disaggregated profiles of individuals or populations cross sectionally or longitudinally using data from individual items or (in the case of AQoL) dimension scores.

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Telehealth

Telehealth is the use of telecommunication techniques for the purpose of providing telemedicine, medical education, and health education over a distance as defined by the International Organisation for Standardisation.[1] Telemedicine is defined as the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status

Telehealth aims to reduce the need to relocate care recipients and decrease acute hospital utilisation by transmitting relevant health information to health professionals and educators and enable diagnosis, treatment and education via methods such as video-conferencing.(Australian Government, 2012) (American Telemedicine Association, 2003) Telehealth may help patients better understand their health condition by providing tools for self-monitoring and encourage better self-management of health problems. Per BMJ 2012:344:3874 doi: 10, 1136/bmj. E 3873 (published 21 June 2012).

Remote patient monitoring (RPM), also referred to as telemonitoring, telecare, telehomecare, is an aspect of telehealth that is used to collect a patient's vital signs, biometric data and subjective data via a monitoring device located in the patient's home or place of residence. (Jaana, Pare, & Sicotte, 2007) The data collected is transferred electronically to a clinician who can screen and analyse the data for anomalies and respond to the patient according to their needs. The patient is then able to remain at home whilst being monitored at prescribed intervals, avoiding the need to travel for their standard healthcare needs.

Commonly RPM is utilised with patients who have one or more chronic conditions including but not limited to chronic obstructive pulmonary disease (COPD) and diabetes.

A number of benefits have been identified by trials of RPM for patients with chronic diseases

[1] http://www.health.gov.au/internet/main/publishing.nsf/Content/e-health-telehealth

including:

- Decreases in mortality, emergency admission rates, re-admission rates and length of stay for patients as well as reduced travel time and costs (Steventon et al., 2012) (Orton, 2011) (Haesum et al., 2012) (G. Pare, Poba-Nzaou, & Sicotte, 2012) (Guy Pare, Sicotte, St Jules, & Gauthier, 2006) (G. Pare, Jaana, & Sicotte, 2007) (G. Pare et al., 2012)

- Increases in patient condition, satisfaction, understanding of patients' own health conditions, increased capacity of facilities and resources for health services and increased collaboration between healthcare professionals. (Fitzner & Moss, 2012) (Stone et al., 2012) (Gellis et al., 2012) (Jaana et al., 2007) (G. Pare et al., 2007)

- Across the studies reviewed the majority of clients using RPM devices had high satisfaction with the use of the devices and of their own health outcomes including increased understanding of their own health. (Sicotte, Pare, Moreault, Morin, & Potvin, 2009) (Gellis et al., 2012)

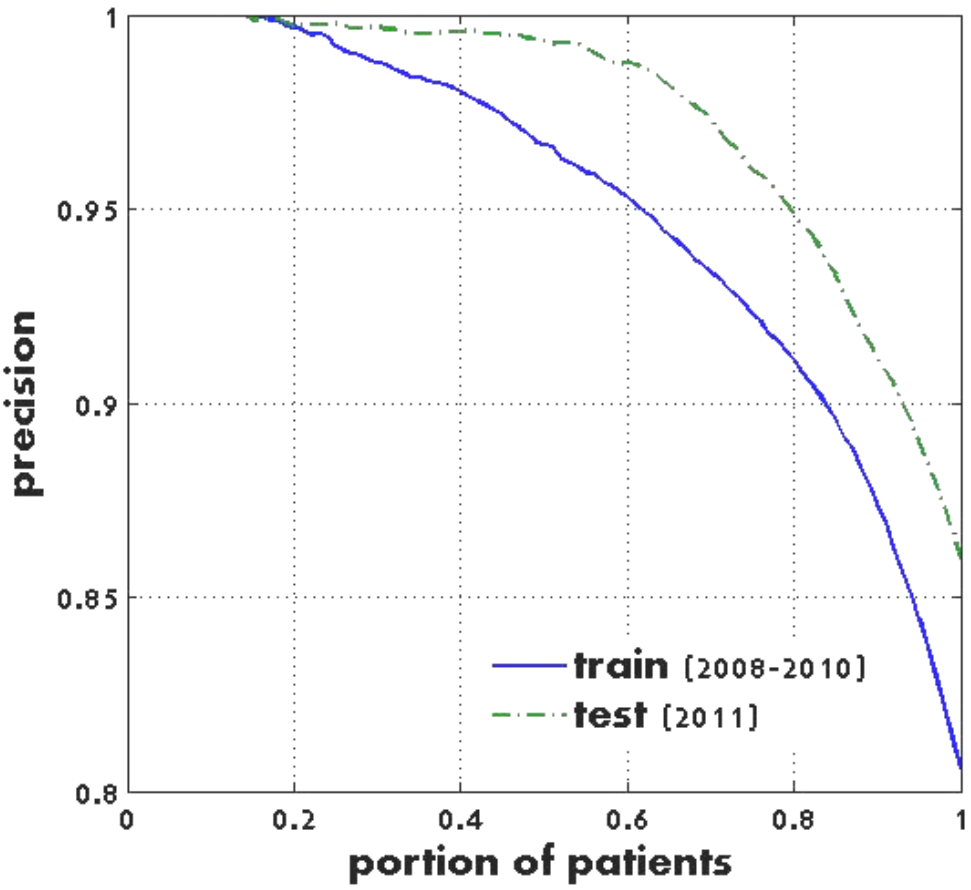
In addition to telehealth care, Barwon health will also combine personalised care and escalation plans developed by a health care team including nurses and consultant physicians to strengthen the pilot program. Detail on this can be found in the study design section of this document. The Telehealth product that Barwon Health selects to use for this pilot study will have all appropriate regulatory approvals for use in the Australian market. Barwon Health are currently completing a tender process for the provision of telehealth on this project.

Centre for Pattern Recognition and Data Analytics (PRaDA)

Barwon Health has recently formed a partnership with Deakin University's, Centre for Pattern Recognition and Data Analytics (PRaDA). The Centre is currently analysing Barwon Health's hospital admission data and has ethical approval to do so. This type of analysis provides an innovative way to review, and identify, groups of consumers admitted to the acute hospital, as well as the likelihood of future admissions. A number of techniques utilised including detailed word association analysis. This enables Deakin University and Barwon Health professionals to understand the 'drivers' of anticipated hospital admissions. The availability of this data, and its associated analysis, will provide enhanced rigour in selecting a population that the Barwon Health Personalised Health Care model can test as a pre-emptive hospital avoidance model.

Using computer modelling the data analysis aims to expose latent patterns in health data and medical records, and assign individuals to these patterns. The method uses characteristics of individuals such as diagnosis, co morbidities, age, gender, admission & length-of-stay history, diagnosis procedures (rarity is also emphasised) past HbA1c measures, past operations and past medications to predict the likelihood of no admission to an acute hospital in the next 12 months . Based on the data analysis, a resultant likelihood of no admission between 0 and 1 can be assigned to a patient. This method has been performed on 2008-2010 Barwon health data with developers being blinded to 2011 data, which has then been used for validation. A paper describing this methodology and its accuracy is currently under review for publication at a peer reviewed journal. Figure 1 below shows the results of this analysis

Figure 1 Probability that a group of patients will NOT be readmitted in the next 12 months



2. AIMS/OBJECTIVES/HYPOTHESES

Aims/Objectives
To evaluate the effects of the personalised health care program which includes care plans, escalation process and tele-health on:

- ED admissions
- Acute Admissions
- LOS on acute admission
- Self-reported GP appointments
- To understand the effects of a model of care on health literacy and self-management
- To assess appropriate outcome measures for a fully powered randomised controlled trial
- To assess the variability of outcome measures to aid in sample size calculation for a fully powered randomised controlled trial
- Recruitment and retention rates
- Compliance with self-reporting
- Qualitative Interview
- Survey

PARTICIPATING SITE
Barwon Health

3. RESEARCH PLAN/STUDY DESIGN

Type of Study – A randomised controlled "proof of concept" pilot study followed by a post intervention qualitative interview of a convenience sample of patients. Analysis will use a constant comparative thematic approach.

4. STUDY POPULATION

Participant Identification
Patients who meet the pre-set eligibility criteria as determined by medical consultants in the project team and the PRaDA *likehood of no admission* parameters (refer to figure 1) set by the team will be eligible to participate in the pilot. See below for detail

Selection Criteria
Inclusion criteria

- Diagnoses of COPD or Diabetes (Type I and Type II)
- PRaDA "likelihood of admission in the next 12 months" value of 0.5-0.8
- Lives in own home

- Over 18 years of age
- Ability \ dexterity to enter and submit own data via a computer or similar device.
- English speaking or carer who is English speaking
- Willingness and ability to take own vital signs and biometric readings via appropriate selected device (e.g) a glucose meter or live with a carer who can.

Exclusion criteria

- Pregnancy
- Vision impairment or hearing impairment which impacts ability to use the telehealth device or complete biometric readings.
- Poor 12 month prognosis
- Severe cognitive impairment as determined by clinical assessment
- Sub-optimal management of mental illness as per clinical assessment
- Current enrolment in Hospital Admission Reduction Program (HARP)
- Active palliative care patient
- Drug or alcohol dependency

Process of identification

The PRaDA software program will review the health records of all current Barwon Health patients with the identified inclusion diagnoses. This data will be supplied by Barwon Health. PRaDA will produce a list of all patients who fit the selection criteria. Barwon Health and Deakin University's PRaDA team have an agreement to share the data and ensure confidential storage of patient information.

5. RECRUITMENT

All patients identified as meeting the selection criteria will be sent a letter regarding the pilot study with some information regarding the pilot study and what would be required of a participant. A reply paid envelope will be provided which includes preferred date, time and best method of contact; those interested to participate could indicate this and return to the research team. The program staff with administration support provided with this contact information (i.e. home. mobile phone, email). Responders interested in participation will be followed up by phone and an appointment arranged to meet and discuss the pilot study and their possible participation and appointment arranged if possible. Appointment reminders will be sent along with any pertinent information such as the PICF prior to agreed time

Non-responders will also be followed up by sending a follow up invitation 2 weeks after the initial invite, The second invite will refer to the first and will highlight that there is a "not interested response" section. Any patient who chooses not to participate in the pilot at this stage will not be contacted again. Rolling enrolment will occur and over a period of 6 months. As patients are enrolled patients will be randomised to the control or intervention arms of the pilot. This gradual recruitment aims to recruit 200 individuals in the intervention group and 200 in the control group. Please see the statistical analyses section for detail on randomisation method

Qualitative and interview Recruitment

A convenience sample of participants in the intervention group will be recruited. Potential participants will be sent an invitation (Appendix D), via the post, to fill in the survey and/or participate in an interview with the researcher and assistant. A consent form (Appendix D) for participating in the interview is attached to the letter, while return of the completed survey will be

taken as consent to participate in the survey.
Follow up with the intervention participants will be made ten working days after the letter has been sent to determine if they are interested in participating.
Note: Nurses employed to work on the program will enrol and consent the patients. Nurses will be provided with training regarding informed consent from Assoc Prof Mark Kotowicz. Consultant physicians will not be identifying, consenting or enrolling participants onto the study and hence any relationship of dependency issues would be mitigated.

Participant recruitment: (please see Appendix A for flow chart)

6. TREATMENT OF SUBJECTS

At the patient's first appointment they will have the opportunity to discuss the information provided in the Participant Information and Consent Form (PICF) with the program staff. If the participant understands the information provided, is satisfied with the responses to any questions they have, and agree to participate they will be asked to provide informed consent by signing the PICF (please see appendix B for consent form). Patients unwilling to participate in the pilot or sign the consent form will not be enrolled and will not be contacted again.

Basline Initial assessment and at 12 months - measures and observations
Diabetes cohort

- Diabetes Type I or II
- HR, Rhythm
- Blood Pressure
- current HbA_1C
- Serum Lipids
- Urine micro albumin
- Weight/height (BMI)
- Summary of health status including complications
- Medications including adjustment regime
- Validation/quality control of individual meter documented
- AQoL
- Health Education Impact Questionnaire
- Interview
- Survey

COPD cohort

- Recent lung function test
- HR, Rhythm
- Blood Pressure
- Weight/height (BMI)
- Barwon Health Respiratory Initial Health Assessment Tool
- 6 min walk test
- Mental health screen (K10)
- COPD Assessment Test (CAT)
- Summary of health status including complications

- Medications including adjustment regime
- AQoL
- Health Education Impact Questionnaire
- Interview
- Survey

7. GENERAL STUDY PROCEDURES

The Pilot Study Service Model

In summary the key aspects of the service model that differentiate it from current service provision includes;

- Personalised health care plans governed by consultants, with a 24-hour escalation process for signs and symptoms of deterioration.
- Tele-health monitoring component that enable virtual monitoring in the home. Enhancing self-care and increasing efficiency of home health services.
- Ability for early health care, nurse, allied health or medical assessment in the most appropriate place- home, clinic or rapid assessment unit as required in order to avoid hospital admission.

The model and infrastructure will permit the current gaps between acute responsiveness and community-based care to be addressed.

Staffing and Reporting

For the pilot phase of the program the staffing model will consist of a Manager role .5 fte role. One full time equivalent (FTE) Clinical Nurse Specialist level with expertise in one or more of Endocrinology, Respiratory or Community based care provision and 2.8 equivalent full time (EFT) nursing staff for the 18 month of active program participation. Administration support will also be available 0.5 FTE.

The Manager will be responsible for overseeing the program, ensuring coordination of patient care, staff management, liaison with key stakeholders and progress monitoring of the program, including overseeing research processes and data collection.

Clinical Nurse Specialist will be employed for the initial 6 months of the program to to facilitate best practice approach to care planning and to facilitate the enrolment process of clients onto the program.

The equivalent of 2.8 full time staff will be responsible for the daily monitoring 7 days per week and direct care provision of the clients in the intervention group. This involves monitoring of the clients health via the information technology system, documenting daily care results in the Digital Medical Record, following up any variances to care plan parameters and consulting with the client as needed. Duties include liaising with the medical team and associated health professionals, such as Allied Health and Clinical Nurse Consultants and conducting home based visits as required.

Administration support will enable running of reports, ensure phone queries can be listed with clinical staff and to progress, support the enrolment process of clients, support the coordinated approach to enrolment of clients and to facilitate the replacement of equipment that is faulty as reported by participants.

As indicated above the BH Personalised Health Care Service team will organisationally report within the CH&RS service directorate and therefore access the standard CH&RS supervision framework

and undertake the directorate education and quality activities.
Data Collection Method for the post intervention evaluation will consist of a survey (Appendix G) made available for all study intervention participants. All patients will be mailed an invitation (Appendix F) to participate in the post intervention evaluation. Participants, regardless of their status within the program, eg. Completed, currently still receiving the intervention, or completed and still receiving the intervention will be offered the opportunity to respond about their experience by survey, the surveys will be returned to the Personalised Health Care mail box.

An invitation will also be extended to study intervention participants to participate in an interview. Invitations for this component of the evaluation will continue until n=12. The study population is seen as homogeneous in their experience. All are living with chronic conditions and all have received the same service intervention over the previous 12 months. It is expected that interviews with approximately 12 participants will produce saturation in response themes and provide evidence enough to produce the required result. Participants regardless of their status within the program, eg. Completed, currently still receiving the intervention, or completed and still receiving the intervention will be offered the opportunity to participate until n=12.

The interview will be conducted using the interview schedule (Appendix H). All interviews will be pre-booked with the patient and an assistant. The assistant will be a staff member from the Personalised Health Care team. The researcher will introduce themselves to the interviewee and will be present in the room to take filed notes during the interview. The interview scheduled questions will be asked by the assistant. All interviews will be digitally recorded for verbatim transcription post the interview. Patients will be offered the option of having the interview undertaken using the facility of video conferencing that has been employed by the program or by arranging a time for the assistant and researcher to visit their home or other agreed meeting place.

8. EFFICACY EVALUATIONS

Participant training and confirmation of care plan

Following identification as per the research protocol, clients will be contacted by the program staff who will introduce the program and, as per the research protocol, enrol the client in one of the two cohorts through a randomisation process as described in the statistical analyses section.

Initial Visit

Following agreement for enrolment and identification into the intervention group a staff member from the program will again contact the client the details of the persons care plan will be developed in consultation and authorised by the clients usual treating consultant \ GP. Prior to the commencement of the pilot study, all participants will be asked to complete Health Literacy and Self-Management questionnaires as well as at specific intervals over 12 months

Follow-up visit

Within five working days the clients will receive a second home-based visit from one of the BH Personalised Health Care team members. At this visit the nurse will introduce and set up the information technology system demonstrating it to the client and providing education on the client's management plan.

Additional follow-up (if required)

The nurse will either call or visit (if participants are experiencing difficulties) for the following 2-3

days (or as client needs dictates) to assist the client in utilising the information technology system and re-enforce education of the clients care plan. Clients will be able to demonstrate full independent use of the system prior to nurse visits ceasing. The nurse will visit at any time through-out the pilot to address clinical care needs or reinforce information technology education if required. There are no limits set to prevent home-based follow-up.

Personalised Health Care Remote Patient Monitoring System

The Remote Patient Monitoring (RPM) system used in this pilot project is a web based platform that can be accessed from any internet connected device. The patient, when accessing the platform, will be directed to their personalised care plan that has a questionnaire designed to educate and guide the client to monitor and support their own health. The peripheral devices that link to the system, enable the monitoring of clinical signs and symptoms such as SaO_2, blood pressure and blood glucose measures.

For the health service clinicians accessing the platform, the RPM system identifies in real time which clients have recorded results at that point in time and which have not, it provides an indication of which results are at variance to the result parameters set for each individual;, thus enabling a rapid and timely response.

The RPM system generates individualised reporting that allows the clinicians to monitor trends within a client's health care over time, enabling treatment to be appropriately adapted as and if required.

The client is required to log in to the system daily, to answer questions about their health and monitor aspects of their health. If clients do not complete their daily monitoring, the RPM system will alert the health service clinicians to this for follow up. The model is only as effective as the level of participation of the client, therefore for clients that are not willing or able to participate by choice or otherwise will need to be identified early, be removed or request to withdraw from the study.

Clients may choose to use their own web connected device to access the RPM system or alternatively Barwon Health will provide a suitable hardware device. If clients choose to use their own internet connected device, appropriate screening will be performed to ensure the device is suitable for purpose, including the quality of internet connectivity at the client's location. Client's using their own internet connection will be reimbursed at an appropriate rate for the amount of data transferred for the purpose of their RPM according to the data rates identified by the preferred vendor. If required Barwon Health will reimburse Internet costs or pay for new connections. If connectivity is not possible due to a patient's residential location, patient will be excluded from participation

Support for the RPM platform will be provided by the vendor and their associated affiliates depending on the client's support issue. Education for clients around use of the RPM device and platform will be provided by BH project staff in the set-up and establishment phase of the study. The vendor will provide the necessary education to BH staff to facilitate the resolution of most issues by the host site. In the event that the issue is beyond the scope and experience of the host site, the vendor or their affiliates will provide the required support. IT Support for the integration of the telehealth component will be provided by the host site's Information Technology Support Department (SWARH).

Personalised Care Plan
In this circumstance the care plan is a plan that assists the client in monitoring his or her own health, and will be the basis from which the nurse monitors the client's health status. The plans are personalised in that the limits and details to be monitored (signs and symptom) are set for the particular individual by the specialist treating team. The plans enable both client and health team to monitor their health status on a daily basis, act on any variables in their health by providing instructions on how to identify changes in health status and how to respond to these changes to prevent further deterioration. The care plan is structured as such that, unlike many care plans commonly used, it will contain within it identifiers for escalation of either treatment by the client themselves and/or flags to the health professional that intervention maybe required.

In Hours Daily Care and Escalation
In line with the client's care plan, clients will record information in the system initially on a daily basis. This information will be monitored by the nurse. If the client does not log in or has a result that is outside the set care plan parameters the nurse will:

- Call the clients and trouble shoot the issues over the phone,
- video call face to face if circumstances indicate a visual need or
- Arrange to conduct a home-based visit if indicated.
- If patient condition warrants escalated intervention the nurse with make contact with the appropriate consultant seeking further directions.

Compliance:
As patients, nursing and medical teams become more familiar with each other, daily assessment may be adjusted according to need i.e. 2nd daily. Should client compliance drop below 70% of planned participation a phone call initially and/or a visit by a member of the program team to occur to understand reasons. Continued non-compliance will eventuate in the client ceasing to be part of the trial resulting in a return of telehealth devices and cessation of contact /visits. Notification of a client's leaving/ removal from the pilot study will be documented and reported to program team and HREC

Clients will be advised and reminded/reinforced throughput the pilot study period that at any time they feel they require emergency care they should follow their usual practice (e.g call 000, ambulance, present to ED).

The current Barwon Health Community Nursing Protocols and Policies ensuring staff and client safety will be utilised to guide all home based visits.

After hours Coverage and Escalation
After hours are defined as after 5:00 pm and before 8:00am The only variance to the system between in hours and after hours is the staff will be the After Hours Community Nurse, and the escalation process for staff will be as per the McKellar After hours roster.

The service will be supported by a 24/24 on call system which during Monday-Friday 8am-5pm will be the BH Personalised Health Care team and after hours will be a rotating roster of on call PHC staff. Staff providing the after-hours support will be able to electronically access both the BH Personalised Health Care system and the BH Digital Medical Record to ensure care advice is appropriate and documented as per standard BH protocols. Training will be provided to the after Hours Community Nurse Coordinator and appropriate ED staff.

In line with other services within CH&RS the escalation process will be firstly to the Service Coordinator, then to the relevant expert consultant if the matter is clinical and unable to be resolved by staff, and finally to the Executive Director of CH&RS. If there is a system issue, that requires immediate attention, escalation will be directly to the Executive Director of CH&RS. The IT escalation protocol will be as per all current clinical Information Systems.

Escalation after-hours will be directed to the already existing McKellar After Hours Manager (who is based at the McKellar site) and then to the Director On- Call. Please refer to the flow chart attached in appendix C for more detail

Exit Strategy post Personalised Health Care program
Patients will be monitored for a 12-month period of time. Following this period if a client's health remains unstable they will continue to be monitored via this service. If for any reason the service ceases to exist then clients will be referred to the appropriate BH community based program for their circumstance and care needs. That will be one (or more) of either

- HARP- for ongoing intensive case management and care coordination
- Primary Care- for interventional community based services
- Community Nursing Services – for home based nursing services

These clients are already supported by the health system, both acute and ambulatory sectors of the service. There is no risk to the ongoing care of these clients of for any reason the pilot program ceases to operate following the period of the research.

This service is providing monitoring over and above the standard care that patients currently receive. If the clients condition worsens to the point that they can not be monitored safely at home then they are likely to be receiving in-patient hospital treatment. The treating specialist consultant will determine the need for a hospital admission.

With the exception of the HARP program, clients will not be excluded from any other community based support programs if their needs indicate eligibility.

Following completion of the pilot program there are 3 possible outcome scenarios predicted as indicated below:

- The client has an improved ability to self-manage their own disease and does not require on-going daily monitoring and support, therefore they are 'discharged' from the pilot and their care followed up via BH Outpatients and their own General Practitioner.
- The client requires ongoing daily monitoring and the pilot project is successful and moves into a sustained program model, in which case the client will be monitored by the service.
- The client requires ongoing monitoring however the pilot project is ceased. In this situation the client will be referred to the HARP program for intensive case management and coordination, monitored via BH outpatients and their General Practice as per a clients normal management. If the client requires ongoing home based nursing support they will also be referred to the BH Community Nursing Program.

9. SAFETY EVALUATIONS

There are no known risks to participating in this study. The results will help determine initial effectiveness of personalised care plans, an associated all hours escalation process and remote

monitoring of your health using remote patient monitoring devices whereby results and information is entered/uploaded into a BH data storage site. From here, health care staff will be able to monitor patient health and provide care with increased efficiency.

Adverse events and Quality Monitoring process

The PHC program will utilise a Data Safety and Monitoring Board to monitor the difference between groups and will be able to cease the study if it is deemed appropriate. The DSMB will also review both and adverse events Serious Adverse events. The DSMB will develop a charter upon formation and determine appropriate statistical measures to inform decision making.

Please refer to the Adverse Events and Quality Management Plan document and the quality monitoring excel spreadsheet in the appendices for more detail

Governance

The Barwon Health Personalised Health Care (BH Personalised Health Care) service pilot will sit in the directorate of Community Health and Rehabilitation Services (CH&RS). Along with the other programs in this directorate, it aims to support people in the community, transitioning back to the community and avoiding hospitalisation wherever safe and possible. Governance for clinical care, safety, quality and performance reporting is the accountability of CH&RS Executive team and Executive Director.

This pilot will be operated in conjunction and close partnership with the Medical Services directorate, with medical input, oversight of patient care and treatment coming from specialist consultants within Respiratory Medicine and Endocrinology.

Evaluation and Monitoring

Barwon Health and its associated partners have been approved to evaluate the program by the Department of Health through this research methodology.

Data Sources/Collection

Data will be collected from hospital data systems, medical records of participating patients and survey / questionnaires/hospital admission data and interview. Data will be stored in password protected files on Barwon Health Computers. Any paper based patient data will be stored in locked cupboards / drawers for a period of seven years. At the conclusion of this period all paper based records will be destroyed.

Data Security and Storage

Clinical Data for the intervention group will be stored in the purchased software system and backed up on a Barwon Health Server. The clinical data will be transferred into the clients Digital Medical Record into a separately labelled section titled “BH Personalised Health Care”. This will enable clinical staff treating the client in other parts of the organisation to be able to see the client’s data and results as required. A flag indicating the client is enrolled in this pilot will be placed in the alert section of the Digital Medical Record.

The senior staff of the Emergency Department will be provided with education of the pilot and the information technology system. The senior staff (NUM and ANUM’s) will be able to access the

Personalised Health Care system; this will ensure immediate access to daily clinical data if and as required via the BH Information Technology system.

It should be noted that this pilot program provides support and monitoring to clients over and above the current support structures that are available in the community for a client with chronic disease therefore the risk to any clients care when on the program is minimal.

Informed Consent
Participants who agree to participate in the trial will be asked to sign a consent form. Only participants who sign the consent form will be able to participate. Participants can leave the trial at any point. (Please see appendix B for consent form).
The PICF will be entered into the patients DMR.

Confidentiality and Privacy
For intervention group members confidentiality of all patient data will be maintained in accordance with normal hospital procedures. For additional data regarding health literacy and hospital utilization for both control and intervention groups the data will be stores in password protected files.

All staff working with the data will have signed Barwon Health's Client Data Confidentiality agreement . Data Linkage will be completed by Barwon Health's "Health information Services - business analysis manager.

All interview and survey data collected will be de-identified and use pseudonyms chosen by the participant. A code sheet linking the participant's pseudonym and their real identity will be stored away from the data on a secure password protected server.
Surveys will be sent to the patients address with marked Patients age in years, gender and HEIQ initial results noted in a code box for office use. No other identifying information will be collected on the survey. As such, the surveys will be non-identified.
All data will be stored on a secure password protected hard drive with the researchers being the only ones with access. The drive will be stored within the Barwon Health computer system. All hard copy notes will be kept in a locked cupboard in a locked room when not in use. All data will be destroyed seven years following the last publication of the project.

Data Storage/Record Retention

Data	Pre and post measures of	Intervention	Control	Monitor only	Program Evaluation	Source
Length of Stay (LOS)	LOS or average LOS(s) at hospitalisation	✔	✔	✔	✘	Data Ware-House

Hospital Admissions	Number of hospitalisations in past 12 months	✔	✔	✔	✘	Data Ware-House	
ED Presentations	Number of ED presentations in past 12 months	✔	✔	✔	✘	Data Ware-House	
Quality of Life	Specific validated questionnaire	✔	✔	✘	✘		
Health Literacy \ Self management	Specific validated questionnaire	✔	✔	✘	✘		
Mortality		✔	✔	✔	✘	Hospital Data	
PRaDA	Predictive value of the patients (intervention vs control vs followed)	✔	✔	✔	✘	PRaDA	
Interviews	NA	✘	✘	✘	✔	Word files/PDF password	

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Expected Duration of Study/Start Times

Participants will receive the intervention over a 12 month period. Recruitment is anticipated to begin in late September2013. There will be a 6 month period of recruitment to achieve the maximum of 400 patients for the intervention and control arms. Full recruitment (400) is anticipated to be achieved by March 2014.

10. OUTCOMES AND SIGNIFICANCE

Statistical Analyses

Sample Size (n=400)

In similar models of care operating, one nurse monitors approximately 100 patients. In line with this, our proposed service model aims to provide proof of concept for this approach. The funding provided by the Department of health to operate the pilot model of care, is specified for 200 patients over a period of 18 months. Therefore the "*Intervention Group*" sample size will be a maximum of 200. The *"Control Group*" will also be 200 in order to monitor comparative changes.

Participant numbers

Individuals identified as potential participants will be allocated a screening number in sequential order. This number will be allocated in a sequential fashion as responses to the initial trial invitation are received by the Returning Officer. Allocation of participants to either the intervention or control arm will be made at the time of consent (as indicated by the signing of the PICF).

Allocation method

Individuals will be allocated by a stratified minimisation randomisation algorithm. Stratification variables will be the individual's primary diagnosis (COPD/diabetes), and the baseline PRaDA risk of readmission in the following 12 months. The risk strata will consist of four evenly spaced risk sets (0.60-0.65, 0.65-0.70, 0.70-0.75, 0.75-0.80). The minimisation algorithm will be implemented within the study's enrolment database.

Individuals agreeing to involvement in the study, and who are subsequently allocated, will be assigned a (sequential) allocation number; the combination of the screening number and the allocation number (for example, XXXXX-XXX) will give the unique individual study number. A master file containing individual UR, name, date of birth and study number will be stored separate to other study documents. This allocation and randomisation process will be guided and performed by Dr Stephen Lane (Barwon Health Statistician\ Research Fellow)

Statistical analyses

Sample size

This study is a pilot intended to gather information surrounding the efficacy and feasibility of the

intervention, and has not been powered to detect any (minimal) clinically relevant difference between the intervention and control arms. Sample size has been guided by available resources and funding.

Methods

Due to the pilot nature of the study, analysis of study data will not follow a hypothesis testing framework. Confidence intervals for efficacy outcomes will be calculated within each group at the 95% confidence level, however no formal significance tests will be made. Hospital admissions will be treated as a binary variable, ED presentations as counts, and LoS as ordinal. Total LoS (summed over all admissions) will be presented.

Allowances for stratification of the sample will be made via the Cochran–Mantel–Haenszel (CMH) test for unadjusted analyses, and adjustment for covariates will further be investigated via logistic regression for binary variables; adjustment for covariates will use Poisson regression for count variables. Analysis of the readmission rates will further be summarised under a time-to-event framework.

Baseline measures will be summarised by group, as will any differences post-intervention. Trial procedures (such as recruitment and retention rates, compliance and monitoring loads) will be monitored and summarised by confidence intervals where appropriate.

Following verbatim data transcription of each interview, a constant comparative thematic analysis method will be used. Two researchers will analysis the data independently and confer to confirm the thematic structure of the data.

General Practitioner (GP) COMMUNICATION STRATEGY

Agency/Agency type	Message	Mode	Time
Medicare Local	Outline of model Update on progress	BH/ Medicare local partnership meetings	Quarterly
Medicare Local	Learning's to date. Demonstration of system with Care-plans	Forum	
Individual GP's- identify all GP's that have clients on MOC	Present an Overview of the model of care	Forum or individual contact via letter/email/phone	
Individual GP's	Printed copy of care-plans mailed to individual GP's following client consent	Mail/email. Any question follow up with phone call	As per client enrolment
Individual GP	Notification of any hospital admission from team	Method of communication to be defined as "usual	As required

		process" being upon discharge a summary with associated clinical result.	
Individual GP's	Notify of discharge from service	Mail with above	Per client discharge
Medicare Local & individual GP's involved in patient care	Project findings	Forum	

PUBLICATION POLICY

It is anticipated that the study will produce journal publications with the following focus area's with the following identified lead authors. No patient specific data will be reported only comparisons of measures of central tendency of control , intervention and followed groups.

Data from the post intervention evaluation qualitative interviews and patient surveys will be published in peer-review journals, reports and conference proceedings.

APPENDICES

Appendix A – Flow chart for overall project with amendments

Appendix B – Patient Informed Consent Form

Appendix C – Letter to Patients

Appendix D – Adverse Events and Quality Monitoring Process

Appendix E – Adverse Events, Quality Monitoring and DSMB Reporting Spreadsheet

Appendix F – Letter to Participants and Consent to interview and survey

Appendix G – Survey

Appendix H– Interview Schedule