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Home Monitoring of Chronic Disease for Aged Care

Organisation: Australian e-Health Research Centre (AEHRC), CSIRO

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FINAL REPORT
May 2016

Copyright and disclaimer

Important disclaimer

I. Contents

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Nepean Blue Mountains Medicare Local

Anglican Retirement Villages – Penrith

Townsville Mackay Medicare Local

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Test and Control Patients

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VI. List of Abbreviations

AB	Asthmatic bronchitis
ACT	Australian Capital Territories
ADSL	Asymmetric Digital Subscriber Line
ADSL2	Asymmetric Digital Subscriber Line - 2nd specification
AF	Atrial Fibrillation
AHD	Atherosclerotic heart disease
AMI	Acute Myocardial Infarction
AP	Angina Pectoris
ART	Arthritis
ARV	Anglican Retirement Villages
AST	Asthma
BT	Bronchiectasis
CAD	Coronary Artery Disease
CCC	Clinical Care Coordinator
CHD	Coronary heart disease
CHF	Congestive Heart Failure
CM	Cardiomyopathy
CMU	Clinical Monitoring Unit
COPD	Chronic obstructive pulmonary disease
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CVD	Cardiovascular disease
DHS	Department of Human Services
DM	Diabetes Mellitus
FTTP	Fibre to the premises
HREC	Human Research Ethics Committee
HT	Hypertension
IHD	Ischaemic Heart Disease
LHD	Local Health District
MBS	Medical Benefits Scheme
NBN	National Broadband Network
NGO	Non-Government Organisation
NIBP	Non-invasive blood pressure
NSTEMI	Non-ST elevation myocardial infarction

PAS	Patient administration system
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally Controlled Electronic Patient Record
PHN	Primary Health Networks
PO	Project Officer
QLD	Queensland
ROI	Return on Investment
SEIFA	Socio-Economic Indexes for Areas
STEMI	ST segment elevation myocardial infarction
TAS	Tasmania
TMC	Telemedcare telemonitoring devices / services
T2DM	Type 2 Diabetes Mellitus
VDSL	Very-high-bit-rate Digital Subscriber Line
VIC	Victoria

1. Executive Summary

This project analyses and documents the effects of introducing at home telemonitoring of vital signs for the management of a heterogeneous group of chronically ill patients. Patients suffering from a wide range of chronic conditions who were frequently admitted to hospital, were selected from nominated hospital lists. The impact of telemonitoring was analysed using a wide range of health and wellbeing outcomes as well as numerous health economic metrics derived from MBS and PBS data and hospital data using the Health Roundtable format. Data was also recorded from the telemonitoring system used in the trial, and questionnaires. The impact of this intervention on the patients, carers and clinicians involved in their care was quantitatively and qualitatively analysed and documented.

In addition, this project reports on the effect of workplace culture and capacity for innovation and organisational change management in successfully integrating a new model of care with long established service models. We have clearly demonstrated that the success metrics for the deployment of telehealth services relate more to on-site clinical leadership, capacity to accommodate change and the flexibility of existing processes and systems than any technical issues associated with the telehealth monitoring equipment or patient adherence to measurement schedules.

The telemonitoring system deployed in this study was developed in Australia, registered with TGA (Therapeutic Goods Administration) and has been extensively used and tested in previous trials. Patients had no difficulty using the telehealth equipment, incorporated it easily into their daily lives and tended to monitor their vital signs and respond to questionnaires on average every two days. This generated a unique longitudinal record of the patient's health status, which with the application of simple predictive analytics could result in the better coordination of care, the reduction of unnecessary healthcare costs, reduced hospitalisation and reduced length of stay.

Highlights of the results obtained in this pilot program, following one year of telemonitoring include;

- 46.3% reductions in rate of MBS expenditure (savings $611-$657)
- 25.5% reduction in rate of PBS expenditure (savings $44-$354)
- 53.2% reduction in the rate of admission to hospital (reduction of 0.22 – 1.0 hospital admissions)
- 75.7% reduction in the rate of length of stay (reduction in LOS of 7.3 – 9.3 days)
- > 40% reduction in mortality
- > 83% user acceptance and use of telemonitoring technology
- > 89% of clinicians would recommend telemonitoring services to other patients

These results are broadly in agreement with international data, but the impact on MBS and PBS expenditure has never been reported before.

An economic analysis of the impact of telehealth was undertaken based on the results of this trial and the experience of establishing telehealth services in six diverse sites in Australia. An operational model based on a single Clinical Care Coordinator managing 100 patients is proposed in future large scale deployments of telehealth.

Analysis of this model suggests that for chronically ill patients, an annual expenditure of $2,760 could generate a saving of between $16,383 and $19,263 pa, representing a Return on Investment (ROI) of between 4.9 and 6.0.

The necessity to align those who pay with those who benefit in achieving as high a ROI as possible suggests that Local Health Districts (LHDs) and the newly established Primary Health Networks (PHNs) are well positioned to implement and manage telemonitoring services and clinical triage call centres. Clinical triage and monitoring services could then be made available for all chronically ill patients irrespective whether they are under the care of a GP, a community nurse employed by the LHD, or a community nurse employed by a Non-Government Organisation (NGO).

From a simple analysis of population health data we conclude that approximately 750,000 people aged over 65[1] with complex chronic conditions and multiple co-morbidities who are admitted to hospital at least once each year would benefit from at home telemonitoring of their vital signs and from on-going clinical monitoring and triage of their health status.

2. Introduction and Background

In industrialized nations approximately 70-78% of healthcare budgets are spent on the management of chronic disease or its exacerbation[1-3] and as the population ages the burden of chronic disease will increase and place healthcare budgets under increasing strain. As a consequence policy makers and health service managers seek innovations that deliver the same or improved health services using proportionately fewer resources. Telehealth services have been demonstrated to be one such innovation in international contexts, but there are low levels of evidence from Australian studies. This study evaluated whether the introduction of in-home telemonitoring services to the management of chronic disease in the community could reduce patient use of the health system and improve healthcare outcomes and their quality of life. We also explored the extent to which real-time risk stratification of these patients was of value to health professionals and the issues and challenges in deploying telemonitoring services in the community.

A strong primary health care system has been acknowledged as critical to the sustainability of health care systems both in developing and industrialised nations and it has emerged as a recurrent theme in Australia in recent years[4-6]. The management of chronic disease, much of which could occur in home and community settings, unnecessarily burdens Australia's hospital-centric public health system.

Telehealth and telecare technologies and services for the management of chronic disease at home and in the community have been of intense interest in developed western economies because of unprecedented growth rates of the aged population and increasing morbidity as population ages. These factors place unsustainable stress on established health care services, and will result in increasing deficits in clinical human resources, expanding disease management programs and patient demand for greater self-management.

Telehealth services, delivered through home telemonitoring, have been demonstrated to deliver cost effective, timely and improved access to quality care [17-25]. These services also reduce social dislocation and enhance the quality of life within and the sustainability of these communities by allowing chronically ill and aged members to stay in their homes and communities longer.

However experience in Australia with the deployment of telehealth services is extremely limited, with most deployments on small scale and lacking detailed analysis of key success factors such as:

- Health care outcomes
- Health economic benefits
- Impact on clinical work force availability and deployment
- Human factors (acceptability, usability by patients, carers, nurses, GPs and administrators)
- Workplace culture
- Organisational change management and business processes

The development of a robust business case and business models for large scale commercial deployment of telehealth services, based on reliable socio-economic evidence, is therefore essential if these services are to be deployed nationally to mitigate the escalating costs of health service delivery and the increasing deficit in clinical work force.

This trial endeavoured to create a robust evidence base for these key success factors and demonstrate an effective and scalable model for internet-enabled telehealth services in Australia. Armed with the insights provided by this evidence base, policy makers may have much of the data they require to implement funding models and create a sustainable telehealth services sector in Australia.

Despite large national investments in health IT, very little policy work has been undertaken in Australia in deploying telehealth in the home as a solution to the increasing demands and costs of managing chronic disease. In contrast in the UK, the first report from the Department of Health (DH) on this subject was published in 2000 [7] and many others have followed since [8-10].

The DH's Preventative Technology Grant (PTG) from 2006-08 provided £80M to local authorities and their partners for investment in assistive technology[10] and most recently £31m of funding for a Whole System Demonstrator (WSD) program had telehealth as an integral part for the management of long-term conditions[11-12].

2.1 Evidence of unsustainable increases in health care costs and in the demand for health workforce

- Health is now the second largest area of government expenditure and the largest employer in Australia (ABS. 2011 Census Data).
- Total Health expenditure has trebled in the last 25 years and in 2011-2012 was $140.241b pa, 9.5% of GDP. Increased spending on public hospital services in real terms was the largest component of the overall increase in spending, accounting for approximately one-third (32.9%) of the increase in that year [1].
- Federal Government accounts for 42.4% of all healthcare expenditure with 27.3% from state and local Governments and 17.3% paid for by individuals. Health insurers contribute approximately 8% [1].
- Hospitals, doctors and medicines dominate our national health spending profile (2011-2012) data [1].
- Prices for dental, hospital and medical services have risen more strongly than all consumer price index (CPI) this decade [16] as seen in Figure 1.

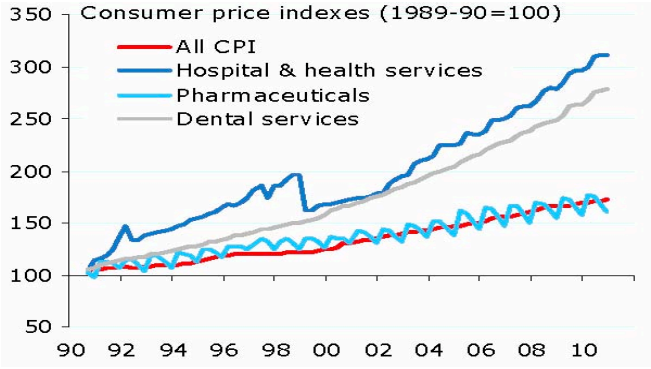


Figure 1 Growth in Consumer Price Index (CPI) for Hospital and other health services [16]

2.2 Evidence for ageing demographics and the increasing burden of chronic disease

In Australia, the proportion of those aged over 65 will increase by 68%, and that of those over 85 will almost triple in the next 40 years. As the population ages the burden of chronic disease increases [13].

- Around 80% of GP consultations relate to chronic disease
- Patients with a chronic disease or complications use over 60% of hospital bed days
- Two thirds of patients admitted as medical emergencies have exacerbation of chronic disease or have chronic disease
- For patients with more than one condition, costs are six times higher than those with only one
- Some people are highly intensive users of services (10% of inpatients account for 55% of inpatient days) or very intensive users (5% of inpatients account for 40% of bed days)
- Hospital admissions increase with age as shown in Figure 2 and length of stay lengthens, particularly for those with chronic conditions and multiple co-morbidities[13,15]
- The biggest and fastest-growing spending category in health is hospitals - they get almost $18 billion in real terms more than in 2002-03, an increase of over 95% [15].

- In 2011–12, there was a 1.6% increase in Australian Government funding for public hospital services compared to an 8.0% growth in state and territory government funding [1].
- Treasury projections based on data from the Australian Institute of Health and Welfare, with tax held constant as share of GDP and based on current arrangements in place at the time of the 2010 Intergenerational report [p 53 of 14], show that state and local expenditure on health will represent 100% of budgets within 30 years [17].
- There is an increasing demand from the "baby boomer" generation for the expansion of disease management programs and greater self-management.
- There are increasing deficits in clinical human resources particularly in rural and remote locations.

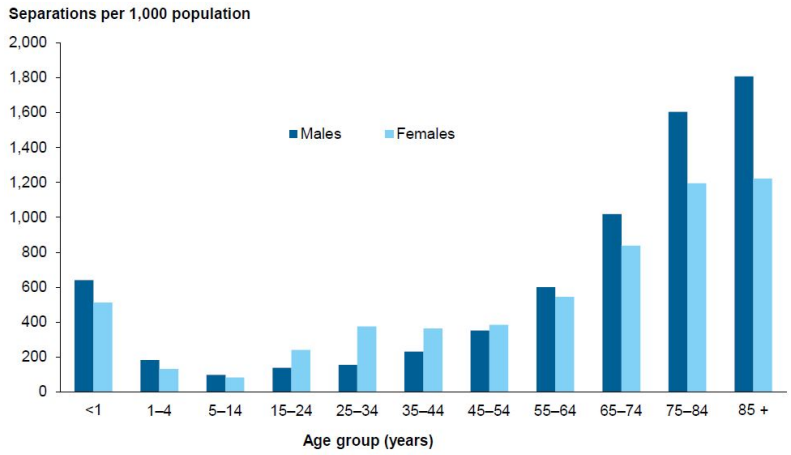


Figure 2 Separations per 1,000 population by sex and age group, all hospitals, 2012–13[15]

2.3 Evidence for telehealth services for the management of chronic disease

The Whole System Demonstrator (WSD)[11,12] in the UK, is the largest randomised control trial of telehealth and telecare in the world, involving 6191 patients and 238 GP practices across three sites - Newham, Kent and Cornwall. Three thousand and thirty people with one of three conditions (diabetes, heart failure and chronic obstructive pulmonary disease (COPD)) were included in the Telehealth Trial.

Headline Findings released by the UK Department of Health in December 2011, demonstrated;

- 15% reduction in A&E Visits
- 20% reduction in emergency admissions
- 14% reduction in elective admissions
- 14% reduction in bed days
- 8% reduction in tariff costs and
- 45% reduction in mortality rates

The largest example of telehealth use is however in the US, where the Veterans Health Administration (VHA) has mainstreamed routine use of telehealth for clinical care within its Coordinated Care and Home Telehealth (CCHT) project [17]. Analysis of data obtained for quality and performance purposes from a cohort of 17,025 CCHT patients shows the benefits of a 25% reduction in numbers of bed days of care, 19% reduction in numbers of hospital admissions, and mean satisfaction score rating of 86% after enrolment into the program. VHA's experience is that an enterprise-wide home telehealth is appropriate and cost-effective in the management of chronic care patients in both urban and rural settings. More recently, the US Department of Veterans Affairs announced that 690,000

US veterans received care in the 2014 fiscal year via telehealth, with 2 million telehealth visits scheduled. That means that 12 percent of all veterans enrolled in VA programs received telehealth care of some kind in 2014[1].

There are many clinical benefits associated with remote patient monitoring with a large range of chronic conditions [16]. Some of the evidence for this was summarized in a recent white paper by the Medical Technology Association of Australia [18] and includes (i) an increase in mean survival time in a sample of 387 diabetic patients who undertook daily monitoring of vital signs [19], (ii) a significant improvement in glycaemic control in diabetic patients who transmitted blood glucose and blood pressure data to a telehealth nurse [20], (iii) a 71% reduction in Emergency Room (ER) admissions in respiratory patients who had oxygen saturation measured by pulse oximetry and monitored daily [21], (iv) a reduction in the number of hospital readmissions in patients with angina [22], (v) significant improvements in health related quality of life and a decrease in mortality in COPD patients using home monitoring [23], (vi) a 43% reduction in hospitalizations and a 68% reduction in bed days of care in cardiac patients who transmitted daily ECG and blood pressure data[24] and (vii) a 50% reduction in the risk of heart failure related readmission and 55% reduction in cardiovascular mortality in chronic heart failure patients monitored at home[25].

The evidence therefore appears overwhelming that at home telemonitoring can deliver significant patient health benefits at lower cost and with a high level of acceptance by patients and their carers. Deployment of telehealth services however is far from widespread. Broadly speaking telehealth services has been embraced most enthusiastically in the US with uptake in Australia and the rest of the Western industrialised nations patchy, tentative and on a small scale rarely proceeding past the trial stage.

Outside of the USA, the United Kingdom has the most evolved infrastructure and government policy framework for supporting at home telemonitoring, and is now promoting a Public-Private Partnership to deploy telehealth services to three million chronically ill patients. In Australia, Government has been preoccupied with the funding of national eHealth infrastructure through the National eHealth Transition Authority (NeHTA)[2], and with the development of the national Personally Controlled Electronic Health Record (PCEHR)[3] which is now being slowly deployed and is receiving limited acceptance from clinicians.

Telehealth video consultations between specialists and patients in Residential Care Facilities or remote area community health services are now being funded through the Medicare system[4] and at last count the Department of Human Services had processed over 169,000 telehealth services provided to over 62,000 patients by over 9,700 practitioners.

The Consumer Directed Care Program which is replacing the existing Federally funded care packages known as Home and Community Care Packages (HACC), Community Aged Care Packages (CACP) and Extended Aged Care in the Home (EACH), also has provision for the supply of at home telemonitoring services.

[1] http://mobihealthnews.com/37325/telehealth-served-12-percent-of-va-covered-veterans-in-2014

[2] http://www.nehta.gov.au/our-work

[3] http://www.health.gov.au/internet/main/publishing.nsf/Content/PCEHR-Review

[4] http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/connectinghealthservices-factsheet-stats

With these initiatives in place, it is probable that Australia will begin to implement large scale at home telemonitoring services over the next few years. However, there are significant uncertainties and impediments that need to be resolved before large scale deployment of telehealth services will become routine. These include the following:

- Concern over funding models. The National Health Insurance system has historically funded provider – patient clinical consultations. There are concerns that telehealth services may lead to cost blowouts in essentially uncapped federal and state healthcare budgets.
- State and Federal Government cost shifting. In Australia the Federal Government funds primary care and aged care and the State Governments fund hospital services. If the Federal Government funds telehealth to reduce unnecessary hospitalisation of those with chronic conditions, the primary beneficiaries will be the state governments. Hence, there is a potential misalignment of those that pay and those that benefit!
- Limited awareness and support for telehealth services both among clinicians, service providers and patients.
- Varying levels of organisational readiness within State Governments, local health districts and not for profit health service providers for the deployment of telehealth services.
- A lack of data on how to identify those patients that would benefit most from at home telemonitoring for their chronic conditions, and a robust process for allocating telemonitoring resources throughout the disease life cycle from early intervention for early stage disease conditions such as Type2 diabetes, through to complex chronic conditions with multiple co-morbidities such as congestive heart failure (CHF) patients with COPD and coronary heart disease (CHD).
- A robust process for selecting competitive at home telemonitoring services that provide the best quality patient data and opportunity for clinical diagnosis. Ensuring that systems are interoperable and standards based and can automatically transfer data securely to either provider controlled or national electronic health records.

Therefore, this Telehealth Trial was designed to provide a robust evidence base with which policy makers and health service managers could make well informed decisions regarding the deployment of telehealth services in an Australian setting.

2.4 High Level Project Time Line

Funding Proposal submitted to NBN Enabled Telehealth Pilots Program (ITA 274/1112) Title: *Home Monitoring of Chronic Disease for Aged Care*	16/05/2012
Announcement of successful applicants under ITA 274/1112	15/12/2012
Contracts signed between CSIRO and Commonwealth Department of Health	18/02/2013
Ethics Approval received from CSIRO HREC	25/03/2013
Removal of NBN restriction for patient selection and connection	31/10/2013
Finalisation of contracts with each of six trial sites	01/03/2013 to 22/05/2014
First Test patient consented and monitoring commenced	29/05/2013
Last Test patient consented and monitored commenced	04/08/2014
Draft Final Report submitted to Department of Health	24/06/2014
Decommissioning of Nepean Blue Mountains Medicare Local Site	01/07/2014
Draft Report submitted to Department of Health	24/06/2014
Final Report to be submitted to Department of Health	27/09/2014
Completion of monitoring of Test Patients	31/12/2014
Data analysis and submission of updated report to Department of Health	26/04/2016

3. Aims and Objectives

This study was designed with the aim of demonstrating how telehealth services for chronic disease management in the community can be deployed nationally in Australia in a range of hospital and community settings and to develop advanced modelling and data analytics tools to risk stratify patients on a daily basis to automatically identify exacerbations of their chronic conditions.

The anticipated Project Outcomes included:

- Patients do not need to travel as regularly to see health professionals
- Through timely and better coordinated care, participants have fewer visits to emergency departments, reduced rates of hospitalisations and other clinical events
- Increased capability for patients to monitor and manage their condition/s from home
- Health providers delivering services more efficiently to a larger number of chronically ill patients
- Clinical and health economic evidence on how NBN-enabled telehealth services can be scaled up nationally to provide an alternative cost effective health service for the management of chronic disease in the community

To measure the outcomes the following research questions were addressed;

- Effect of telemonitoring on health service utilisation
  - Unscheduled visits to hospital, visits to GPs and Nurse visits
  - Cost and frequency of laboratory tests and other clinical procedures
- Effect of telemonitoring on patients outcomes
  - Quality of life, progression of chronic condition, wellbeing, medication adherence
- Service implementation and deployment
  - Existing model of care, service design , adoption and appropriation
- User experience and service implementation
  - Satisfaction, useability, acceptance, workload, anxiety and strain among study participants including health professionals, administrators, patients and carers
- Service implementation issues
  - How the new home monitoring service was implemented at each site
    What impact has this had on the process and outcomes of normal care delivery?
  - How are existing service practices evolving as a result of the new service
  - What can be learnt from different implementation approaches?
- Cost effectiveness analysis
  - Analysis of reductions/increases in costs borne by patients as a result of telehealth
  - Analysis of reductions/increases in costs borne by the commonwealth and on the ground service providers and patients as a result of the deployment of telehealth services

The Project Objectives were to:

- Demonstrate and document how telehealth services could be successfully deployed across Australia, by piloting services in five different settings across five states with a range of health service provider's, including Local Health Districts, Medicare Locals and not for profit community organisations.

This was demonstrated by deploying and demonstrating the operation of telehealth monitoring in a multi-site multi-state case matched control trial (Before-After-Control-Impact (BACI) design) of chronically ill patients living in their own homes in the community. This has never previously been attempted in Australia.

- Demonstrate the clinical and health economic evidence on how telehealth services could be scaled up nationally to provide an alternative cost effective health service for the management of chronic disease in the community.
- Patient selection was based on frequency of admission to hospital for a range of chronic conditions. This better reflects the population health realities of the healthcare system.
- Provide evidence that at home telemonitoring has the potential to reduce unscheduled admissions to Accident and Emergency (A&E) compared to the control group.
- Provide evidence for an impact on hospital admissions, mortality, clinical events and symptoms and improvements in functional measures and patients' and carers' experiences with care.
- Evaluate health economic benefits
- Evaluate impact on clinical work force availability and deployment
- Evaluate impact of human factors (acceptability, usability by patients, carers, nurses, GPs and administrators, impact on workplace culture)
- Evaluate impact of workplace culture
- Evaluate impact of organisational change management and business processes
- Develop a new evidence based data analytical technique for the risk stratification of patients' health status daily and demonstrate that this facilitates the management of large numbers of patients by orchestrating an optimal and timely allocation of resources to avoid unnecessary hospitalisation
- Demonstrate connectivity to PCEHR developments both through the use of MBS and PBS data to track changes in Test and Control patient outcomes and by demonstrating how clinical reports can be generated from at home telemonitoring data and automatically loaded to the individual patient's PCEHR record.

For each of the above objectives, operation of the trial at five different sites representing two different models, one Hospital Based and the other Community based, for the management of chronic disease in the community allowed the identification and analysis of site specific differences in workplace culture, organisational change management and staff and management capabilities that contribute to differences in measured health, social and economic outcomes.

Trial scope

Case matched control (BACI) trial of five sites (two sites in the Nepean Blue Mountains area were ultimately merged into a single site for logistical reasons) in five states and Territories each with 25 test patients and 50 control patients in both public and private healthcare settings.

- Deployment and evaluation of state of the art telehealth technology in the home for the monitoring of vital signs, delivery of clinical questionnaires and messaging between patients and carers.
- Development, deployment and preliminary testing of a new risk stratification schema to support nurse coordinators in orchestrating and optimising the delivery of care only and when required, to achieve the best healthcare outcome.

4. Methods

4.1 Organisation Charts

Establishing an appropriate Governance model for managing such a complex project is critical in order to comply with the requirements of the National Statement on Ethical Conduct in Human Research (2007) - Updated March 2014[5], the specific requirements of multiple Human Research Ethics Committees and the statutory requirements of the Therapeutic Goods Administration regarding the use of medical devices for monitoring health status.

The Organisational structure shown below in Figure 3 was established in April 2014. Clinical groups met on a weekly basis and were chaired by the Project Manager or the Clinical Trial Coordinator. The four research teams also met weekly to monitor progress against project milestones. The Project Management Committee met monthly to monitor and review progress of the project against its stated aims and objectives. This Management Committee was Chaired by the Project Director and included representatives from each site as well as two clinicians, one representing the interests of General Practice and the other, Chairing the Adverse Events and Death Review committee which met whenever necessary.

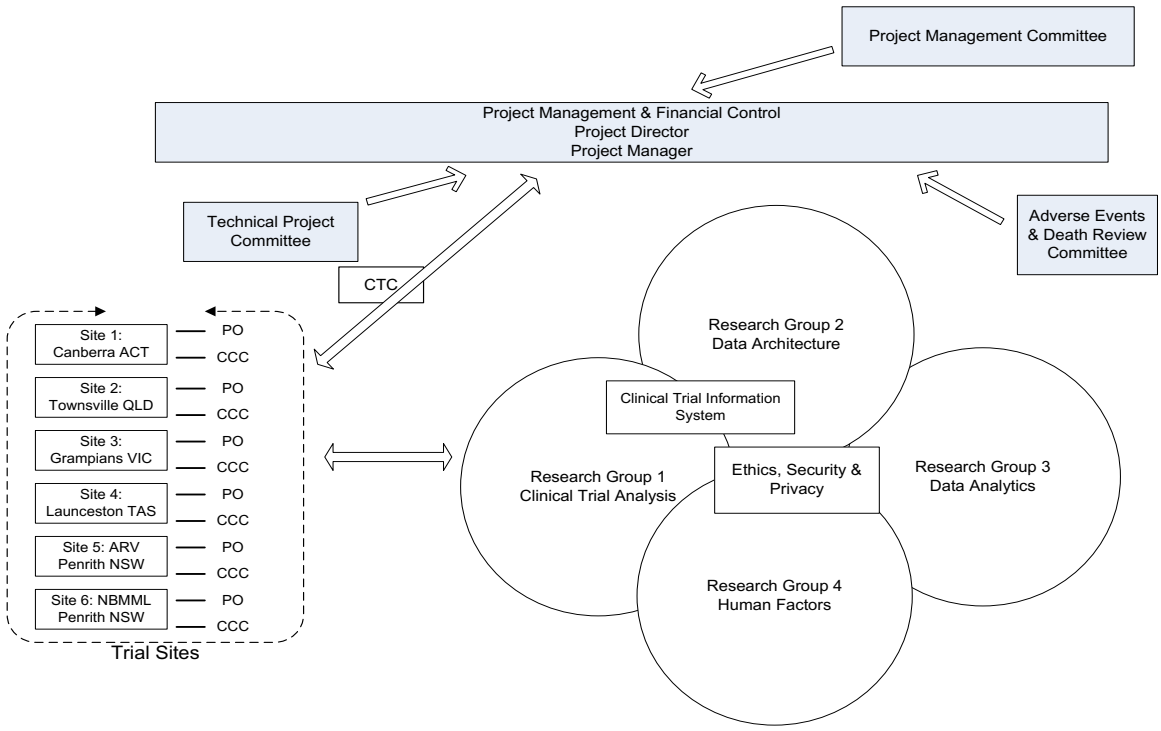


Figure 3 Project organisation chart

Notes:

- In August 2014, NBMML was decommissioned and patients from that site were transferred to ARV in Penrith for ongoing monitoring and management. Results for only five sites are therefore reported in this document.
- PO – Project Officer, responsible for patient recruitment and all research related tasks for the project
- CCC – Clinical Care Coordinator, responsible for clinical monitoring and management of Test patients
- CTC – Clinical Trial Coordinator, responsible for overall management of in-field activities.

[5] https://www.nhmrc.gov.au/guidelines/publications/e72

4.2 Operational Responsibilities

In Australia health services are delivered through a range of sectors, including public sector (federal, state), private for profit or not-for-profit organisations and sometimes a mix of these sectors. Chronic disease services usually involve multiple service providers (e.g., GPs, specialists, community nursing, allied health etc.) and require coordination between these stakeholders. Coordinated care programs have been introduced by using a central worker (nurse coordinator) who coordinates with service providers to develop a care plan dedicated to individual patients and provides ongoing follow-up to the patients. Patients with chronic conditions are usually triaged by assessment centres and assigned to different levels of care programs according to their disease severities. These programs can range from hospital-based to community-based and from federally funded to state funded.

Part of this study's intervention involved the introduction of the new role of telehealth nurse as a Clinical Care Coordinator (CCC) at each site. The role of the CCC was to monitor each participant's vital signs and liaise with GPs, specialists, and community nurses who may be caring for the participant.

A Project Officer (PO) was also allocated to each site and fully funded by the project to manage operational activities for the study and thereby separating patient care from study operations.

Project Officers and CCC at each site had the following operational responsibilities under the coordination of the CCC. Figure 4 shows detailed operational responsibilities and workflow for project staff.

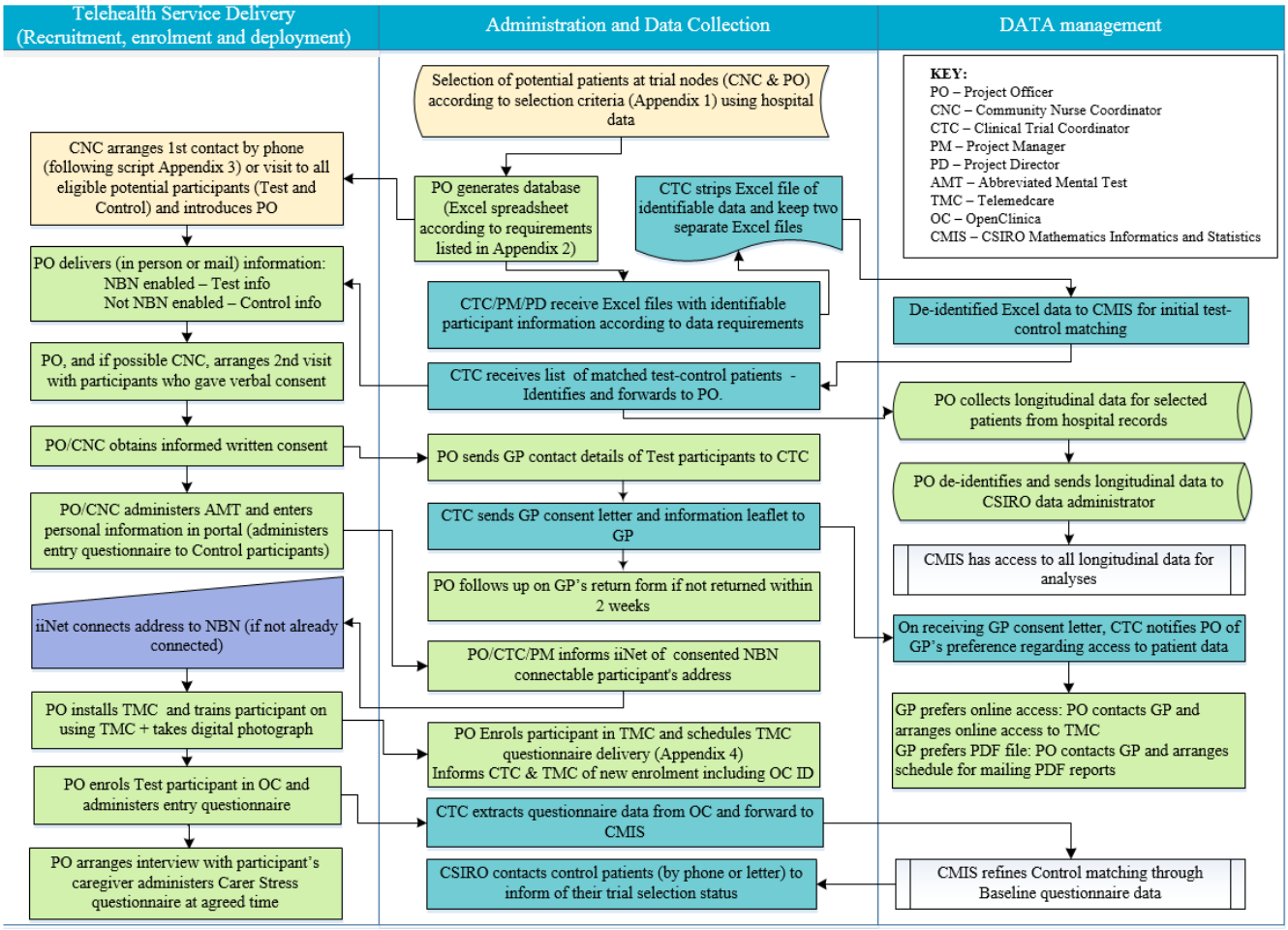


Figure 4 Operational responsibilities and workflows for Project staff

4.3 Selection of Telemonitoring Service

The CSIRO conducted a comprehensive technology assessment at arm's length from the study team to select a telehealth service provider for the study. Participants in the selection panel included senior CSIRO research and management staff and representatives from partner organisations.

The Table 1 Table 1below lists the selection criteria considered during the assessment.

Table 1 Telemonitoring Service Selection Criteria

#	CRITERION	DESCRIPTION AND/OR SPECIFIC REQUIREMENTS
1	Vital sign monitoring	Mandatory features: ECG, heart rate, spirometry, non-invasive blood pressure, oxygen saturation, body weight and body temperature. Optional: Glucometry (integrated or manual entry)
2	Interactive features	Participant/clinician video conferencing and messaging features. Support for scheduling and delivery of clinical and study specific questionnaires to participants. Quality/ease of use by participants and clinicians. Multi-language support.
3	Standards and regulatory compliance	Approval from relevant regulatory bodies, specifically Australia's TGA and preferably also European CE Mark and US FDA. Compliant with Health Information Exchange (HIE) and HL7 standards and Service-oriented architecture (SOA) for Web Services.
4	Clinical decision support capabilities	Ability to export de-identified raw data signals from the system for research and analysis. Expert system for daily patient risk profiling
5	Ability to support the study	Demonstrated experience and participation in telehealth clinical trials and research projects in Australia Australian based software and hardware R&D capability and capacity to support the research requirements of the CSIRO. Combined in-person and remote customer support for the on the ground patients and clinical teams Patient, clinician and study team training capability. Total cost of equipment/services over the lifetime of the study.

The technology selection panel selected the TeleMedCare[6] Systems Clinical Monitoring Unit (CMU), depicted in Figure 5 on the next page, and associated clinical web services, noting that not all features offered by the device were utilized in this study. The selection of this telehealth system was based on the factors below:

[6] http://www.telemedcare.com/

- All vital sign measuring devices are part of the system minimising issues that can happen by having separate devices connecting to a central unit
- The entire telehealth system together with measuring devices and software are TGA approved
- Telehealth system has no battery requirements as the unit is mains powered
- No incompatibility and calibration issues given the unit is designed to work together with all its devices
- New version was assessed as being very user friendly to operate
- All these factors including the costs fit within the time and budget of the trial

The site POs and CCCs configured the telemonitoring system to reflect clinical best practice for the patient's clinical condition. Typically patients would have some or all of the following vital signs measurements scheduled at a convenient time, typically in the morning;

- Non Invasive Blood Pressure (NIBP) using combined oscillometric and auscultatory techniques
- Pulse oximetry to measure arterial blood oxygen saturation
- Single channel ECG, using either the build in surface electrodes or a custom cable and clamps
- Spirometry, including measurements of;
    - VC – Vital capacity
    - PEF – Peak Expiratory Flow Rate
    - FEV1 – Volume expired in first second
- Body Temperature
- Body weight (±100gm accuracy)
- Glucometer – BGL blood glucose concentration

In addition to scheduled times, patients could take their vital signs at any time. A full suite of clinical questionnaires was also available. These were scheduled and administered by the CCCs. The TMC clinical monitoring unit also permits secure messaging and video conferencing between patients and their care coordinators.

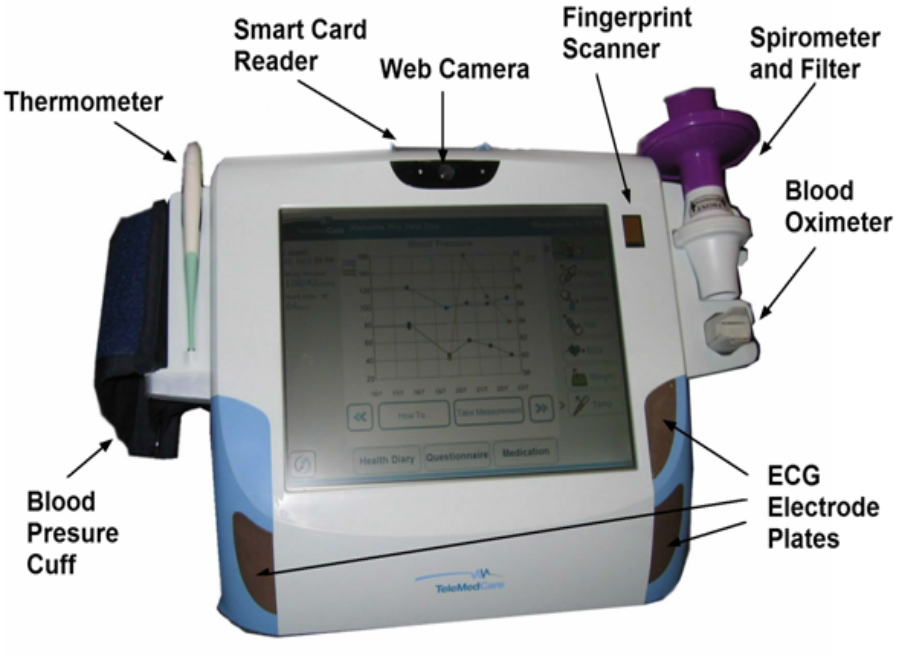


Figure 5 Telemedcare Clinical Monitoring Unit (CMU)

4.4 Clinical Trial Protocol

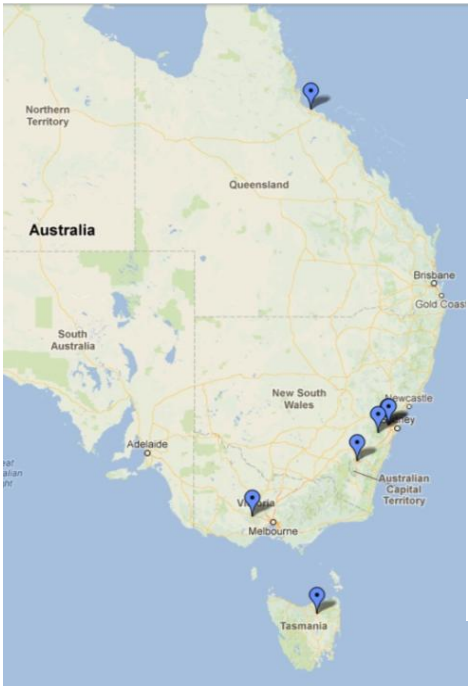
The Clinical Trial Protocol received clearance from multiple Human Research Ethics Committees (Table 2) and was registered with the ANZ Clinical Trial Register[7] (ID 364030).

This study was designed as a dichotomous, prospective, case matched before-after-control-impact (BACI) trial with 25 intervention and 50 control patients at each of six sites. The sites were widely distributed along the Australian Eastern seaboard as shown below in Figure 6. The Intervention was the provision of telemonitoring equipment for the collection of vital signs and the administration of questionnaires. Control patients received normal care.

Trial sites were originally selected on the following criteria:

- early participation in the rollout of the fibre-to-the-premises (FTTP) National Broadband Network (NBN);
- geographical location and demographic profile;
- variations in models of care used to manage chronic disease to be generally representative of the variety of models of care for the management of chronic disease existing in Australia.

Criterion (i) was subsequently modified to relax the NBN-supplied FTTP requirement as a consequence of the election of a new Commonwealth government in September 2013.



- Site 1: ACT - Canberra Hospital and ACT Health
- Site 2: QLD - Townsville and Mackay Medicare Local (TMML)
- Site 3: VIC - Ballarat and Grampians
- Site 4: TAS -Launceston Hospital and TNO
- Site 5: NSW -ARV Penrith
- Site 6: NSW - Nepean Blue Mountains Medicare Local (NBMML)

Figure 6 Trial sites along eastern seaboard of Australia and Tasmania

[7] http://www.anzctr.org.au/

In July 2014, NBMML was merged with ARV thus leaving five remaining sites. Of these, two in TAS and ACT, were hospital based with access to specialist nurses and medical registrars and the remaining three were community based with normal care being delivered primarily by GPs and/or community nurses.

The healthcare settings for the five local organizations ranged from hospital-based (ACT, TAS), Medicare Local (QLD), and community-based at Local Health District (VIC) to a private aged-care and homecare organization (ARV). Most of the sites had existing chronic disease management programs of some form. The ACT team had worked on a home telemonitoring program for a number of years before this trial. Other sites (VIC, QLD) had some prior experience with other telehealth applications. Clinical Care Coordinators at TAS and ACT were physically based at hospitals and worked closely with multidisciplinary teams consisting of specialist nurses, medical registrars and staff specialists.

In this study we analysed and compared the performance, subject to the availability of data, across three distinct groups with TAS and ACT as hospital based services, QLD, VIC and NSW as community based services, compared to the total cohort of patients across all sites.

Ethical approval was obtained from the Commonwealth Science and Industrial Research Organisation (CSIRO) Animal, Food and Health Sciences Human Research Ethics Committee (ref #13/04, approved March 2013), Adelaide Australia, and the ethics committee for each site. Approval to access MBS and PBS data was also obtained from the Commonwealth Department of Health and Ageing and the Department of Human Services, Canberra Australia as shown in Table 2 below.

Table 2 Ethics Committee Approvals

ETHICS COMMITTEE	APPROVAL #, DATE.
Commonwealth Science & Industrial Research Organisation (CSIRO)	13/04, 25 March 2013.
Department of Health & Ageing	25/2013, 7 August 2013.
Nepean Blue Mountains LHD	LNR/13/NEPEAN/79, 1 July 2013.
Townsville MacKay LHD	HREC/13/QTHS/56, 7 June 2013.
Ballarat LHD	HREC/13/BHSSJOG/29, 27 May 2013.
Canberra Hospital and ACT Health	ETHLR.13.122, 29 May 2013.
Tasmania North Health Service (Launceston Hospital)	Accepted CSIRO HREC Approval

4.5 Selection of Participants

Since random selection of patients was not possible because of small sample sizes and the initial requirement that Test patients be selected from areas connected to the NBN, a Before After Control Intervention (BACI) design was adopted that foregoes assumptions of normality. The BACI paired samples design provides greater control over confounding variables, increases the power of the study and improves the chances of finding a significant result with a smaller number of samples if the impact is relatively small.

The research protocol required the recruitment of 75 participants at each of the six sites to achieve a total sample size of 450. Of these 150 were to be recruited as Test patients and 300 Control patients. At each site 25 participants were to be allocated to the intervention, with 50 remaining control participants receiving normal care as per their site's existing model of care.

Eligible candidates were identified primarily by searching the hospital patient administration system (PAS) for patients who satisfied the eligibility criteria described in Table 3. Some candidates were also identified by site clinical staff familiar with their medical history. A total of 1430 eligible patients were identified from hospital lists provided by ACT (520), NSW(230), QLD(187), TAS (210) and VIC (282). Patient lists were obtained from Townsville Hospital, Canberra Hospital, Nepean Blue Mountains Hospital, Ballarat Hospital and Launceston Hospital.

Candidates were eligible to participate in the study if they met all inclusion and none of the exclusion criteria listed in Table 3 and became participants on the signing of informed consent in the presence of an independent witness.

Table 3 Clinical criteria for eligibility

Criteria	Type	Description
Age	Inclusion	50 years old and over at consent.
Cognitive capacity	Inclusion	Abbreviated Mental Test (AMT)[27] score >7.
Unplanned acute admissions	Inclusion	A rate of unplanned acute admission with the required principal diagnosis code(s) indicated below: a) > 2 in the last 12 months, or b) > 4 in the previous 5 years.
ICD-10-AM principal diagnosis code(s) for each unplanned acute admission	Inclusion	Code(s) for each unplanned acute admission indicate a diagnosis for one or more of the following chronic conditions: a) Chronic Obstructive Pulmonary Disease (J41 – J44, J47 and J20, with secondary diagnosis of J41-J44, J47), b) Coronary Artery Disease (I20 – I25), c) Hypertensive Diseases (I10 – I15, I11.9. Note: Hypertensive Heart Failure (I11.0) is included in Congestive Heart Failure), d) Congestive Heart Failure (I11.0, I50, J81), e) Diabetes (E10-E14), f) Asthma (J45).
Unsuitable conditions	Exclusion	The study team considered the presence of the following conditions to be unsuitable for participation in the study: a) Any form of cancer, b) Any neuromuscular disease c) Any psychiatric conditions.
Care team	Inclusion	The eligible patients were to be under the care of any of the following: a) Community nurse and / or b) General Practitioner
Care programs	Inclusion	Participation in one of the following government care programs: a) Commonwealth Chronic Disease Management b) Commonwealth Coordinated Veterans' Care Program c) NSW Connected Care Program
Unsuitable care programs	Exclusion	Participation in one of the following government care programs: a) Commonwealth Extended Aged Care in the Home

For the purposes of our study unplanned admissions were all admissions other than:

1. Admissions from the waiting list (including both the surgical list and the medical waiting list);
2. Admissions listed as "regular same day planned admissions" which were admissions that were intended regular and planned same-day admissions for an on-going phase of treatment, such as renal dialysis or chemotherapy.

Following the signing of a consent form and completion of the Entry Questionnaire (see 4.5 below), Test patients were connected to the internet and supplied with the TMC telemonitoring system and trained on its use by the PO. Their vital signs were monitored daily except on weekends and questionnaire responses, recorded via the Telemedcare CMU, were monitored as per schedule in Table 6 by the CCC. On site visits and technical support as well as the obtaining of Consent and the administration of Exit questionnaires were the responsibility of the PO.

Control patients also completed the Entry questionnaire but otherwise continued to receive normal care. For each intervention participant, six control candidates were automatically case matched on gender, age, chronic condition and Socio-Economic Indexes for Areas (SEIFA)[8]. On their consent the two closest matching control candidates commenced as participants in the study. The remaining four candidates were held in reserve. Table 4 below demonstrates the case matching process.

Generally, the closer the match the greater the likelihood of finding a significant result with a smaller number of samples if the impact is relatively small.

Table 4 Example of case matching of Control patients with Test patients

TEST/CONTROL	AGE	GENDER	MAJOR DIAGNOSIS	SEIFA[1] INDEX FOR POSTCODE	STRENGTH OF MATCH Perfect Match=0
TEST	54	M	COPD	1023	
CONTROL 1	56	M	COPD	1025	1.68[2]
CONTROL 2	54	F	HD	1022	2.16[3]
WEIGHTS	0.2	1	1	0.16	

[1] SEIFA 2011 Socio-Economic Indexes for Areas.
SEIFA provides measures of socio-economic conditions by geographic area[25]

[2] |54-56| x 0.2 + 1 x 0 + 1 x 0 + |1023-1015| x 0.16 = 1.68

[3] |54-54| x 0.2 + 1 x 1 + 1 x 1 + |1023-1022| x 0.16 = 2.16

Ideally, as many as four matches were sought for each Test patient, and the closest match was then selected as the case matched control for that Test patient. In many cases only one acceptable match was available.

4.6 Questionnaire Instruments

A number of questionnaire instruments were developed or adapted from the literature for use in the trial. All patients enrolled in the study were required to take an Entry and Exit Questionnaire. This questionnaire instrument was developed from a base CSIRO CAFHS Human Research Ethics Standard Screening Medical Questionnaire[9] with the addition of other questionnaire instruments either wholly or in part, measuring demographic, lifestyle, health and disease characteristics. Key elements of the Entry and Exit Questionnaires are described in Table 5 below.

[8] http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifa

[9] http://my.csiro.au/Support-Services/Human-Research-Ethics-in-CSIRO/Health-and-Medical-Research-Ethics/Human-Research-Ethics-Committee.aspx

Table 5 Key elements of the Entry and Exit Questionnaires

Section	Source/Questionnaire
1-3	CSIRO Standard Screening Medical Questionnaire[7]+ additional trial specific questions
	‡Selected questions from Living with Diabetes Study[28]
	‡Selected questions from Fat and Fibre Barometer[29]
4	Active Australia[30]
5	Kessler 10[31]
6	Dimensions from HeiQ (Living with and managing medical conditions)[32]
7	EQ-5D[33]
8	Dimensions from HeiQ (Social Isolation)[32]
9	Morisky Medication Adherence[34]

In addition to the Point of Entry and Exit questionnaire, a number of questionnaires were scheduled and administered to Test patients (and caregivers when applicable) during the trial with varying frequency. These are described in Table 6 below. A user questionnaire was also administered to clinicians at the end of the study.

Table 6 Questionnaire Instruments and their schedule

QUESTIONNAIRE	ADMINISTERING SCHEDULE
COPD (Developed by the Austin Hospital)	Daily
CHF (Developed by the Austin Hospital)	Daily
*EQ-5D (Quality of life)]	Weekly
*Kessler 10 (Mental health)	Monthly
*heiQ – selected domains (Self-monitoring, Health services navigation and Social isolation)	Entry, 6 months, Exit
*Morisky Medicine Adherence Scale	Entry, 6 months, Exit
Caregiver Strain Index[35] (administered to patient caregiver)	Entry, 6 months, Exit
Abbreviated Mental Test[27]	At consent
User acceptance and Satisfaction (to patient) [36]	6 months and at exit of study
User acceptance and Satisfaction (to clinicians) [36]	At end of the study

* The questions from these questionnaires were also included in the Participant Point of entry and -Exit Questionnaires which were administered at entry and exit by the PO and through the TMC monitoring device at 6 months. In some cases the Exit questionnaire was administered to Test patients through the TMC device.

The scheduling for these questionnaires was set in the TMC system by the PO, after liaising with the CCC on disease specific questionnaires (COPD and CHF). All frequently administered questionnaires, such as the COPD and CHF, EQ5D and K10 questionnaires were scheduled and administered to Test patients through the TMC monitoring device.

4.7 Additional Information on Entry and Exit Questionnaire Instruments

As mentioned in 4.6, the instruments listed in Table 7 below were used in the Entry Questionnaire administered to all Test and Control patients. Table 7 provides additional information on the measures and scores used in the trial. The Entry Questionnaire was administered to Test participants at the time of deployment of their TMC telemonitoring device. In most cases data were entered directly into the OpenClinica portal, an open source clinical trial software for electronic data capture and clinical data management.

However in some cases the responses were collected on paper and then entered in the database at a later more convenient time. This was mainly due to time limitations at the patients' homes especially when the telemonitoring device installation took a bit longer than usual (configuration issues or other technical issues).

Table 7 Entry Questionnaire instruments and their interpretation

Domain	Questionnaire	Measure	Meaning of Score
Demographic information	CSIRO Demographics Questionnaire + additional trial specific questions	Gender, Age, weight and height (BMI), occupation, marital status, income, computer skills, social media and NBN connectivity	Individual and coded scores
Behaviour information	Selected questions from Living with Diabetes Study and Fat and Fibre Barometer	12 questions relating to alcohol intake, tobacco smoking, fruit and vegetable consumption, meat and fish, fibre, fat and salt intake	Individual and coded scores
Physical Activity	Active Australia Survey	Participation in leisure-time physical activity	<150min/week: insufficiently active ≥150min/week: sufficiently active
Psychosocial functioning	Kessler 10 (K10)	10 questions assessing how a patient has been feeling in the last four weeks	Score 10-50; 10 defines patient not experiencing feelings of distress and 50 being severe level of distress • Score < 20 are likely to be well • Score 20-24 are likely to have a mild mental disorder • Score 25-29 are likely to have moderate mental disorder • Score 30 and over are likely to have a severe mental disorder
Living with and Managing Medical Conditions; Social Isolation	Dimensions from HeiQ	16 questions relating to living with and managing medical conditions and 5 questions relating to social isolation	Equally-weighted total scores on all heiQ sub-domains are calculated and re-scaled (total scores of the questions divided by the No of the questions) to range from 1.0 to 4.0. Higher scores refer to self-reports of more positive effect of a self-management program

Domain	Questionnaire	Measure	Meaning of Score
Quality of Life	EQ5D	Scores derived from responses to five generic questions on health status • mobility • self-care • usual activities • pain/discomfort anxiety/depression VAS records respondent's self-rated health on a vertical, visual analogue scale (0-100) where the endpoints are labelled 'Best imaginable health state' and "Worst imaginable health state	Results presented as Index (Australian) VAS presented as number from 0-100 with 0 the worst and 100 the best imaginable health state
†Medication adherence	Morisky Medication Adherence Scale	Eight item self-report scale on medication adherence	Low adherence (<6), Medium adherence (6 to <8), High adherence (=8)

For Control participants, the Entry Questionnaire was administered after written consent to participate in the trial was obtained during a face to face meeting with the PO.

4.8 Use of Focus Groups, Structured interviews and Questionnaires

A multi-method approach was adopted for the study of implementation, user acceptability and useability. Table 8 summarizes study methods, participants and data collected and included in this report.

Table 8 Research methods for evaluating useability and acceptability of telehealth services

METHODS		STUDY PARTICIPANTS	DATA COLLECTED
Questionnaire	Patient satisfaction and acceptance (at six-month and twelve-month time points)	All test patients	Questionnaire at six-month and at exit of the study
	Clinician satisfaction and acceptance (end of the trial)	All CCCs and POs	End of trial
	Patient declining or withdrawing	Patients who do not commence or complete the trial	At point of refusal or withdrawal
Semi-structured interview	During the first phase of the trial (Aug-Sep 2013)	CCCs and POs of 6 sites (including managers at some sites)	Interview transcriptions
	Ongoing implementation (Dec 2013)	CCCs and POs of 6 sites (including managers at some sites)	
	During field studies (Oct 2013, Mar-Apr 2014, Aug 2014)	Study participants of "Field study"	

METHODS		STUDY PARTICIPANTS	DATA COLLECTED
Field study and interviews	Around six-month time point of telemonitoring at four sites: TAS (Oct 2013) VIC, ACT, Old (Mar-Apr 2014) NBM, ARV (Aug 2014)	CCCs and POs of 6 sites (including managers at some sites); Two GPs and one GP group (one GP per site at VIC and Qld; a group of eight GPs at TAS) 2 patients and a patient group (1 patient and 1 carer per site at VIC, Qld, ACT; a group of 8 patients and their carers at VIC)	Notes; Reports; and Interview transcriptions;
POs and CCC's notes	Recorded success stories and issues as "Observation and Story" in CSIRO portal	POs and CCCs of 6 sites	Descriptions of observations and issues

4.9 Data Models

As described earlier, patient data were obtained from multiple sources and integrated into a single unified database linked via the unique OpenClinica ID (OCID). A Data Model was developed which provided the template for data analysis by linking outcomes and objectives to specific data variables and identifying the data sources. This data model underpinned nearly all quantitative analysis presented in this report. The data model is presented below in Table 9.

Table 9 Data Model for evaluating outcomes and objectives

OUTCOME / OBJECTIVE	DATA VARIABLE	DATA SOURCE
CONFIRMATION OF SELECTION CRITERA	Admitted to hospital for their condition at least twice in the previous year, or > 4 times in previous five years	Hospital data in Health Roundtable format - obtained from local hospital for previous five years. • Date admitted • Date discharged • Reason for admission (ICD 9/10 Codes) • Procedures carried out
REDUCED HOSPITALISATION	Number of Unscheduled admissions to hospital for their condition	MBS Flag (In Hospital) data in Health Roundtable format • Date admitted • Date discharged • Reason for admission (ICD 9/10 Classification) • Medication administered • Procedures carried out
REDUCED USE OF CLINICAL SERVICES	Number of visits to/by GP Number of visits to/by specialists	MBS records MBS records

OUTCOME / OBJECTIVE	DATA VARIABLE	DATA SOURCE
(Impact on Clinical Workforce availability and deployment)	Number of visits by community nurse Number of visits to/by allied health (ie occupational therapist) Changes in prescription history Communication with CCC	MBS records MBS records (If reimbursable from Medicare) PBS CCC Logs from CSIRO Portal
ORGANISATIONAL CHANGE MANAGEMENT AND IMPACT ON WORKPLACE CULTURE	Administrative / operational changes implemented/required in order to implement the telehealth service.	Questionnaires and structured interviews. • Within first three months • Every six months thereafter
USEABILITY OF MONITORING EQUIPMENT	Compliance with monitoring schedule, recorded daily. Extra measurements taken by patient (When? Which?) Compliance with questionnaire administration (When? Which?) Use of Video conferencing Overall data usage	TMC Logs TMC Logs TMC Logs TMC Logs iiNET provided logs
USEABILITY/ACCEPTABILITY FOR PATIENTS OF MONITORING EQUIPMENT	Ease of Use Quality of training received Patient embarrassment if visitors know they are being monitored Acceptability as an item of furniture Easy or hard to take measurement Important/Not Important in patients' self-management Responsiveness of Clinical Care Coordinator in responding to changes	Questionnaires delivered via TMC • Midpoint of trial • At end of trial
CARERS EXPERIENCE WITH TELEHEALTH (Community Nurse/Carer)	Ease of use of (i) equipment and (ii) Clinician website Changes to previous clinical models of care Effectiveness in improving ability to deliver care Impact on workload	Questionnaires and structured interviews of Community Nurses • At end of trial
CARER'S EXPERIENCE WITH TELEHEALTH (Relative or other carer)	Effect on Carer stress Effect on carer workload Effectiveness in improving ability to deliver care	Questionnaires and structured interviews • Midpoint of trial • At end of trial

OUTCOME / OBJECTIVE	DATA VARIABLE	DATA SOURCE
GP EXPERIENCE WITH TELEHEALTH	Ease of use Changes to clinical models of care Effectiveness in improving ability to deliver care Impact on workload	Questionnaires and structured interviews of Patients' GP • Within 3 months of first deployment • Midpoint of trial • At end of trial
USEABILITY, ACCEPTABILITY OF CLINICIAN WEB INTERFACE	Ease of Use Quality of training received How many hours required Value and ease of use of Video conferencing	Questionnaires delivered via TMC • One month after first deployment • Midpoint of trial • At end of trial
HEALTH ECONOMIC OUTCOMES	Daily cost of hospitalisation Cost of procedures carried out whilst in hospital Cost of visits to/by GP Cost of visits to/by Allied Health (ie Chiropodist or OT) Cost of visits by Community Nurse / Carer Cost of travel to GP Loss of earnings if patient was still employed, from days taken off for illness or visits to health professionals	Hospital data in Health Roundtable format Hospital data in Health Roundtable format MBS Data MBS Data MBS Data MBS Data Use Google Maps to determine distance travelled from home address to address of service location, then apply standard costing model. Ie flag fall + km charge Estimate from patient salary and time spent on each visit
COST OF DELIVERING TELEHEALTH SERVICES	Cost of Clinical Care Coordinator(s) Cost of Clinical Nurses/Carers Cost of providing network services Cost of providing telehealth monitoring services Depreciated costs of capital equipment Estimate of cost of space for monitoring centre at each site	Health service provider and logs recorded Health service provider and logs recorded iiNET billing at commercial rates TMC commercial daily subscription costs Our own project records Estimates from Health service Provider

4.10 Methodology for Data Analysis

This project was designed to integrate data vital signs and questionnaire responses from the telemonitoring devices deployed to Test patients with questionnaire data administered to Test and Control patients as well as PBS, MBS and hospital data obtained for both Test and Control patients. Detailed data analysis was carried out primarily on the 100 Test and 137 Control patients (Refer Section 5.1.2 for final patient numbers included in this analysis), but this group was also be subdivided according to (i) primary diagnosis (Cardiac, Respiratory or Diabetes) (ii) whether monitoring was carried out in hospital or community settings or (iii) by site (QLD, NSW, ACT, VIC and TAS). Consideration was given to the size of the resulting cohort and the reliability and public health value of the resulting analysis.

Primary analysis was carried out on the impact of telemonitoring on total MBS and PBS expenditure as well as on number of admissions and length of stay. In Appendix 8.3, these analyses are extended using a number of methods to individual parameters such as number and cost of GP visits, number and cost of visits to specialists and number and cost of tests and procedures prescribed.

It was quickly determined that most data was time varying, as one would expect, given that many health related events and costs increase as patients age. The impact of telemonitoring on the trajectory of these increases is therefore of particular interest, and it became essential to model these changes using a variety of Before and After Control Intervention (BACI) time varying analysis methods such as linear regressions against time, linear mixed effects modelling and cumulative sums of differences.

Baseline characteristics are described for time intervals as mean ± SDs for continuous symmetrical variables and means and 95% Confidence Intervals (CI) for skewed data. Confidence limits were calculated according to the method of Zou, Taleban and Huo [41]. All statistical tests are two-tailed matched pair t-Tests, and a p value of < 0.05 was used to indicate statistical significance. Statistical analysis is performed using Stata Release V.12 (TX: StataCorp LP), SPSS 17, MATLAB and Microsoft Excel.

The results of these analyses on primary parameters such as Questionnaire Data, MBS and PBS costs, as well as number of hospital admissions and length of stay are presented in Chapter 5 with a more fine grained analysis undertaken on individual sites and specific second order parameters, presented in Appendix 1.

4.10.1 Questionnaire data

Baseline characteristics are described for both groups using mean ± SDs for continuous symmetrical variables and medians and 95% CI for skewed data. Categorical variables are presented as counts and percentages. Comparisons is made between the two groups at baseline using the cases available. The $\chi 2$ test (or Fisher's exact test) is used for categorical variables, the two-sample t-test for continuous variables and the Wilcoxon rank-sum test for skewed variables. Within-group differences from baseline to last point are examined using the paired t-test for symmetrical data and the Wilcoxon signed-rank test for skewed data.

All statistical tests were two-tailed, and a p value of < 0.05 was used to indicate statistical significance. Statistical analysis was performed using Stata Release V.12 (TX: StataCorp LP), SPSS v17 and Microsoft Excel.

4.10.2 PBS, MBS and Hospital data

Raw data were received from numerous sources as shown in Figure 7, typically as EXCEL spreadsheets.

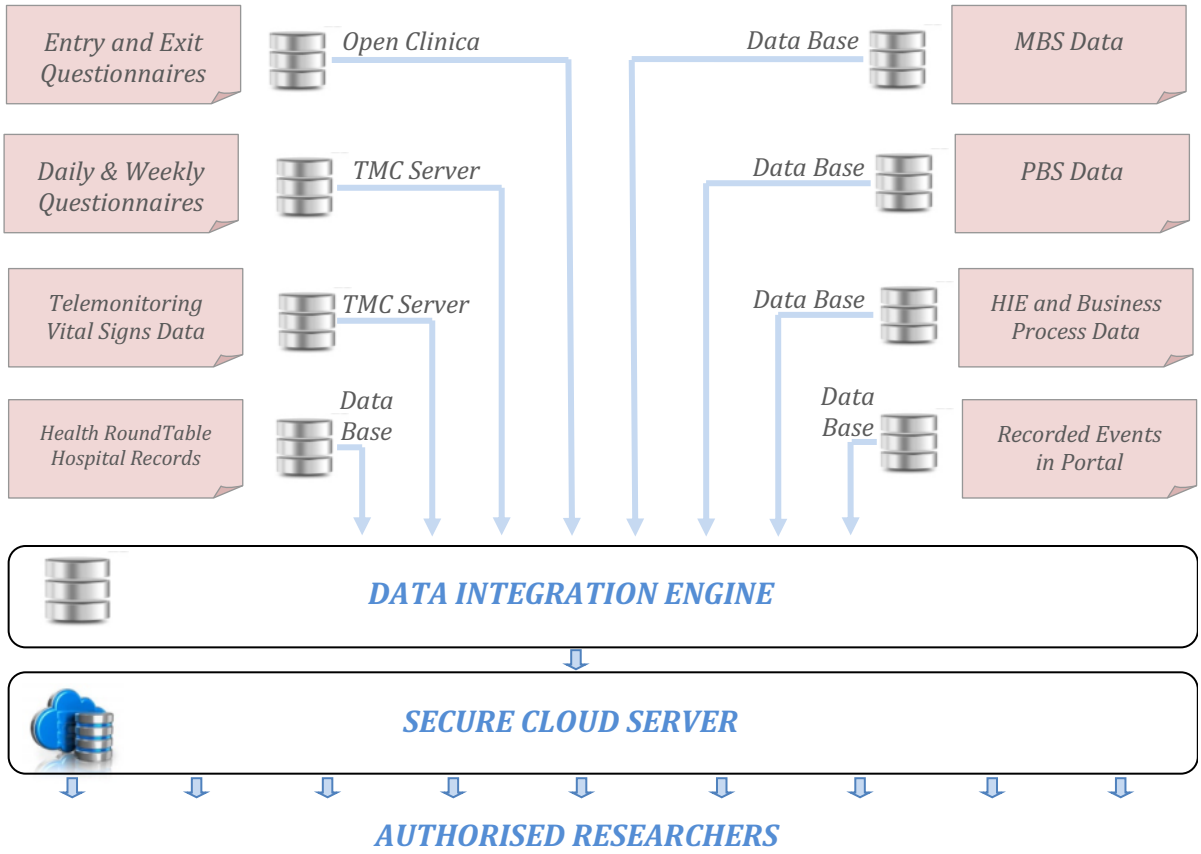


Figure 7 Schematic diagram of different data sources and their secure integration

On receipt of raw data, the file extension was checked and if in EXCEL format, the file was converted to CSV (Comma-Separated Version) format. The conversion was done by opening the excel file in MS Excel xxx.xlsx and saving it as xxx.cvs. Once the data file was in the CVS format, the next step was to insert it into a relational database. To do this, a table structure with its attributes was defined. The attributes were based on the columns in the CSV file. Once a table structure was defined, it was created inside the MySQL database using the *sql* command.

Once the table was created, the CSV data was ported into the database table, using the MySQL *load infile* function which allowed the data to be populated inside the database table without having to write a single line of programming code but simply using a script.

Once data was in the data base, various SQL query commands (e.g., *select, update, delete*) were used to produce various results required for reports. To facilitate this, the MySQL workbench, a client application that connects the backend database and retrieves the data from the database table according to SQL queries was used. The results were saved as CSV files which could be opened in MS Excel.

To generate various graphs according to the query results, either built-in Excel graph function were used or Visual Basic programming was used if the graph was complex. Statistical analysis was performed using Stata Release V.12 (TX: StataCorp LP), SPSS, R, MATLAB and Microsoft Excel.

PBS, MBS and Hospital data were all synchronised to the date when the telemonitoring commenced. As Test patients were connected to telemonitoring equipment over a period of months, synchronising to the date monitoring begins had the added advantage that seasonal effects were averaged out. PBS, MBS costs for every patient were averaged over 30 day periods, typically for 36 x 30 day periods back from date of connection and 12 x 30 days forward. This approximated to analysing data over three years before and one year after the intervention. In Appendix 8.3, we present BACI lme modelling analysis where seasonal variations were specifically considered.

Hospital admissions data and length of stay were similarly treated, except that the time interval chosen was 100 days. This was a preferred interval as hospital admissions were much less frequent and would generate data with a large number of zero entries. Similarly, 12 x 100 day periods back from the time of connection and 4 x 100 day forwards were analysed.

PBS, MBS and Hospital data were analysed as time series, where data across all test patients were averaged over each time period and plotted before and after the time of intervention. Normality of data was tested in each case and where necessary sqrt or LogNormal transforms were applied. The time series before and after intervention were then investigated using linear regression and Analysis of Covariance methods. Before and after data were analysed both as being separate lines with different slopes or the same line having the same slope. ANCOVA was then applied to test whether the slopes are significantly different at the 95% confidence level.

This analysis was applied to (i) Test patient data (ii) Control patient data and (ii) Difference (Control-Test) data.

These time series analyses permitted the determination of how well Test patients and Control patients were indeed matched, controlled for possible effects of the intervention on Control patients and by analysing differences, eliminated possible seasonal and other possible time varying influences.

5. Results

This complex and ambitious project envisaged the recruitment of 25 Test patients at each of six sites, consented and monitored for a period of one year, with another 50 case matched control patients tracked over the same period. One group was decommissioned, which resulted in a target cohort of 125 Test patients and 250 Controls

At the end, noting the complexity of mounting a clinical trial across six sites and five states and Territories, with different workplace cultures and different capacity for organisational change management, we were able to achieve the following results;

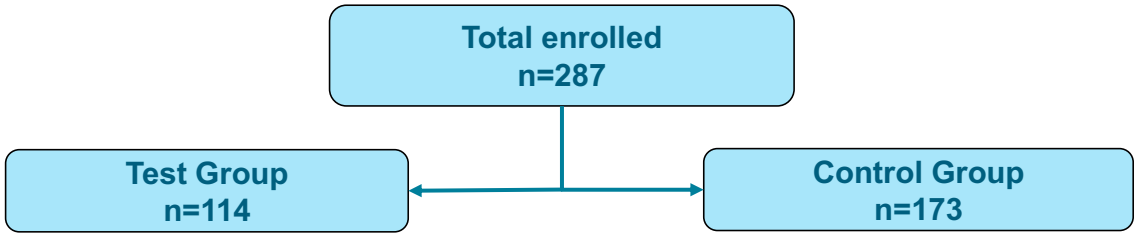


Figure 8 Final cohort of Test and Control patients

5.1 Patient recruitment of Test and Control Patients

The trial design required that patients at each site be selected from a list of eligible patients provided by the major public hospital at that site. Canberra Hospital and ACT Health, Nepean Blue Mountains LHD, Townsville Mackay LHD, Launceston Hospital and Ballarat Hospital all provided lists from which Test and Control patients could be selected.

Our target numbers were to recruit 25 Test patients and their 50 matched Control patients at each of the six sites selected. As one site was decommissioned due to slow enrolment, and merged with another, our final target was to recruit 125 Test patients and 250 Control Patients. Ultimately we recruited and consented 114 Test Patients and 173 Control patients as shown in Figure 8, but of these only 71 Test patients and 110 Control patients were from the hospital lists provided.

The majority of patients NOT on the hospital lists, were either from VIC or NSW. In Victoria patients from the Djerriwarrh Health Services, would primarily be admitted to Bacchus Marsh & Melton Regional Hospital rather than Ballarat Hospital. In the Nepean Blue Mountains area, most patients were consented by ARV and were not necessarily on the Nepean Blue Mountains LHD list. In every case however, local PO's would ensure that patients recruited into the project were eligible for inclusion

The results of recruitment of 114 Test patients and consenting 173 Control patients is described in Table 10 below.

Table 10 Patient demographics and recruitment at each site

	TAS		ACT		VIC		NSW		QLD		TOTAL	
	Hospital Based				Community Based							
Eligible patients from Hospital lists provided	210		520		282		230		187		1429	
	T	C	T	C	T	C	T	C	T	C	T	C
Patients consented												
Patients consented, did not commence	5		5		10*(4)		5		3(1)		23	
Patients Consented from Hospital lists	29	56	16	22	0	1	7	4	19	27	71	110
Patients consented from **outside** Hospital list	-	4	-	1	26	48	10	8	7	2	43	63
All Patients Consented	29	60	16	23	26	49	17	12	26	29	114	173
Age (SD)	69.4 (9.0)	72.8 (9.7)	70.7 (8.2)	73.7 (8.6)	69.7 (7.6)	68.9 (8.8)	77.3 (9.1)	71.0 (12.9)	70.5 (10.7)	74.1 (8.5)	71.1 (9.3)	71.9 (9.4)
Number of **Male** patients	18	35	11	14	19	24	9	7	16	17	73	97
Age (SD)	69.5 (10.1)	73.3 (9.7)	70.5 (7.6)	72. 6 (7.2)	70.3 (7.8)	70.2 (8.4)	76.0 (7.3)	66.4 (12.8)	69.9 (8.9)	74.3 (8.6)	70.8 (8.6)	72.1 (9.2)
Number of **Female** patients	11	25	5	9	7	25	8	5	10	12	41	76
Age (SD)	69.2 (7.3)	71.9 (9.8)	71.0 (10.2)	75.4 (10.7)	68.0 (7.5)	67.5 (9.2)	78.7 (11.1)	77.4 (11.2)	71.5 (13.7)	73.9 (8.6)	71.6 (10.4)	71.7 (9.9)

*agreed to be controls

Matched Control patients were to be ideally recruited and consented as soon as possible after Test patients were recruited, but as Control patients did not receive any intervention, their health status could be retrospectively tracked from MBS and PBS Data and hospital data over the same time period as the Test patients were monitored.

The time course of recruiting and connecting 114 Test patients to the telemonitoring equipment and of consenting 173 Control patients are shown in Figure 9 below.

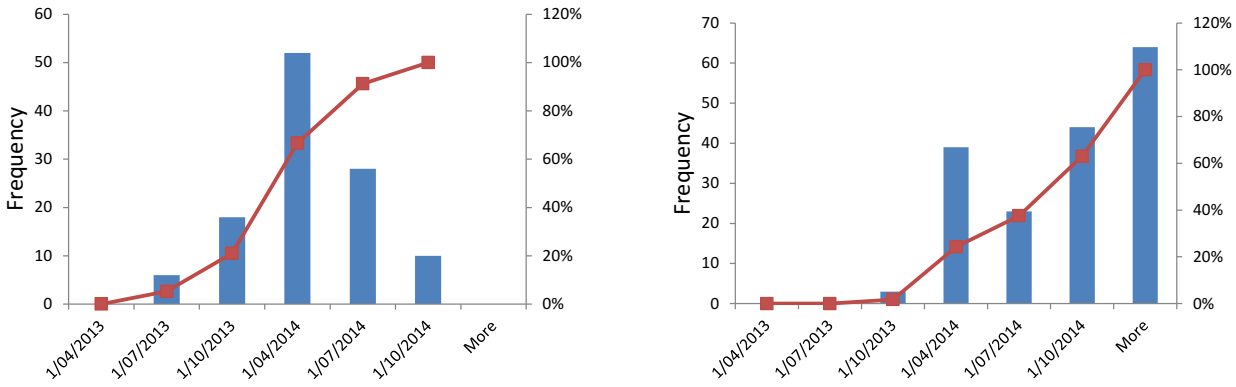


Figure 9 Time course of (a) connecting 114 Test patients, and (b) consenting 173 Control Patients

5.1.1 Reasons for declining or withdrawing from the study

As described in Section 4.4, potential eligible candidates were identified primarily by searching the hospital patient administration system (PAS) for patients who satisfied the eligibility criteria as described in Table 3. Some candidates were also identified by site clinical staff familiar with their medical history.

It was the role of the PO to contact participants, confirm eligibility, provide information and to enquire whether eligible individuals were interested and willing to consent to, and participate in the trial. Outcomes of the recruitment process are reported as follows:

Individuals excluded from trial (subsequent to initial screening)

When contacted, a total of 41 individuals were found not eligible, and therefore not asked to consent (Test n=26; Control n=15). The main reasons were: number/diagnoses of hospitalisations not meeting inclusion criteria, resident/moving to Aged Care facility, diseases of the nervous system such as Parkinson's disease, disorder of cognitive processes (dementia), severe visual impairment, not speaking English and cancer diagnoses.

Individuals declining participation

Data for individuals declining the trial (Test n=95; Control n=33) are presented in Table 11. There was little difference in gender with 52% male and 48% females not wanting to participate. Table 11 describes the reasons stated by individuals with the numbers representing the counts per reason, as some participants stated more than one reason.

The numbers presented therefore exclude potential participants who were found not eligible (and therefore not asked to consent) when contacted.

Table 11 Reasons given by patients for declining to participate in the trial

REASON FOR DECLINING THE TRIAL	Number of times cited (%)
Not interested / lack of motivation or commitment	71 (55%)
Perceives participation in the trial to be too much of an effort	39 (30%)
Competing life demands	21 (16%)
Perceives the TMC device too difficult to use	15 (12%)
Do not feel they would benefit from the intervention	12 (9.4%)
Deterioration in health and/or medical care needs	10 (7.8%)
Logistical reasons	10 (7.8%)
Concerns regarding privacy	7 (5.5%)
Study Design	1 (0.8%)
Other	12 (9.4%)

The main reason reported for declining to participate in the trial was a lack of interest (55%) followed by participation in the trial being perceived as too much effort (30%). Most of the individuals, who did not feel that they would benefit from the intervention, indicated that they had plenty of care in place and felt well supported by family/friends and/or GP. Although the age of those who declined was not always available, the average age of the cohort of patients who declined was quite high (77.8±10). The reason given for declining, that they perceived the TMC too difficult to use, was cited by only 12% and only 6% had concerns about privacy. Competing life demands were mainly cited as being too busy with work or caring for a partner, too much going on and travel/going away for a long period of time, whereas logistical reasons included not wanting the internet, and relocation. The 'Other' reasons reported were notion of own non-compliance, fear of out of pocket cost for internet, recovered enough from condition, not in the right state of mind and not wanting a daily reminder of sickness and poor health.

Withdrawal from trial after consent but prior to deployment of monitoring equipment (Test participants only)

A number of individuals who undertook (signed consent) to take part in the trial as Test participants (n=27) were not able to commence due to the reasons provided in Table 12:

Table 12 Main reasons for consented Test patients not commencing monitoring

REASON FOR NOT COMMENCING MONITORING (TEST PARTICIPANTS)	N
GP/Specialist refused consent	2
Participant not contactable to arrange TMC deployment	5
Could not successfully be connected to Internet (NBN or ADSL)	8
Living environment not suitable for TMC deployment	4
Change in personal circumstances	8

According to CSIRO Ethics Approval (ref #13/04), involvement in the trial as Test participant required the approval from their treating practitioner. Two of the consented participants had to be withdrawn from the trial after they consented, due to refusal by their GP and Cardiologist, respectively, to consent.

The requirement at the start of the trial for high speed broadband connectivity lead to significant delays for many participants from date of consent to deployment of the telemonitoring device. This was due to poor internet connection availability, arising from significant delays in broadband network roll-out. As a result, a number of participants (n=5) were not contactable by the time roll-out progressed to their area. Eight dwellings could ultimately not be connected to the internet which led to the inability to connect the telemonitoring device.

Other problematic circumstances include the living environments of participants found to be not suitable for TMC deployment due to limited space or inappropriate living conditions. Finally, changes in personal circumstances were responsible for the withdrawal of 8 potential Test participants and these included deterioration in health, family care responsibilities and loss of interest due to unforeseen long waiting times.

Withdrawal from trial post TMC deployment (Test participants only)

Reason for Test participants not remaining in the study (n=18) are reported in Table 13. These participants discontinued monitoring and requested the TMC device to be removed before they completed the trial. The average time from TMC deployment to the last measurements received from the withdrawn participants was 7 months (range 1-14 months) with 10 participants monitoring for at least 6 months. The average age of participants who did not complete the trial was 71 years (range 54-87 years) and a Spearman's correlation was run to assess any relationship between age and number of months monitoring before withdrawal. There was no significant correlation between participant age and the number of months spent monitoring prior to withdrawal (P=0.7). The numbers reported are counts per reason, as some participants stated more than one reason.

Table 13 Reasons given by patients for withdrawing from the trial

REASON FOR WITHDRAWING FROM TRIAL	Number of times cited
No longer interested / lack of motivation or commitment	4
Do not feel benefits from the intervention	6
Changes in circumstances (no longer meeting inclusion criteria, deterioration of health, difficulty using TMC)	10
Competing life demands (work, family, stress)	4
Logistical reasons	5

The main reason leading to cessation of monitoring and ultimately withdrawal before completion of the trial was deterioration in health (n=10) and one of these participants moved to an Aged Care Facility after 10 months of monitoring. Two participants who both had been monitoring for less than two months withdrew because they felt they could not cope, one cited stress and the other felt there were too many measurements and questionnaires

and found language a barrier. Two of the participants who indicated that they did not feel they were benefiting from the intervention suffered from deteriorating health but lack of time to do daily checks and getting tired of the internet dropping in and out were also cited as reasons for not benefiting from the intervention.

One patient was withdrawn after 3 months of monitoring due to tremor, poor compliance with the measurement schedule and unwillingness to be monitored by the assigned nurse.

5.1.2 Demographics of study groups at baseline

All patients from the Master list of 114 Test patients and 173 potential Control patients, had PBS and MBS data available for the period 1st July 2010 to 31st Dec 2014. However on careful analysis it was observed that some patients had missing data, in some cases for periods as long as 3-6 months. All these patients had multiple chronic conditions and were hospitalised at least twice in the previous year, and in most cases were taking between 6-10 medications a day. It was therefore completely unexpected and inexplicable that DHS PBS and MBS records were missing data for such protracted periods of time.

Despite detailed analysis of these data anomalies, the DHS was unable to provide an explanation, and as a result, data from a number of Test patients and Control patients were rejected for further analysis. The matching process described in Table 4 led to a final matched cohort of 100 Test patients and 137 Control patients as shown in Table 14 below.

Table 14 Basic demographics of Test and Control participants at baseline.

Demographics (Number/Age/Gender)	TAS		ACT		VIC		NSW		QLD		TOTAL	
	Hospital Based				Community Based							
	T	C	T	C	T	C	T	C	T	C	T	C
Number of patients	25	55	13	19	25	35	14	8	23	20	100	137
Age (SD)	70.2 (9.0)	72.9 9.0)	71.0 (7.7)	74.1 (8.1)	69.8 (7.6)	69.6 (7.7)	76.25 (7.4)	69.6 (14.2)	70.7 (10.2)	73.9 (8.6)	71.2 (8.7)	72.2 (8.9)
Number of **Male** patients	16	31	10	11	19	17	8	6	14	11	67	76
Age (SD)	70.4 (10.3)	73.2 (8.8)	70.4 (8.0)	74.2 (6.4)	70.4 (7.6)	71 (5.3)	77.5 (6.2)	65.2 (13.6)	68.7 (8.5)	73.0 (9.0)	70.9 (8.6)	72.2 (8.4)
Number of **Female** patients	9	24	3	8	6	18	6	2	9	9	33	61
Age (SD)	69.9 (6.6)	72.5 (9.5)	73.1 (7.5)	74.0 (10.6)	67.9 (8.2)	68.2 (9.4)	74.6 (9.2)	83 (2.3)	73.8 (12.4)	74.9 (8.5)	71.7 (9.1)	72.1 (9.7)

There were no significant differences between age, gender or BMI of Test and Control patients at baseline. Sixty seven percent of Test patients were male and 33% female, with these figures almost reversed for the Control patient group.

The primary diagnosis for each patient was recorded during the initial questionnaire and was then confirmed both from the DHS data base and when available, the hospital data base.

Most patients had more than one condition listed as a primary diagnosis. For simplicity primary disease conditions were grouped in the broad categories of Cardiac Disease, Respiratory Disease, Diabetes and Other. Figure 10 (a) plots the distribution of disease conditions for Test and Control patients as a % of each group. Since patients often had more than one primary diagnosis, percentage values could add to more than 100%.

The broad category of Cardiac disease included AF, AHD, AMI, Aortic valve stenosis, AP, CAD, CHD, CHF, CM, CVD, HT, IHD, NSTEMI and STEMI. Respiratory disease includes AB, AST, BT and COPD. The Diabetes Category included DM and T2DM, and the Other disease category included ART, Bowel Condition, Cellulitis, Prostate Cancer, Renal Disease and Renal failure.

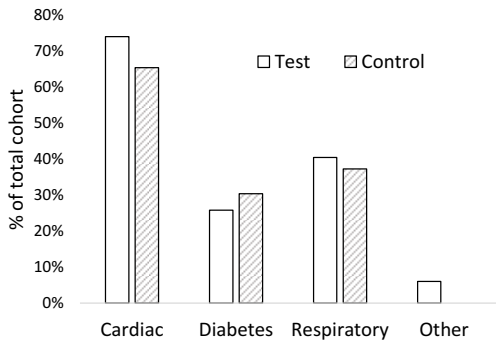
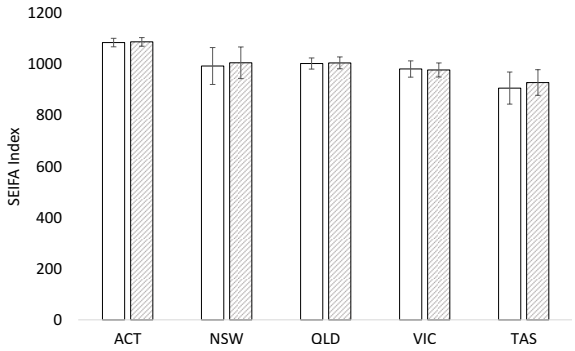


Figure 10 (a) Primary Diagnosis



(b) Distribution of SEIFA index across sites

In subsequent analysis, patients were characterised as having a primary diagnosis of Cardiovascular disease (50), Respiratory disease (30) or Diabetes (20). As illustrated in Figure 10 (b) there were no statistical differences observed between Test and Control patients either with respect to the SEIFA status or their primary disease diagnosis.

Figure 11 shows the wide distribution of commencement dates for the telemonitoring of vital signs.

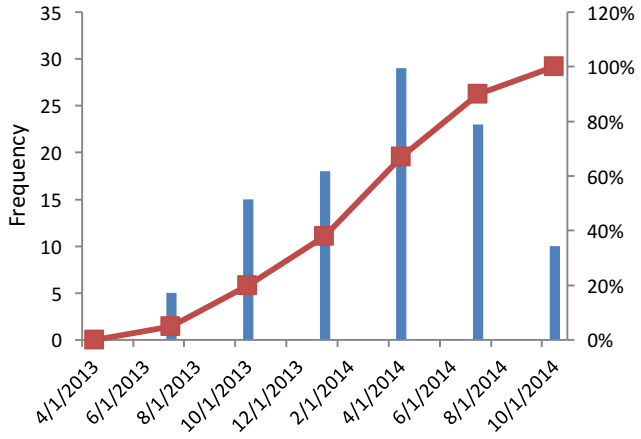


Figure 11 Distribution of commencement dates for monitoring of vital signs

Test patients were monitored on average for 276 days, (Figure 12) with no significant difference between average monitoring durations for female patients (266 days) and male patients (281 days). Seventy five percent of all Test patients were monitored for periods exceeding 6 months.

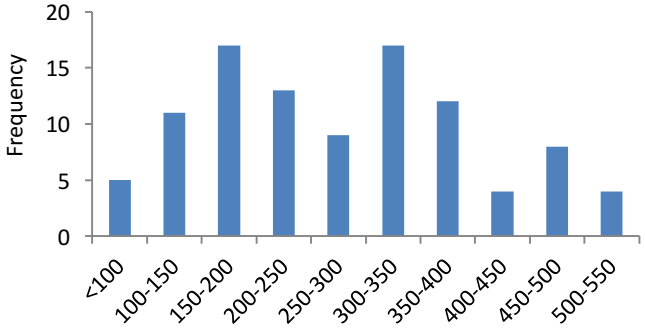


Figure 12 Distribution of number of days of monitoring of Test Patients (N=100)

The average age of patients at the commencement of monitoring of Test patients is shown in Table 15.

Table 15 Age of Test and Control patients at start of telemonitoring

	N	TEST	N	CONTROL
ALL Patients	100	71.1 ± 8.7	137	71.7 ± 9.0
Male Patients	67	70.8 ± 8.6	76	71.2 ± 9.1
Female Patients	33	71.7 ± 9.1	61	72.3 ± 8.9

The age of each Test patient at commencement of monitoring was compared to the age of their respective controls at that time. Control patients were on average 0.46 years older that Test patients. This difference was not statistically significant for either male or female patients.

The results that follow relate exclusively to this cohort of 100 Test Patients and 137 matched Control patients.

5.1.3 Baseline health characteristics of Test and Control patients at point of entry

As explained in Section 5.1.2, a cohort of 100 Test and 137 matched Control patients were included in a baseline analysis to evaluate health characteristics between the two groups after matching. In the analysis, when two matched Control patients were available per Test patient, their data were averaged. Baseline characteristics are described for both groups using mean ± SDs for continuous symmetrical variables and medians and IQR for skewed data. Comparisons is made between the two groups at baseline using the cases available and the number of participants who completed the specific Entry Questionnaire items are indicated in Table 16. The two-sample t-test was used for continuous variables and the Wilcoxon rank-sum test for skewed variables.

All statistical tests were two-tailed, and a p value of < 0.05 was used to indicate statistical significant. Statistical analysis was performed using Stata Release V.12 (TX: StataCorp LP).

Table 16 Self-Reporting measures, for Test and Control patients at Entry

QUESTIONNAIRE		TEST	N	CONTROL	N	P value
Kessler K10 (Median, IQR)		18.5 (14.0 – 26.0)	94	18.0 (13.5 – 23.0)	97	0.25
Morisky (Median, IQR)		7.0 (6.75 - 7.75)	97	7.0 (6.13 – 8.0)	97	0.76
EQ5D Index Mean ± SD (95%CI)		0.62 ± 0.25 (0.57 – 0.67)	98	0.64 ± 0.23 (0.59-0.68)	96	0.55
heiQ	Self-monitoring score Mean ± SD (95%CI)	3.1 ± 0.33 (3.0 - 3.17)	98	3.07 ± 0.33 (3.01 - 3.15)	97	0.66
	Health service navigation Mean ± SD (95%CI)	3.23 ± 0.45 (3.2 - 3.3)	98	3.24 ± 0.42 (3.15 - 3.32)	96	0.99
	Social isolation Mean ± SD (95%CI)	3.06 ± 0.52 (2.96 - 3.16)	97	3.02 ± 0.54 (2.91 - 3.13)	97	0.62

There were no significant differences between the Test and Control participants at baseline in terms of health characteristics. The Kessler10 scores (measurement of depression) were in the normal range for both groups. The EQ-5D index, which records the participants' self-rated quality of life, showed both groups to be below 0.7, an indication of fair self-rated health. Selected constructs from the heiQ questionnaire were included in the Entry Questionnaire and comprise self-monitoring, health service navigation and social isolation.

No significant differences were observed in any of these scores, however, both groups showed relatively high scores for Self-monitoring (comparable with benchmark statistics at baseline for the Australian population (3.03) which refers to self-reports of more positive effect).

Health service navigation and social isolation scores were also relatively high, comparable with the Australian population (3.1 and 2.91 respectively), and were similar in both the study groups.

5.2 Usability and Acceptability of Telemonitoring to Patients, Clinicians and Carers

5.2.1 Patient experience with the telemonitoring technology

Test patients answered the User Satisfaction Questionnaire at the end of the project. The questions about telemonitoring technology included participants' perceptions of technology complexity and compatibility.

We received responses from 56 participants. All test patients were overall satisfied with using the monitoring device (Table 17). They found the instruction on using the TMC device easy to understand. Responses indicate that few participants found the device cumbersome, unnecessarily complex, or thought that they would need a technical person's support in using the device. Majority of participants found the TMC easy to use (87.5%) and felt confident in using it (85.7%) despite 32.1% of them reporting that there were occasions of frustration. In terms of compatibility, majority of participants found that using the monitoring device could be incorporated in their daily routine (80.4%), fits in with their daily life (71.4%) and the way they would like to manage their health (76.8%).

Table 17 Patient responses to User and Satisfaction Survey - Telemonitoring equipment

ITEM	% Agreed or strongly agreed N=56
COMPLEXITY	
• TMC* easy to use	87.5
• I sometimes find the TMC system frustrating to use	32.1
• Instructions on the TMC are easy to understand and follow	83.9
• Using the TMC system is cumbersome	19.6
• I needed to learn a lot of things before I could get going with the TMC	23.2
• I found the TMC unnecessarily complex	7.1
• I think that I would need the support of a technical person to be able to use the TMC	12.5
• I feel very confident using the TMC	85.7
• I find the various functions in the TMC are well integrated	83.9
COMPATIBILITY	
• TMC is a tool that would be easy to incorporate into my daily routine	80.4
• The TMC fits right into the way I like to manage my health	76.8
• Using the TMC fits well with my lifestyle	71.4

* TMC system is the Telemedcare telemonitoring system supplied to Test patients.

We also asked questions about the patients' experience of empowerment, experience with telehealth nurse, service observability and overall satisfaction in a User Satisfaction questionnaire at the end of the trial.

We received responses from 49 participants. The majority of patients (73.5%) were satisfied with their internet connections and most (89.6%) reported that they were satisfied with the telemonitoring service (Table 18). Their overall experience with the telehealth nurses was positive in terms of the time and discussions they received from the nurses. However only 12.2% of patients' reported that their GPs reviewed the telemonitoring results during patients' visits and only 34.7% patients agreed that telemonitoring improved their communications with GPs

As shown in Table 18, test patients found that telemonitoring improved their knowledge about their conditions (69.4%) and symptoms to watch for (77.6%). They reported that they had become more involved in monitoring their health conditions (79.6%) and improved their self-care (71.4%) as a result of telemonitoring. A small number felt that seeing their vital signs every day and talking to telehealth nurses made them anxious or worried. A large majority (89.8%) of them responded that they would recommend telemonitoring service to other people.

Table 18 Patient responses to User Satisfaction Survey – Telemonitoring service

ITEM	% positive (e.g. agree/satisfied and strongly agreed/very satisfied) N=49
EMPOWERMENT EXPERIENCE	
Daily monitoring of my vital signs has improved my knowledge about the nature of my health condition	69.4
Daily monitoring of my vital signs has improved my knowledge about the symptoms I should watch for	77.6
Daily monitoring of my vital signs has improved my knowledge about the way I can better manage my health condition	59.2
As a result of using the telemonitoring service, I have involved more in monitoring my health condition	79.6
As a result of using the telemonitoring service, I have been able to better manage my health condition	61.2
As a result of using the telemonitoring service, I feel more secure about my health condition	69.4
As a result of using the telemonitoring service, I have improved my self-care	71.4
EXPERIENCE WITH TELEHEALTH NURSE	
How do you feel about the service provided by the telemonitoring nurse in terms of the time given to you by the telemonitoring nurse	87.8
How do you feel about the service provided by the telemonitoring nurse in terms of contacting you when there is a need to discuss your measurement	79.2
How do you feel about the service provided by the telemonitoring nurse in terms of helping you to understand your conditions	77.1
In an overall and general sense, how satisfied are you with the telemonitoring service you received from the telemonitoring nurse?	75.0
OBSERVABILITY	
The effects of monitoring my health using the telemonitoring service are apparent to others	38.8
I would recommend using the telemonitoring service to other people	89.8
OVERALL SATISFACTION	
Overall how satisfied are you with the telemonitoring service?	89.6
Would you like to continue using the telemonitoring service after the trial?	57.1
OTHER EXPERIENCE	
Talking to telemonitoring nurse over the phone makes me worry about my condition	4.1
Seeing my vital signs everyday has made me anxious about my chronic condition	12.2
How often has your GP referred to your measurements during your visits?	12.2
Telemonitoring has improved my communication with my GPs	34.7
How satisfied are you with your internet connection?	73.5

All the Test patients interviewed were keen to use home telemonitoring and positive about its value. They appreciated that their measurements were being monitored and the feeling of being looked after by nurses. A patient from Queensland commented:

"*This gives me great piece of mind. I am getting to know the variations, and when I have a bad reading I take it easy. Without this thing I would just go about like normal and get myself in trouble*."

"*I know the ladies behind are seeing my data and will call me if need be, it is like seeing my GP*."

"*I have a lot of faith in it and I show it to my mates, it is like having a doctor at home*."

5.2.2 Patient compliance with monitoring schedules

Generally there was a high level of satisfaction with the telehealth service and the ease of use of the telemonitoring technology. Compliance with the measurement protocols scheduled for each patient was generally high with patients carrying out their scheduled measurements and questionnaires at least once every two days. Given the demanding schedule of measurements and questionnaires, this is considered a considerable achievement and more than sufficient to develop a comprehensive longitudinal patient record in the home.

A strong correlation was found between the level of involvement of the CCCs and patient compliance. The higher the CCC engagement with the patient and the monitoring of patient data, the higher was the level of compliance from the patient. Clinical Care Coordinators generally viewed every patient's record daily and tracked time spent on each patient using the CSIRO WEB portal.

Patient compliance with their scheduled daily measurements were calculated by tracking the total number of scheduled events and then counting the actual number of measurement activities completed. The ratio of these provided a robust measure of compliance. Overall patient compliance data is shown in Table 19. Test patients successfully completed 177,416 measurements of vital signs and responded to 26,649 questionnaires over the period of 16 months. Patient compliance with their scheduled daily measurements were calculated by tracking the total number of items completed and comparing to number of items scheduled over the same period of time.

Table 19 Patient compliance with measurement and questionnaire schedules (ALL Test patients)

Item of Activity Location: (All sites)	Number of Scheduled Items	Number of Items Completed	% Compliance
VITAL SIGNS MEASUREMENT			
Blood Pressure	30,679	20,551	66.99%
ECG	30,327	19,817	65.34%
Pulse Oximetry	30,834	20,216	65.56%
Blood Glucose	12,464	8,739	70.11%
Spirometry	20,692	10,876	52.56%
Body Temperature	27,297	17,143	62.80%
Body Weight	25,122	14,124	56.22%
Average Compliance (Measurements)	**177,416**	**111,466**	**62.83%**
CLINICAL QUESTIONNAIRES			
CHF (Daily)	12,139	6,179	50.90%
COPD (Daily)	8,679	4,335	49.95%
Quality of Life EQ5D (Weekly)	3,761	2,235	59.43%
Mental Health K10 (Monthly)	943	534	56.63%
Living With and Managing Medical Conditions (HeiQ)	919	621	67.57%
Medications Adherence	208	93	44.71%
Average Compliance (Questionnaires)	**26,649**	**13,997**	**52.52%**

These data show that on average, patients were recording their vital signs a little better than every two days, representing a compliance rate of approximately 62.8%, and they were taking questionnaires at approximately 52.5% of the scheduled rate.

Similarly, for Questionnaires the HeiQ (Living With and Managing Medical Conditions) were completed 67.6% of the time whilst the Medications Adherence questionnaire was on average completed only 44.7% of the time.

Table 20 Patient compliance with measurement schedules (TAS +ACT patients)

Item of Activity Location: (TAS + ACT)	Number of Scheduled Items	Number of Items Completed	% Compliance
VITAL SIGNS MEASUREMENT			
Blood Pressure	13,399	9,204	68.69%
ECG	13,464	9,129	67.80%
Pulse Oximetry	13,482	9,090	67.42%
Blood Glucose	4,209	3,295	78.28%
Spirometry	9,433	6,325	67.05%
Body Temperature	13,392	8,958	66.89%
Body Weight	12,131	7,938	65.44%
Average Compliance (Measurements)	**79,510**	**53,939**	**67.84%**
CHF (Daily)	5,688	3,096	54.43%
COPD (Daily)	5,225	3,088	59.10%
Quality of Life EQ5D (Weekly)	2,161	1,209	55.95%
Mental Health K10 (Monthly)	281	201	71.53%
Living With and Managing Medical Conditions (HeiQ)	173	76	43.93%
Medications Adherence	173	69	39.88%
Average Compliance (Questionnaires)	**13,701**	**7,739**	**56.48%**

Patients under the care of the hospital based CCCs were on average more compliant both for the recording of vital signs, and their measurement schedules, comfortably averaging more than 50% compliance with both, as demonstrated in Table 20.

Table 21 Patient compliance with measurement schedules (NSW+VIC+QLD)

Item of Activity Location: (NSW+VIC+QLD)	Number of Scheduled Items	Number of Items Completed	% Compliance
VITAL SIGNS MEASUREMENT			
Blood Pressure	17,280	11,347	65.67%
ECG	16,863	10,688	63.38%
Pulse Oximetry	17,352	11,126	64.12%
Blood Glucose	8,255	5,444	65.95%
Spirometry	11,259	4,551	40.42%
Body Temperature	13,905	8,185	58.86%
Body Weight	12,991	6,186	47.62%
Average Compliance (Measurements)	**97,905**	**57,527**	**58.76%**
CHF (Daily)	6,451	3,083	47.79%
COPD (Daily)	3,454	1,247	36.10%
Quality of Life EQ5D (Weekly)	1,600	1,026	64.13%
Mental Health K10 (Monthly)	662	333	50.30%
Living With and Managing Medical Conditions (HeiQ)	746	545	73.06%
Medications Adherence	35	24	68.57%
Average Compliance (Questionnaires)	**12,948**	**6,258**	**48.33%**

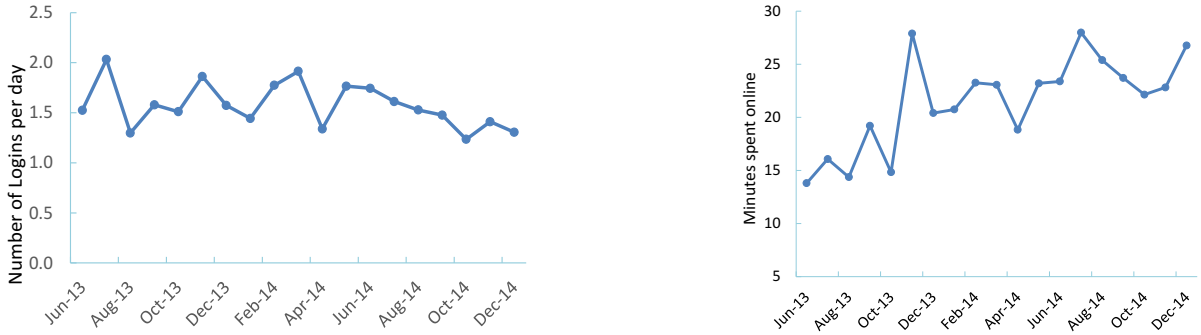
Patients under the care of community based CCCs were on average a little less compliant as seen in Table 21 (58.76% versus 67.84%) with their measurement of vital signs and considerably less compliant with their questionnaires (48.33% versus 56.48%) then patients under the care of hospital based CCCs.

5.2.3 Usage of TMC Clinician Portal and CSIRO Portal by Care Coordinators

TMC Clinician Portal

The TMC Clinician portal allowed authorised clinicians to view and if necessary, to edit patient data recorded. It provided a number of facilities for setting flags which would indicate that patient's measurements have exceeded individual bounds. These could be set globally for the whole patient cohort, or individually to reflect individual patient conditions.

Project policy was that patient data had to be viewed at least once a day during the Monday to Friday working week. The data shown Figure 13 spent on average <30 minutes a day reviewing patient data from 20 patients (on average most sites had around 20 parients).



a. Average logins per day / Clinician

b. Time per login reviewing patient data

Figure 13 Use of the TMC Clinician Web portal by Clinical Care Coordinators

This would suggest that a CCC working full time (6.5 hours working time) and responsible ONLY for monitoring patient data could manage a theoretical maximum of 20 x (6.5 hours x 60 minutes /30) = 260 patients a day. With additional time required to manage complex cases, communicate with GPs and carers and generally coordinate the patient's care, the realistic figure is likely to be in the order of 100-150 patients.

We note that in TAS patient monitoring was carried out by three specialist nurses and in the ACT monitoring was undertaken by a panel of specialist nurses. In the remaining sites monitoring was usually carried out by a single community nurse. The results shown in Figure 14 are broadly in line with project policy and indeed exceed the minimum requirement of reviewing the patient data at least daily.

CSIRO portal

The CSIRO Portal provided a useful depository of information on progress with the trial, a dissemination system for the distribution of information and procedures and a social forum where CCCs and POs could share their experiences. Clinical Care Coordinators were also encouraged to use the CSIRO Portal to track their activities and their contact time with patients or their carers. The plots in Figure 14 indicate the hospital based sites of TAS and the ACT were logging in to the CSIRO portal on average 1.4-1.6 times a day. For the community based sites, CCCs were logging in on average just over once a day.

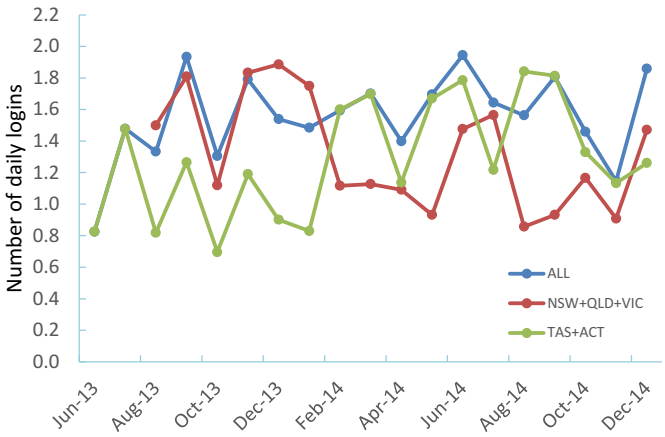


Figure 14 Record of average daily logins to the CSIRO Portal / clinician

5.2.4 Clinicians' perceptions of telemonitoring benefit to patients

Positive feedback was received from POs and CCCs in terms of improving patient knowledge about the nature of their chronic conditions and symptoms (Table 22). 89% of them responded that telemonitoring had improved the patients' self-care and made patients felt more secure about their health conditions and a similar percentage believed that telemonitoring would have a role in improving the overall quality of care provided to patients and would recommend the service to other patients.

POs and CCCs reported issues in interacting with GPs and specialists and only 33% rated these interactions as satisfactory. They also had problems in terms of incorporating the telemonitoring into their daily routine as we have seen in the questionnaire and interviews.

Table 22 Project Officers and Care Coordinators perception of benefits to patients

ITEM	% positive (e.g. agree/satisfied and strongly agreed/very satisfied) (N=9)
EXPERIENCE IN DELIVERING THE SERVICE	
Interacting with patients	67.0%
Monitoring the patients	56.0%
Interacting with GPs	33.0%
Interacting with Specialists	33.0%
USABILITY	
The TMC user interface for the clinicians was easy to use	56.0%
CSIRO portal interface was easy to use	56.0%
PERCEIVED BENEFIT TO OVERALL QUALITY OF CARE	
Made the patient feel more secure about their health condition	89.0%
Improved the patient's self-care	89.0%
Improved how the patient monitors their health condition	89.0%
Telemonitoring has a role in improving the overall quality of care provided to patients	89.0%
Improved patient knowledge of the symptoms they should watch for	78.0%
Improved patient knowledge of the way they can better manage their illness	78.0%
Improved patient knowledge of the nature of their clinical condition	67.0%
Improved how the patient manage their health condition	44.0%
COMPATIBILITY AND OBSERVABILITY	
I would recommend telemonitoring service to other patients	89.0%
I would recommend telemonitoring service to other clinicians	78.0%
Overall how satisfied are you with the telemonitoring service?	56.0%
My role in the telemonitoring trial has been easy to incorporate into my daily routine	22.0%

All CCCs, POs and GPs we interviewed believed that home telemonitoring would have potential positive impact on the early intervention for chronic disease patients (Table 22). Some CCCs and POs (e.g. TAS, VIC) and GPs (e.g.,QLD) found that their patients have improved knowledge about their chronic conditions and were able to learn the meaning of their measurements and to discuss these with clinicians. One of the POs reported the following during a site visit:

"*By talking to patients (e.g. during the visits to home for software updates) I have learned that people are being more and more empowered by TMC information and being able to go to GPs to talk about measurements, learn more about their health. They can see things going up and down every day. One of the biggest opportunities for reducing hospitalization is by CCCs picking up clinical deterioration and sometimes patients are picking up these. A patient said that she was reassured that someone is keeping an eye on her*."

Majority of GPs we interviewed pointed out that telemonitoring would be more useful in rural settings. One of the physicians who worked in hospital believed that it could play an important role in early discharge of patients from hospital.

POs and CCCs also made comments about the benefits of telemonitoring in the questionnaire. The following are examples of these comments:

- Identifying deterioration or new issues
- Offering support to each individual patient to meet their needs, not just when their readings are outside their parameters
- Patients can see their readings and this enables them to make informed choice
- Empowerment of the client to self-manage through awareness and education
- As a result of early detection, care is sought earlier hence reducing/avoiding hospital admissions
- It is extremely useful for patients as they are confident taking care of their own health and peace of mind that there is someone to assist them if necessary.
- The visual effect of seeing data reinforced their interest in their own health, especially male patients

The PO at TAS summarised her reflections of the trial in the questionnaire:

"*I perceived the improved clinical management benefits to include fewer acute exacerbations through early detection and fewer subsequent hospitalisations. This should lead to patients receiving the right care in the right place. It should also improve long term health outcomes for the patients*.

Benefits to the health system include reducing the burden on high demand, high cost acute hospital beds. Telemonitoring also has the potential to reduce the burden on sections of primary health care by potentially reducing GP visits. GP visits could potentially be more productive by provision of patient trend data enabling good clinical management decision making."

"*At this project site, the project has been very successful in achieving all of these outcomes to varying degrees*."

5.2.5 Carers' perceptions of telemonitoring benefit to patients

Family members of the patients we visited have been supportive of patients' use of telemonitoring. Their knowledge about patients' chronic conditions has been improved as well. The following is feedback from a patient's wife:

"*I tend to stress out a lot over my husband. Since we have the machine at home, I feel I could ring the GP and say to him my husband is sick*."

"*The nurse's visit to us is a big plus. We learned things from her. She is the one who put us on the lung seminar*."

5.3 Impact of telemonitoring on patient expenditure on MBS and PBS items.

The quantitative statistically robust evaluation of health and social economic outcomes are a cornerstone of this project and the clinical trial protocol in Chapter 4 describes in detail how the project objectives were to be met once the numerous data bases from at home telemonitoring and questionnaire instruments, PBS and MBS data from the DHS and hospital data (when available) were fully integrated and analysed.

In this section data is analysed using conventional statistical methods. Because of the temporal nature of health data and the underlying trends caused by the increasing burden of chronic disease with increasing age, before and after comparisons can be difficult. We have chosen to use 30 days as the time period over which we analysed and report our results, and introduce three different methods which will assist with the interpretation of underlying trend effects.

Method 1: Regression analysis and ANOCOVA analysis of differences in slopes

In this method we used 30 day intervals for MBS and PBS analysis and 100 day intervals for number of admissions and length of stay. All data were time aligned so that the time interval "0" represented the day when telemonitoring commenced, and 0 to -35 is the period of 36 x 30 days BEFORE the intervention and 1 to 12 represents the 12 x 30 days AFTER the intervention. The disadvantage of this method is that the effects of seasonal variations cannot be assessed and indeed are minimised because of averaging effects. This method however emphasises that the intervention is the first order effect that we are seeking to analyse.

In Method 1, Before and After data for MBS costs, PBS costs, number of admissions to hospital and length of stay in hospital were analysed for (i) the whole patient cohort, (ii) males separately and (iii) female patients separately, as well as patients with (i) Cardiac conditions, (ii) Lung disease and (iii) Diabetes as their primary condition. In addition, patients monitored in a community setting and those monitored in a hospital setting were analysed separately.

Method 2: Mixed linear effects modelling

Linear mixed-effects models (LME) are an important class of statistical models that incorporate both fixed- and random effects terms in a linear predictor expression from which the conditional mean of the response can be evaluated. These models are often used to analyse correlated data as is often encountered in biostatistics. Linear mixed-effects models are extensions of linear regression models for data that are collected and summarized in groups. These models describe the relationship between a response variable and independent variables, with coefficients that can vary with respect to one or more grouping variables. Complex models can be developed that simultaneously consider seasonal time variations as well as differences between multiple test sites.

Method 2 enhances the analysis undertaken using Method 1 by introducing seasonal effects and site specific effects

Method 3: Cumulative sum of differences

This method can be used to identify time dependent changes in the differences between Test and Control patients, following the telemonitoring interventions. By considering differences (Test-Controls) only seasonal and other common effects are eliminated and differential effects of the telemonitoring intervention can be more easily identified. However a disadvantage is that it is impossible to quantify the specific effects of the intervention on the Test patients in absolute dollar terms

We have chosen to present the results of Method 1 in the Results chapter and to leave additional detailed analysis using Methods 2 and 3 can be found in Section 5.10 and Chapter 8. This choice was made to focus the analysis on the first order effect of telemonitoring on the outcomes and to minimise possible seasonal effects. More importantly the use of linear regressions permits the easy quantification of effects in absolute dollar terms.

Throughout these results independent samples t-test is used when two separate sets of independent and normally distributed samples are obtained, one from each of the two populations being compared.

However as explained in the Chapter 4, the project design makes random selection of Test and Control patients impossible and the alternative Before and After Control Intervention (BACI) design was adopted.

As a consequence statistical comparisons in this study can only be validly made on Test – Control matched pairs and tested using the paired samples or repeated measures t-tests. In addition the time course of before and after data can be assessed using linear regression and ANCOVA analysis of slopes to identify statistically significant difference.

MBS and PBS data was available for 100 Test patients and 137 Control patients. When two matched Control patients are available their data was averaged.

A preliminary graphical analysis of both PBS and MBS data, using the MATLAB function *normplot* as well as the Chi-square goodness of fit test indicated that the data was not normal. Both lognormal and sqrt transformations were found to be effective in normalising the data. The sqrt transformation was chosen as a little better and applied to data before the linear regression was carried out.

This was repeated both for Test patient data and Control patient data. Difference data calculated from Control – Test for each data point was found to be normally distributed and did not need the application of the *sqrt* transform.

5.3.1 Descriptive statistics for matched Test and Control patients

In order to compare the statistical match of test and control patients at the onset of telemonitoring, individual PBS and MBS costs and events were summed over a period of 100 days just prior to the beginning of the intervention and compared to the first 100 days of monitoring for each individual patient.

When a Test patient has more than one Control, the data for the two Control patients were averaged to obtain a matched pair.

Table 23 Baseline comparison between Test and matched Control patients before and after intervention.

Variable	Control Before	Test Before	P Value	Control After	Test After	P Value
Number of visits to GPs	4.2 (3.4 - 5.1)	5.7 (4.4 - 7.1)	0.04*	4.2 (3.4 – 5.0)	5.6 (4.4 - 6.8)	<0.01**
Cost of visits to GPs	183.7 (146 - 223)	245 (189 - 306)	0.35	193.8 (153 - 236)	250.4 (196 - 308)	0.09
Number of visits to/by Allied Health	0.5 (0.3 - 0.8)	0.6 (0.3 - 0.9)	0.42	0.5 (0.3 - 0.7)	0.7 (0.4 - 1.1)	0.20
Cost of visits to/by Allied Health	25.1 (14.6 - 41.7)	30.2 (17 - 51.8)	0.40	24 (15.4 - 35.8)	38.1 (21.1 - 66.5)	0.32
Number of visits to Specialists	1.3 (0.9 - 1.9)	1.6 (1.1 - 2.2)	0.15	1.3 (0.9 - 1.9)	1.9 (1.3 - 2.7)	0.04*
Cost of visits to Specialists	130.6 (85.6 - 192)	159.1 (105 - 232)	0.22	133.2 (85.5 - 200)	198.3 (127 - 298)	0.15
Number of medications prescribed	25.5 (22 - 28.4)	28.1 (23.8 - 31.9)	0.21	25.6 (22.2 - 28.5)	28.3 (23.7 - 32.5)	0.37
Total Cost of medications prescribed	1076.7 (867 - 1288)	959 (814 - 1088)	0.3	1163.3 (928 - 1404)	979.5 (817 - 1130)	0.25
Total Cost of Procedures/Tests	525.1 (320 - 830)	625.1 (385 - 976)	0.35	419.6 (269 - 630)	543.8 (353 - 806)	0.22
Total Cost of Laboratory Tests	134.8 (91 - 192)	133 (89.3 - 191)	0.43	104.9 (74.1 - 143)	109.8 (75.9 - 153)	0.39
Total cost of MBS and PBS items	2019.7 (1633 - 2406)	2029.9 (1697 - 2338)	0.17	2078.5 (1678 - 2479)	2076.9 (1738 - 2391)	0.17
Patient travel cost in visiting GPs	39.2 (27.3 - 54.3)	44.4 (30 - 63.3)	0.48	40.8 (28.1 - 57.1)	44.9 (30.8 - 63)	0.34

Note: The annual value for each parameter can be easily obtained by multiplying each entry by 3.65.

There was significant difference between the number of visits to the GP recorded for Test and Control patients, both for the 100 days before the intervention and immediately after the intervention, although the number of visits did not change substantially. A slight increase in the number of visits to specialists made by Test patients after the intervention was also observed. No other parameters were significantly different. The above table demonstrates that Test patients and their Controls were well matched with respect to the PBS and MBS items identified in Table 23.

However traditional BACI before-and-after analyses can provide misleading results when outcomes are non-stationary as is shown diagrammatically below in Figure 15;

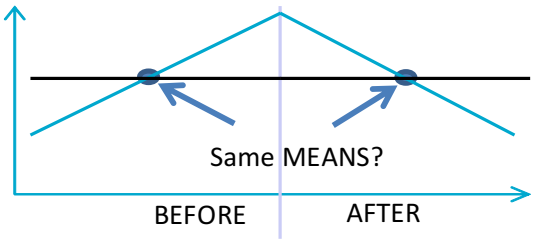


Figure 15 Before and after means may appear identical when data is non stationary

5.3.2 Linear regression analysis of impact of telemonitoring intervention on total MBS expenditure

For this analysis all out of hospital MBS costs were summed over 30 consecutive day intervals. These costs included, most out of hospital costs for the majority of MBS Item numbers available, as outlined below in Table 24;

Table 24 MBS Item Numbers included in analysis

ITEM DESCRIPTION	MBS ITEM Numbers Included
GP Visits – Normal Hours	3,23,24,35,36,37,44
GP Visits – After Hours	597,598,599,2504,2517,2521,2525,2546,2552,5000,5020,5023,5028,5040,5060,5063
Primary Care Assessments and Care Planning	700,703,705,707,715,721,723,729,731,732,739,743,750
Specialist Visits – other than Psychiatric	104,105,110,116,119,132,133,141,143,385,503,511,828,830,832,880,6007,6009,6011,6015
Allied Health	53,54,57,59,60,65,10951,10953,10954,10958,10960, 10962,10964,10966, 10987,10993, 10996,10997, 80010 – 82215
Laboratory tests (Haematology, chemistry, immunology, tissue pathology, cytopathology, basic tests and collection costs)	65060 - 73940

Costs were available as Cost of visit, Government Contribution to cost and Patient Contribution. In most cases the Patient Contribution was zero and accordingly the Cost of visit alone was considered. Hospital flags or In hospital costs were ignored as we were informed that these were only set if in-hospital costs were in fact charged, which in many cases they may not be. In the plots below (Figure 16) the zero x coordinate is at the start of telemonitoring.

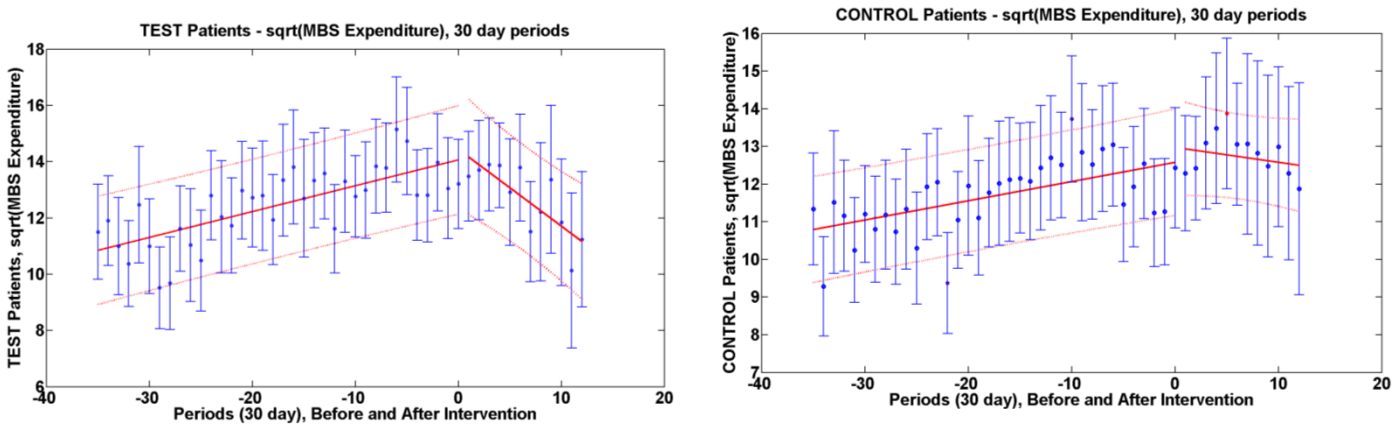


Figure 16 sqrt(MBS Costs) plotted for (a) Test patients and (b) Control patients at 30 day intervals. Linear regression lines are calculated after removal of outliers, which are marked in red

Linear regression was carried out using the *fit* command in the MATLAB statistics toolbox. Outliers, marked in red are excluded from the linear regression. The command *predobs* was used to plot 95% Prediction Intervals as light dotted red lines. Note that prediction intervals indicate a 95% probability that a future observation at x will fall within its boundaries. Standard goodness of fit measures, including SSE – sum of squares due to error, R^2 – the coefficient of determination, the R^2 value adjusted for degree of freedom and the stdError – fit standard error or root mean square error are also available. These are used together with one–way analysis of covariance (anocova) to determine whether the slopes of the BEFORE and AFTER portions of the linear regression lines are different.

The Difference data (Control-Test) is similarly analysed, but without the application of any transform.

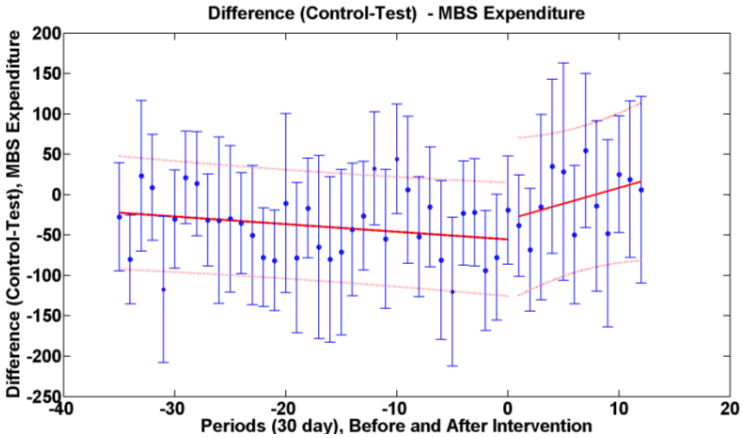


Figure 17 Plot of Differences (Control - Test) for MBS expenditure against 30 day intervals

If the Control patients were exactly matched to Test patients for MBS expenditure, the BEFORE part of the linear fit would have a zero slope and an intercept very close to zero as shown in Figure 17. A close look at the plot of differences shows that the slope is in fact negative and the intercept at the point of commencement of telemonitoring is -$55.38 on average, indicating that MBS expenditure over a 30 day period for Test patients was greater than that for Controls at that time. If projected over a year this difference in expenditure is close to $670.

For the plots shown above the linear regression fits and the results of the anocova analysis are given in tabular form below in Table 25.

Significant differences are indicated by <0.05*, < 0.01** and <0.001***.

Table 25 Linear regression and anocova analysis for sqrt(MBS expenditure) – All patients

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.05098	-0.03953	0.1	12.58	12.98
	(0.0293, 0.0727)	(-0.1305, 0.0515)		(12.13, 13.02)	(12.29, 13.66)
TEST	0.0919	-0.2729	<0.001**	14.06	14.44
	(0.0625, 0.1213)	(-0.4236, -0.1222)		(13.47, 14.66)	(13.33, 15.55)
P	0.0268*	0.009**			
DIFF (Control - Test)	-0.9446	3.916	0.1025	-55.38	-30.91
	(-2.073, 0.1839)	(-3.251, 11.08)		(-78.71, -32.05)	(-83.66, 21.84)

Table 25 shows that the only significant difference was in the slope of the BEFORE segment and the slope of the AFTER segment for Test patients, indicating that there was a significant reduction in MBS expenditure following the start of telemonitoring.

A similar analysis was undertaken for subgroups within the total patient cohort to test whether these results were different for male (67; Table 26) and female (33; Table 27) participants, patients with predominantly cardiovascular (50;), respiratory (30; Table 29) or diabetic disease (20; Table 30), and those who were monitored within a community environment (62; Table 31) or within a hospital environment (38;). These tables are provided below.

Table 26 Linear regression and anocova analysis for sqrt(MBS expenditure) –MALE patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0565	-0.101	0.0212*	12.48	13.55
	(0.0343, 0.0788)	(-0.3048, 0.1028)		(12.03, 12.92)	(12.05, 15.05)
TEST	0.085	-0.3023	<0.001***	13.65	14.41
	(0.0612, 0.1088)	(-0.5747, -0.0298)		(13.17, 14.13)	(12.4, 16.41)
P	0.08	0.2			
DIFF (Control - Test)	0.002462	2.48	0.4614	-43.13	-18.25
	(-1.303, 1.308)	(-6.512, 11.47)		(-68.65, -17.62)	(-84.72, 48.22)

Table 27 Linear regression and anocova analysis for sqrt(MBS expenditure) – FEMALE patients only.

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.05126	-0.0638	0.167	13.04	12.72
	(0.0202, 0.0823)	(-0.2345, 0.1068)		(12.41, 13.67)	(11.52, 13.93)
TEST	0.05415	-0.3003	0.0025**	13.99	14.67
	(0.0165, 0.0918)	(-0.6168, 0.0162)		(13.23, 14.75)	(12.4, 16.95)
P	0.904	0.1568			
DIFF (Control - Test)	-0.8574	5.585	0.1733	-50.77	-67.11
	(-2.511, 0.7962)	(-6.333, 17.5)		(-85.98, -15.56)	(-148.7, 14.51)

Table 28 Linear regression and anocova analysis for sqrt(MBS expenditure) – CARDIAC patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0728	-0.1134	0.03*	13.01	13.29
	(0.0397, 0.1058)	(-0.2965, 0.0697)		(12.33, 13.69)	(11.91, 14.67)
TEST	0.1039	-0.1973	0.0024**	14.31	13.73
	(0.0681, 0.1396)	(-0.4004, 0.0058)		(13.58, 15.03)	(12.25, 15.22)
P	0.1999	0.4964			
DIFF (Control - Test)	-1.324	0.835	0.605	-65.39	3.024
	(-2.946, 0.2974)	(-7.975, 9.645)		(-98.14, -32.64)	(-63.86, 69.91)

Table 29 Linear regression and anocova analysis for sqrt(MBS expenditure) – RESPIRATORY patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0881	0.0567	0.7152	13.16	12.69
	(0.0524, 0.1239)	(-0.0963, 0.2097)		(12.41, 13.9)	(11.53, 13.84)
TEST	0.0708	-0.3984	<0.001***	13.34	15.17
	(0.0348, 0.1067)	(-0.6472, 0.1497)		(12.63, 14.06)	(13.29, 17.05)
P	0.4878	0.0024**			
DIFF (Control - Test)	0.8285	12.94	0.004**	4.638	-89.32
	(-0.894, 2.551)	(5.511, 20.37)		(-30.74, 40.01)	(-144, -34.65)

Table 30 Linear regression and anocova analysis for sqrt(MBS expenditure) – DIABETIC patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	-0.0054	-0.0043	0.9907	11.36	12.39
	(-0.0407, 0.0299)	(-0.217, 0.2084)		(10.60, 12.11)	(10.83, 13.94)
TEST	0.0956	-0.3345	0.0022**	14.66	16.08
	(0.0491, 0.1421)	(-0.6846, 0.0156)		(13.67, 15.65)	(13.56, 18.6)
P	<0.001***	0.0839			
DIFF (Control - Test)	-1.221	8.573	0.0924	-68.56	-93.61
	(-3.457, 1.016)	(-3.84, 20.99)		(-115.8, -21.33)	(-182.9, -4.336)

Table 31 Linear regression and anocova analysis for sqrt(MBS expenditure) – COMMUNITY monitored patients

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0497	-0.1053	0.0162**	12.32	13.67
	(0.0265, 0.073)	(-0.2635, 0.0530)		(11.84, 12.8)	(12.48, 14.86)
TEST	0.0755	-0.4224	<0.001***	14.22	15.35
	(0.0475, 0.1035)	(-0.6647, -0.18)		(13.65, 14.79)	(13.56, 17.13)
P	0.1558	0.0257*			
DIFF (Control - Test)	-0.5152	-0.028	0.9	-71.88	3.119
	(-1.794, 0.7639)	(-12.07, 12.02)		(-96.83, -46.93)	(-85.54, 91.77)

Table 32 Linear regression and anocova analysis for sqrt(MBS expenditure) – HOSPITAL monitored patients

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0819	0.0542	0.7308	13.62	11.84
	(0.0459, 0.1179)	(-0.0232, 0.1315)		(12.85, 14.38)	(11.28, 12.41)
TEST	0.101	-0.1088	0.0423*	13.81	13.38
	(0.0592, 0.1428)	(-0.2545, 0.0370)		(12.97, 14.65)	(12.31, 14.46)
P	0.4883	0.0388			
DIFF (Control - Test)	-0.4694	9.429	0.0212	-23.37	-82.55
	(-2.295, 1.357)	(3.513, 15.34)		(-61.45, 14.71)	(-126.1, -39.01)

5.3.3 Impact of telemonitoring on MBS expenditure

A review of these tables leads to the following conclusions;

- For every subgroup there was a significant decrease in slope AFTER the start of telemonitoring
- For males, cardiac patients, and community based patients there were apparent significant reductions in slope for control patients before and after the intervention. The remainder showed no significant change.
- Additional anocova analysis comparing slope of the combined before and after data as a single line to the before data alone, Figure 18 showed that for male patients, for cardiac patients and for patients monitored in the community, there was no significant difference with P=0.9289, P=0.3582 and P=0.5636 respectively.

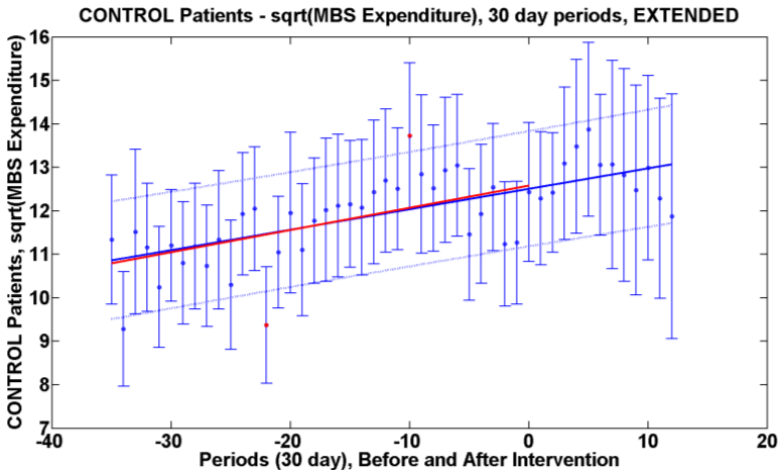


Figure 18 Linear regression and anocova comparison of regression line before intervention (red trace) and regression line fully extended for time periods after intervention for ALL MBS Controls (blue trace).

- Although there were clear changes in slope for Differences, they were only significant for respiratory patients (P=0.004) and those being monitored through hospital programs (P=0.0212)
- There were significant differences in the slope of Before and After data between Test and Control patients, over the three years preceding the intervention. For all patients and for diabetic patients these differences were significant with P= 0.0268 and P<0.001 respectively.

In every case other than for respiratory patients the slopes for Test patients were higher than for Control patients indicating that Test patients were in general increasing their expenditure on MBS items at a faster rate than Control patients, suggesting that in all probability they were sicker. This can be demonstrated by comparing the annual rate of MBS expenditure at the point of telemonitoring intervention. This is estimated by using the intercept value, squaring it and applying the scaling factor 365/30 to obtain an estimate of the per annum expenditure.

Table 33 Estimate of annual expenditure on MBS Items for all patient cohorts

PATIENT COHORT	TEST	CONTROL
All patients (N=100)	$2405	$1925
Male patients only (N=67)	$2267	$1895
Female patients only (N=33)	$2381	$2069
Patients with Cardiac disease as their primary diagnosis (N=50)	$2491	$2059
Patients with Respiratory disease as their primary diagnosis (N=30)	$2165	$2107
Patients with Diabetes as their primary diagnosis (N=20)	$2615	$1570
Patients managed in a community setting (N=62)	$2460	$1847
Patients managed in a hospital setting (N=38)	$2320	$2257

- The Table 33 above demonstrates clearly that on average, Test patients at the start of the telemonitoring intervention have significantly higher costs on MBS items than their matched Control patients. If these MBS costs can be considered a proxy for general well-being (healthier individuals generate lower MBS costs), then we can conclude that our Test patients were considerably sicker than their matched controls.
- The largest difference was observed for diabetic patients where Test patients generated $2,615 of MBS costs per annum whilst their controls generated $1,570, more than a thousand dollars less.

The estimates of annual MBS expenditure based on the linear regressions presented in the previous section provide a graphical representation that for almost every patient cohort in the study, MBS expenditure and its rate of increase was higher for Test patients than their matched controls. Patients from the ACT and Tasmania, managed by hospital based care coordinators appear to have been the most closely matched with respect to MBS expenditure.

5.3.4 Annual savings in MBS expenditure

- The linear regressions for sqrt(30day MBS costs) developed for Test patients, Control Patients and Differences (Control-Test) provide a best fit estimate of expenditure before and after intervention. To calculating estimates of per annum expenditure, we need to convert sqrt(30 day MBS costs) to annual costs. As a result the functions before and after intervention become quadratic and calculations of savings require the differencing of predicted costs after one year based on a projection of BEFORE data one year past the start of intervention, and the area under the TEST patient curve for one year past intervention. This is shown below in some detail for MBS costs for all Test patients.

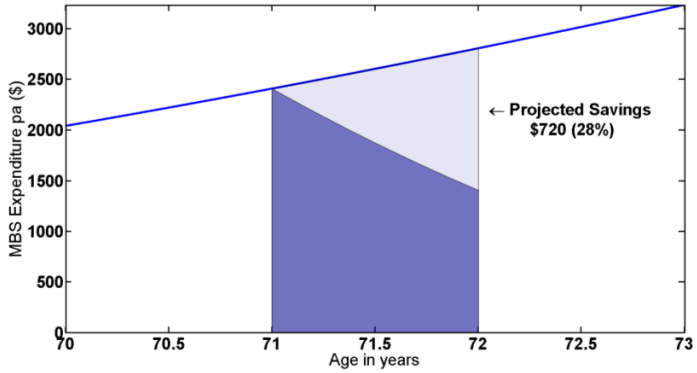


Figure 19 Estimate of impact of telemonitoring on MBS expenditure

- In Figure 19 above the average age of Test patients at the start of intervention is used as the reference point. The linear regression for sqrt(MBS costs over 30 days) is converted to annual expenditure and is projected forward to predict expenditure at age 72. The total MBS expenditure for the year is estimated from the area under the annual expenditure curve from age 71 to age 72. However following intervention, the slope of the regression line changes and the area of the curve beneath the actual expenditure curve, shown in dark blue estimates the actual MBS costs for that year. The difference represents the saving over one year, estimated to be $720 or 28% of the projected expenditure.
- However the assumption that the two curves meet exactly at the onset of intervention is a simplification that may over-estimate the savings. If indeed the impact of intervention takes some time to take effect, we would expect the point of intersection to fall sometime after the start of telemonitoring, subject to the variability of the expenditure data.

- This is in fact what is observed in the majority of cases as shown in Figure 20 below.

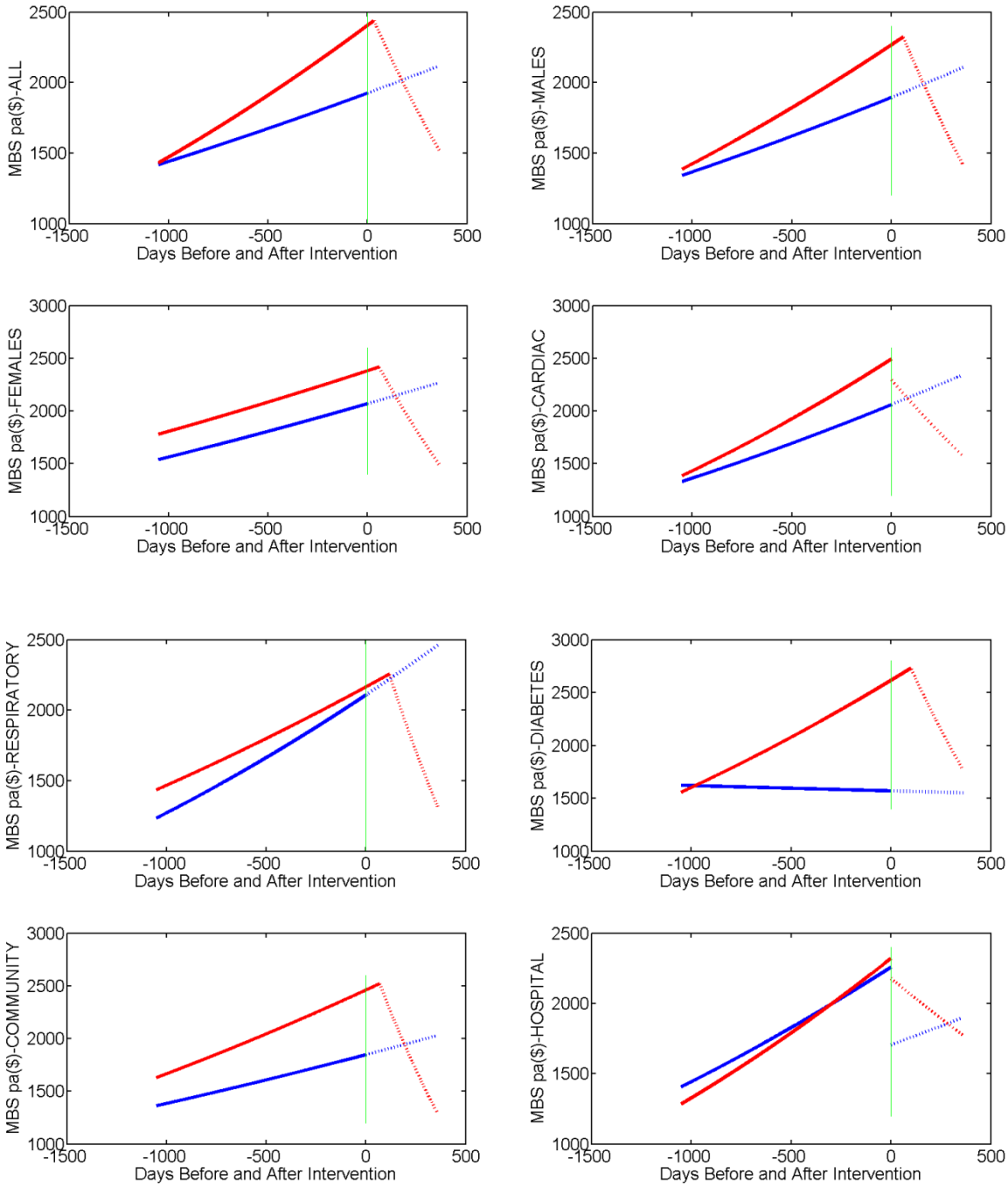


Figure 20 Estimates of annual MBS expenditure for TEST patients (red) and CONTROL patients (blue), before (solid) and after (dotted lines) intervention.

Note: Regression lines for Control patients that were not significantly different after intervention, are shown as simple extension of the regression line before intervention.

Control patients did not demonstrate any significant changes in regression slopes other than for Controls for Hospital Monitored Test patients who demonstrated a significant *drop* in their MBS expenditure after the intervention of $624. We note that this drop is not associated with a change in slope (P=0.7308) but rather a drop in MBS expenditure immediately after the start of the intervention on the Test patients. The reasons for this drop cannot be easily explained, other than to note that this patient cohort is small (N=38) and these data exhibit considerable natural variability.

The estimates of annual MBS expenditure based on the linear regressions presented in the previous section provide a graphical representation that for almost every patient cohort in the study, MBS expenditure and its rate of increase was higher for Test patients than their matched controls. The very large difference shown for diabetes patients may be a function of the small number of patients in this cohort (N=20). Patients from the ACT and Tasmania, managed by hospital based care coordinators appear to have been the most closely matched with respect to MBS expenditure.

We also note that the point of intersection of cost curves before and after intervention for six of the eight patient cohorts, fall between 31 days for all patients and 117 days for patients with respiratory disease. It is tempting to speculate that this represents the delay from the start of intervention to when an effect on MBS expenditure begins to have effect.

Estimating before and after costs, and therefore savings, using the methods outlined above, are likely to result in more realistic estimates. As an example, overall savings in MBS costs based on the simplified method shown in Figure 19 are estimated at $720 whilst with the more robust method described above falls to $611. It is likely that the best estimate of savings in MBS expenditure is between $611 and $720 per annum (see Table 34).

Table 34 Estimates of MBS costs and savings of Test patients one year before and one year after the intervention

PATIENT COHORT	Rate of MBS Expenditure at start of Intervention	Predicted Rate of MBS Expenditure at Year +1 (Without Intervention)	Estimated Rate of MBS Expenditure at Year +1 (With Intervention)	% Reduction in rate of MBS expenditure over one year	Predicted Annual Cost of MBS items after Intervention	Actual Annual Cost of MBS items after Intervention	Savings in MBS Expenses over one year	% Savings in MBS expenses over one year
All patients (N=100)	$2,405	$2,803	$1,504	46.3	$2,602	$1,991	$611	23.5
Male patients only (N=67)	$2,267	$2,623	$1,401	46.6	$2,444	$1,914	$529	21.7
Female patients only (N=33)	$2,381	$2,611	$1,477	43.5	$2,495	$2,001	$495	19.8
Patients with Cardiac disease as their primary diagnosis (N=50)	$2,491	$2,951	$1,562	47.1	$2,719	$1,915	$804	29.6
Patients with Respiratory disease as their primary diagnosis (N=30)	$2,165	$2,454	$1,296	47.2	$2,308	$1,899	$409	17.7
Patients with Diabetes as their primary diagnosis (N=20)	$2,615	$3,046	$1,755	42.4	$2,828	$2,344	$484	17.1
Patients managed in a community setting (N=62)	$2,460	$2,788	$1,269	54.5	$2,623	$1,975	$648	24.7
Patients managed in a hospital setting (N=38)	$2,320	$2,752	$1,768	35.7	$2,534	$1,969	$564	22.3

5.3.5 Analysis of Differences (Control – Test) for MBS expenditure

In the estimate of costs as outlined above, no compensation is made for any changes in Control that may have occurred after intervention as no significant changes were observed in seven out of the eight patient cohorts examined. Control patients did not demonstrate any significant changes in regression slopes other than for Controls for Hospital Monitored Test patients who demonstrated a significant *drop* of $624 in their MBS expenditure after the intervention. This drop in MBS expenditure of Control patients cannot be explained and may be simply a consequence of the data spread and the relatively small number of patients (N=38) in this cohort. However, if this drop in MBS expenditure for Controls is taken into consideration, then the relative change in MBS expenditure for Test patients relative to their Controls in this cohort is negligible, indeed negative at -$60.

Changes in MBS expenditure of Test patients relative to their Controls can also be estimated by using the linear regression equations developed for differences between Control and Test expenditure, using similar methods as outlined above.

Since no transform was applied to difference data, there is no need to calculate areas, as the mean of end points at start of intervention and one year later will provide the same result. The results are shown below in Table 35.

Table 35 Estimates of MBS savings of Test Patients relative to Control patients one year after the intervention, using differences (Control – Test).

PATIENT COHORT	Diff Year 0	Projected Diff at Year 1	Projected Average Diff	Average Diff after Intervention	Savings relative to Controls
All patients (N=100)	-$674	-$812	-$743	-$85	$657
Male patients only (N=67)	-$525	-$524	-$525	-$38	$487
Female patients only (N=33)	-$618	-$743	-$680	-$544	$136
Patients with Cardiac disease as their primary diagnosis (N=50)	-$796	-$989	-$893	$99	$991
Patients with Respiratory disease as their primary diagnosis (N=30)	$56	$177	$117	$237	$120
Patients with Diabetes as their primary diagnosis (N=20)	-$834	-$1,012	-$924	-$696	$228
Patients managed in a community setting (N=62)	-$875	-$950	-$912	$36	$948
Patients managed in a hospital setting (N=38)	-$284	-$353	-$319	-$539	-$220

In the table above, savings are calculated on the basis that there were no significant changes in Controls following the intervention. The results of calculating relative savings in MBS expenditure of Test and Control patients are broadly similar, as shown in Table 36 below;

Table 36 Comparison of MBS savings calculated from Test patients alone and from Differences (Control-Test)

	ALL (N=100)	MALES (N=67)	FEMALES (N=33)	CARDIAC (N=50)	RESPIRATORY (N=30)	DIABETES (N=20)	Community Monitored (N=62)	Hospital Monitored (N=38)
Using TEST Patients Only	$611	$529	$495	$804	$409	$484	$648	-$60*
Using DIFFERENCES	$657	$487	$136	$991	$120	$228	$948	-$220
Average	$ 634	$508	$316	$898	$265	$356	$798	-$140

*Includes compensation for a significant decrease in Control costs for this patient cohort after intervention

It is encouraging that for the two largest patient cohorts where data are likely to be most reliable, the differences between the two methods are negligible. The data above suggests that the greatest per annum reductions in MBS expenditure were for Cardiac patients ($898) and patients monitored in a Community setting ($798).

5.3.6 Linear regression analysis of impact of telemonitoring intervention on total PBS expenditure

The time course of PBS expenditure was analysed in a manner similar to that used for MBS expenditure, although it was noted that PBS data showed significantly higher variability. PBS data was provided in a simpler format than MBS data with Date of Supply, Patient Contribution, Government Contribution and Class of drugs (ATC Code) provided. For our study we only considered total cost of PBS Items.

Linear regression was carried out as before, using the *fit* command in the MATLAB statistics toolbox. Outliers, marked in red were excluded from the linear regression. The command *predobs* was used to plot 95% Prediction Intervals as dotted red lines shown in Figure 21. Note that prediction intervals indicate a 95% probability that a future observation at x will fall within its boundaries. Standard goodness of fit measures, including SSE – sum of squares due to error, R^2 – the coefficient of determination, the R^2 value adjusted for degree of freedom and the stdError – fit standard [;;; or root mean square error are also available. These are used together with one–way analysis of covariance (anocova) to determine whether the slopes of the BEFORE and AFTER portions of the linear regression lines are different.

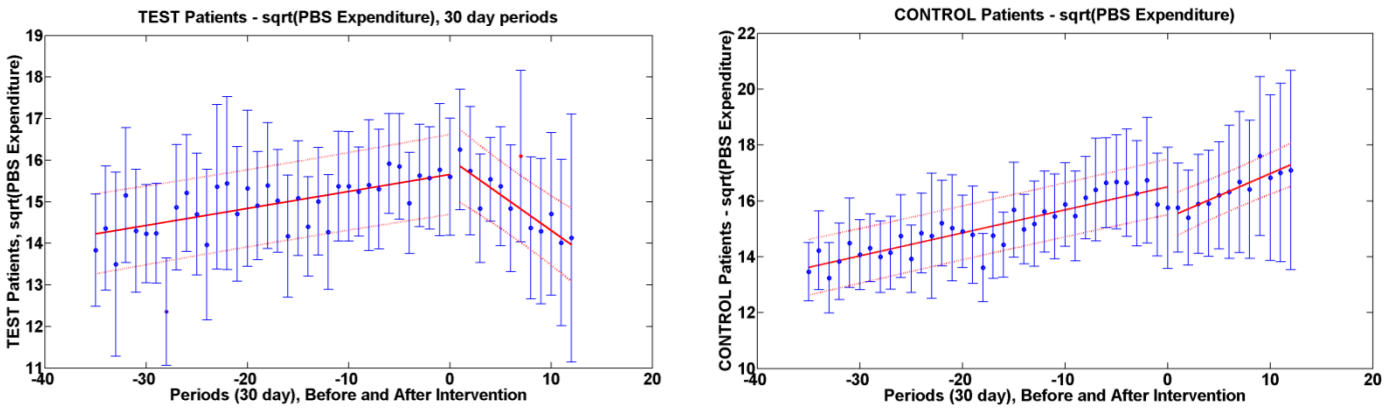


Figure 21 sqrt(MBS Costs) plotted for (a) Test patients and (b) Control patients at 30 day intervals. Linear regression lines are calculated after removal of outliers, which are marked in red

The Difference data (Control-Test) is similarly analysed (Figure 22), but without the application of any transform.

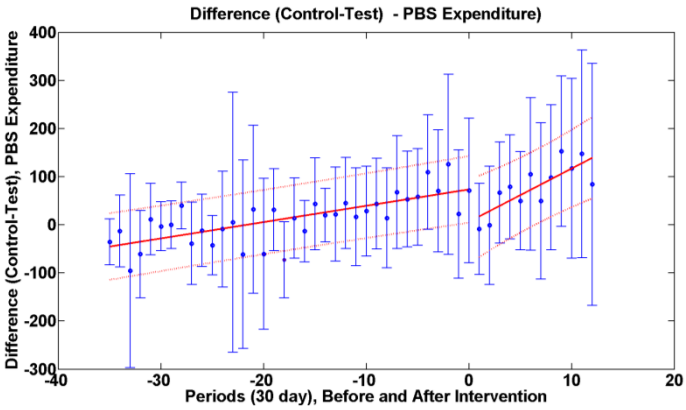


Figure 22 Plot of Differences (Control - Test) for PBS expenditure against 30 day intervals

As before, if the Control patients were exactly matched against PBS expenditure, the BEFORE part of the linear fit would have a zero slope and an intercept very close to zero. A close look at the plot of differences shows that the slope is in fact positive and the intercept at the point of commencement of telemonitoring is $73.67 on average, indicating that PBS expenditure over a 30 day period for Control patients was greater than that for Test patients at that time. If projected over a year this difference in PBS expenditure is close to $896.

It is interesting to note that for MBS expenditure, expenditure was higher for Test patients. For the plots shown above the linear regression fits and the results of the anocova analysis are given in tabular form in Table 37 below. Significant differences are indicated by * <0.05, ** < 0.01 and ***<0.001.

Table 37 Linear regression and anocova analysis for sqrt(PBS expenditure) – All patients

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0824	0.1584	0.0462*	16.5	15.39
	(0.0671, 0.0976)	(0.1012, 0.2155)		(16.19, 16.81)	(14.97, 15.81)
TEST	0.0408	-0.1717	<0.001***	15.66	16.03
	(0.0260, 0.0557)	(-0.2361, -0.1074)		(15.36 - 15.96)	(15.55, 16.5)
P	P < 0.001***	P < 0.001***			
DIFF (Control - Test)	3.392	11.06	<0.0084**	73.67	6.51
	(2.337, 4.448)	(4.842, 17.27)		(52.11, 95.22)	(-39.23, 52.25)

The analysis above shows that the ALL slopes of before and after segments were significantly different. The AFTER slope for Control patients was marginally significant (P=0.046) but **increased** rather than decreased. For Test patients, the AFTER slope was significantly lower than the BEFORE slope (P<0.001). The slope of PBS expenditure for Control patients was also higher than for Test patients, a reversal of what was observed for MBS expenditure. These differences between the time course of PBS and MBS expenditure may suggest that a higher PBS expenditure and better adherence to medications schedules may be associated with a better healthcare outcome and thus a reduced expenditure on MBS Items.

A similar analysis was undertaken for subgroups within the total patient cohort to test whether these results were different between male (67; Table 38) and female (33; Table 39) participants, patients with predominantly cardiovascular (50; Table 40), respiratory (30; Table 41) or diabetic disease(20; Table 42), and those who were monitored within a within a community environment (62; Table 43) or within a hospital environment (38; Table 44). These tables are provided below.

Table 38 Linear regression and anocova analysis for sqrt(PBS expenditure) –MALE patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0956	0.0616	0.4533	16.64	15.38
	(0.0771, 0.1140)	(-0.0116, 0.1349)		(16.26, 17.02)	(14.85, 15.9)
TEST	0.0491	-0.1965	<0.001***	15.77	15.99
	(0.0275, 0.0707)	(-0.3236, -0.0693)		(15.33, 16.2)	(15.05, 16.93)
P	0.0015**	<0.001***			
DIFF (Control - Test)	3.062	2.151	0.7904	68.19	5.149
	(1.699, 4.425)	(-5.719, 10.02)		(40.71, 95.67)	(-51.6, 61.9)

Table 39 Linear regression and anocova analysis for sqrt(PBS expenditure) – FEMALE patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0714	0.3349	<0.001***	16.62	15.38
	(0.0441, 0.0987)	(0.1720, 0.4979)		(16.03, 17.2)	(14.18, 16.58)
TEST	0.0309	-0.1605	0.0082**	15.35	16.17
	(0.0031, 0.0588)	(-0.2949, -0.0262)		(14.79, 15.9)	(15.21, 17.14)
P	0.0392*	<0.001***			
DIFF (Control - Test)	3.188	27.76	<0.001***	82.01	11.33
	(1.411, 4.965)	(21.56, 33.96)		(44.24, 119.8)	(-34.29, 56.95)

Table 40 Linear regression and anocova analysis for sqrt(PBS expenditure) – CARDIAC patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0866	0.1395	0.4517	16.18	14.19
	(0.0586, 0.1146)	(0.0707, 0.2083)		(15.61, 16.75)	(13.7, 14.68)
TEST	0.046	-0.1893	<0.001***	14.92	15.56
	(0.0287, 0.0632)	(-0.3542, -0.0244)		(14.57, 15.27)	(14.49, 16.63)
P	0.0164*	<0.001***			
DIFF (Control - Test)	3.11	7.688	0.3672	77.84	-42.72
	(1.31, 4.909)	(-3.926, 19.3)		(41.55, 114.1)	(-121.5, 36.05)

Table 41 Linear regression and anocova analysis for sqrt(PBS expenditure) – RESPIRATORY patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0678	0.0751	0.9343	16.44	16.45
	(0.0389, 0.0966)	(-0.1863, 0.3366)		(15.86, 17.03)	(14.7, 18.2)
TEST	0.0423	-0.0238	0.4523	16.04	15.66
	(0.0156, 0.0690)	(-0.2801, 0.2325)		(15.5, 16.57)	(13.92, 17.4)
P	0.1903	0.5452			
DIFF (Control - Test)	1.139	1.27	0.9728	28.28	73.59
	(-0.1092, 2.387)	(-11.17, 13.71)		(1.567, 54.99)	(-17.95, 165.1)

Table 42 Linear regression and anocova analysis for sqrt(PBS expenditure) – DIABETIC patients only

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0915	0.5278	<0.001***	17.35	15.98
	(0.0552, 0.1279)	(0.2302, 0.8254)		(16.61, 18.09)	(13.79, 18.17)
TEST	0.0181	-0.3171	<0.001***	16.67	18.01
	(-0.0156, 0.0518)	(-0.4688, -0.1654)		(16.02, 17.33)	(16.89, 19.13)
P	0.004**	<0.001***			
DIFF (Control - Test)	4.283	47.2	<0.001***	75.38	-28.98
	(2.28, 6.285)	(32.94, 61.46)		(37.52, 117.2)	(-133.9, 75.97)

Table 43 Linear regression and anocova analysis for sqrt(PBS expenditure) – COMMUNITY monitored patients

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0485	0.0161	0.557	15.34	14.79
	(0.03, 0.0670)	(-0.1197, 0.152)		(14.98, 15.71)	(13.86, 15.71)
TEST	0.032	-0.2991	<0.001***	15.48	16.51
	(0.0121, 0.0518)	(-0.4387, -0.1595)		(15.09, 15.86)	(15.49, 17.54)
P	0.2184	0.002**			
DIFF (Control - Test)	0.6645	10.7	0.004**	-1.802	-61.48
	(-0.6433, 1.972)	(3.649, 17.76)		(-27.87, 24.27)	(-113.4, -9.559)

Table 44 Linear regression and anocova analysis for sqrt(PBS expenditure) – HOSPITAL monitored patients

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.1479	0.0781	0.4386	18.56	17.36
	(0.1132, 0.1826)	(-0.0862, 0.2425)		(17.85, 19.27)	(16.18, 18.54)
TEST	0.0463	-0.0756	0.0519	15.78	15.9
	(0.0204, 0.0721)	(-0.1922, 0.0410)		(15.27, 16.28)	(15.04, 16.75)
P	<0.001***	0.0986			
DIFF (Control - Test)	7.311	13.68	0.255	185.1	83.4
	(5.267, 9.356)	(4.173, 23.19)		(144.8, 225.4)	(18.2, 148.6)

5.3.7 Impact of telemonitoring on PBS expenditure

A review of these tables leads to the following conclusions;

- For all Test patients (P <0.001) and most subgroups there was a significant decrease in slope AFTER the telemonitoring intervention, except for Respiratory patients (P=0.4523) and patients monitored in an Hospital environment (P=0.0519) where the decrease was visible but was not significant
- For the complete Control patient cohort there was a marginally significant (P=0.0462) increase in slope after the intervention, and very significant increases in slope for Female patients (P<0.001) and Diabetic patients (P<0.001). However further ancova analysis comparing Control data before to the combined before + after data these three patient groups showed that in no case was the difference in slope significant (Figure 23), with P values of 0.1543, 0.3523 and 0.1115 respectively.

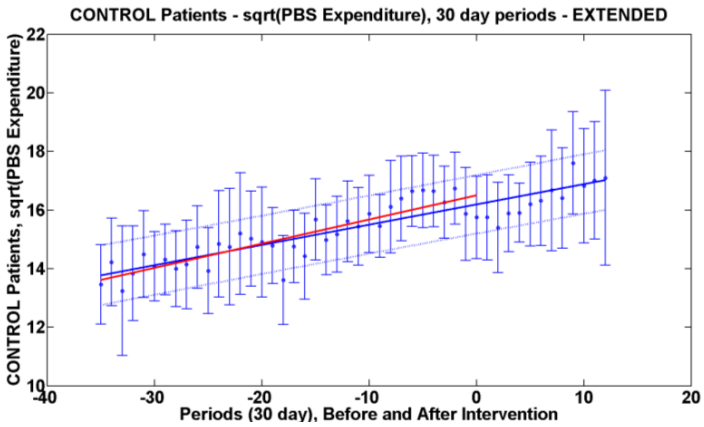


Figure 23 Ancova analysis of differences in slope of before data segment to combined before + after data for the complete patient cohort (N=100). As P > 0.05 the slopes were not different.

- However surprisingly, although there was no significant difference in slope for Male patients and those suffering from cardiac disease, ancova analysis of the segment before intervention to the combined before + after segment did show a significant change (P=0.0044 and P=0.0222 respectively) associated with a significant drop in the intercept of the regression line, below that for the data before intervention.
- The slopes before and after for Difference data were significant overall (P=0.008), for female patients (P<0.001), for diabetic patients (P=<0.001) as well as for patients monitored in community settings (P=0.004). For all other patient cohorts, the slopes before and after changed in the direction indicating that costs for Test patients were falling after the intervention, but were not considered significant (P>0.05).
- There were significant differences in the slope of Test and Control patient data, over the three years preceding the intervention, for the total cohort of patients (P<0.001), as well as for male patients (P<0.0015), female patients (P=0.0392), cardiac patients (P=0.0164), diabetic patients (P=0.004) and patients monitored in hospital environments (P<0.001). Differences were not significant for respiratory (P=0.1903) and patients monitored in the community (P=0.6645).
- For the total patient cohort, the slopes of controls were significantly larger than the slope of Test data after the telemonitoring intervention. This was observed for every patient cohort other than for respiratory patients (P=0.5452) and patients monitored in hospital settings (P=0986).

Differences in PBS expenditure at the start of telemonitoring can be easily estimated as before by using the intercept value, squaring it and applying the scaling factor 365/30 to obtain an estimate of the per annum expenditure. As these estimates are based on a three year history they are likely to be reliable.

Table 45 Estimate of annual expenditure on PBS Items for all patient cohorts

PATIENT COHORT	TEST	CONTROL
All patients (N=100)	$2984	$3312
Male patients only (N=67)	$3026	$3369
Female patients only (N=33)	$2867	$3361
Patients with Cardiovascular disease as their primary diagnosis (N=50)	$2708	$3185
Patients with Respiratory disease as their primary diagnosis (N=30)	$3130	$3288
Patients with Diabetes as their primary diagnosis (N=20)	$3381	$3662
Patients managed in a community setting (N=62)	$2916	$2863
Patients managed in a hospital setting (N=38)	$3030	$4191

Table 45 above demonstrates that Control patients at the start of the telemonitoring intervention have generally higher PBS expenditure than Test patients, but these differences are not likely to be significant. This is the opposite to what was observed for MBS expenditure and it is tempting to suggest that Test patients were sicker (higher MBS expenditure) because they were either less adherent with their medications regime or were under-medicated for their condition. Overall Control patients spent $328 more than Test patients per annum on their medications. The largest per annum difference of $1,161 was observed for patients managed in a Hospital setting. This difference is difficult to explain.

5.3.8 Annual savings in PBS expenditure

The linear regressions for sqrt(30day PBS costs) developed for Test patients, Control Patients and Differences (Control-Test) provide a best fit estimate of expenditure before and after intervention. Before calculating real costs, we need to convert sqrt(30 day PBS costs) to annual costs. As a result the functions before and after intervention become quadratic and calculations of savings require the differencing of predicted costs after one year based on a projection of BEFORE data one year past the start of intervention and the area under the TEST patient curve for one year past intervention. This is shown below in some detail for PBS costs for all Test patients.

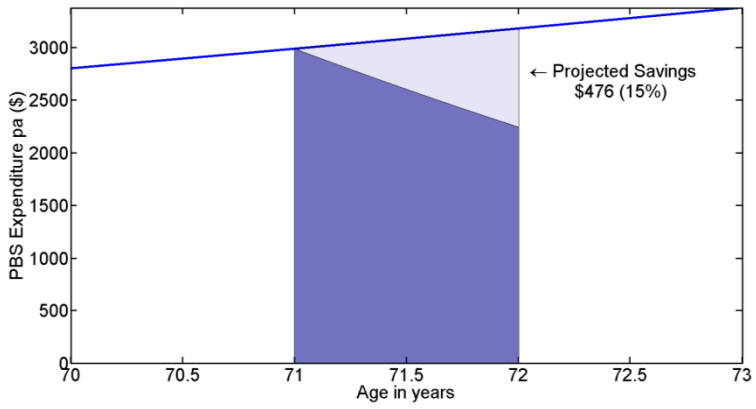


Figure 24 Estimation of savings on PBS Expenditure curve projected forward one year

In Figure 24 above the average age of Test patients at the start of intervention is used as the reference point. The linear regression for sqrt (PBS costs over 30 days) is converted to annual expenditure and is projected forward to predict expenditure at age 72. Note that the predicted rate of annual PBS expenditure in the absence of the telehealth intervention was $3,176, and this was reduced by 29.5% to $2,240.

The total savings in PBS expenditure for the year can be estimated from the area under the annual expenditure curve from age 71 to age 72 before and after intervention. Following intervention, the slope of the regression line changes and the area of the curve between the predicted and the actual expenditure curve, shown in dark blue estimates the actual PBS costs for that year. The difference represents the saving over one year, estimated to be $476 or 15% of the projected expenditure.

However the assumption that the two curves meet exactly at the onset of intervention is a simplification that may over-estimate the savings. If indeed the impact of intervention takes some time to take effect, we would expect the point of intersection to fall sometime after the start of telemonitoring, subject to the variability of the expenditure data.

The estimates of annual PBS expenditure based on the linear regressions presented in Figure 24, provide a graphical representation that overall PBS expenditure and its rate of increase, was higher for Control patients than Test patients. The only exception appears to be for Community based patients who at the point of intervention were closely matched to their controls.

The largest difference in PBS expenditure at the start of intervention was for patients monitored by hospital based services. We also note that the point of intersection of cost curves before and after intervention for seven of the eight patient cohorts, fall between 27 and 129 days. The longest delay before an impact is observed was 129 days for female patients and 120 days for diabetic patients. It is tempting to speculate that this represents the delay from the start of intervention to when an effect on PBS expenditure begins to be noticed.

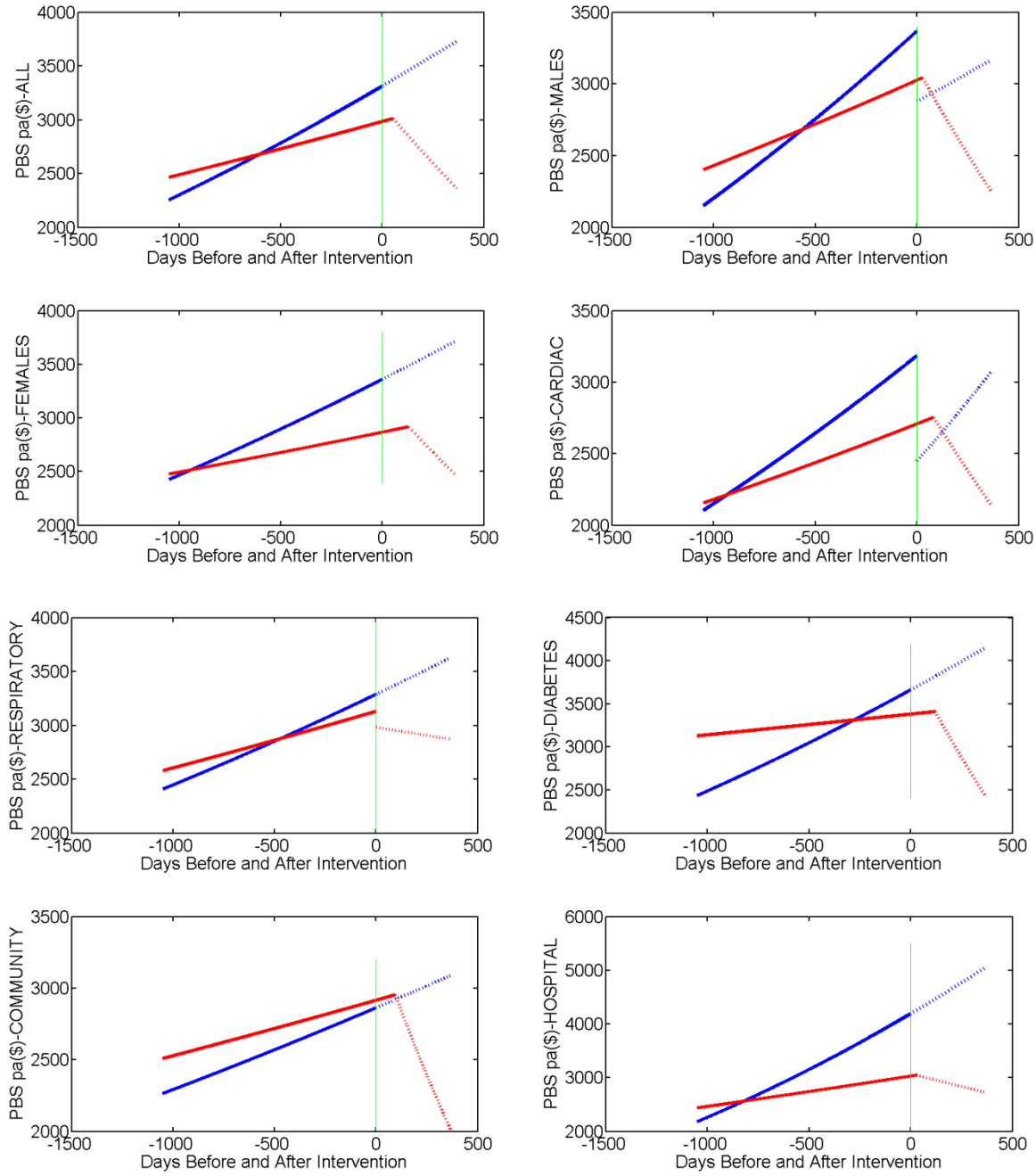


Figure 25 Estimates of annual PBS expenditure for PBS Test patients (red) and Control patients (blue), before (solid lines) and after (dotted lines) intervention.

Note: Regression lines for Control patients that were not significantly different after intervention are shown as a simple extension of the regression line before intervention.

Estimating before and after costs and therefore savings, using the methods outlined above, are likely to result in more realistic estimates. As an example, overall savings in PBS costs based on the simplified method shown in Figure 25 are estimated at $476 whilst with the more robust method described above falls to $354 (see Table 46). It is likely that the best estimate of savings in PBS expenditure lies within this range.

Table 46 Estimates of PBS costs and savings for Test patients one year after the intervention

PATIENT COHORT	Rate of PBS Expenditure at start of Intervention	Predicted Rate of PBS Expenditure at Year +1 (Without Intervention)	Estimated Rate of PBS Expenditure at Year +1 (With Intervention)	% Reduction in rate of PBS expenditure over one year	Predicted Annual Cost of PBS items before Intervention	Actual Annual Cost of PBS items after Intervention	Savings in PBS Expenses over one year	% Savings in PBS expenses over one year
All patients (N=100)	$2,984	$3,176	$2,365	25.5	$3,080	$2,726	$354	11.5
Male patients only (N=67)	$3,026	$3,259	$2,250	31.0	$3,142	$2,665	$477	15.2
Female patients only (N=33)	$2,867	$3,009	$2,459	18.3	$2,938	$2,757	$181	6.2
Patients with Cardiac disease as their primary diagnosis (N=50)	$2,708	$2,915	$2,138	26.7	$2,812	$2,504	$308	10.9
Patients with Respiratory disease as their primary diagnosis (N=30)	$3,130	$3,334	$2,874	13.8	$3,232	$2,929	$303	9.4
Patients with Diabetes as their primary diagnosis (N=20)	$3,381	$3,471	$2,437	29.8	$3,426	$3,068	$358	10.4
Patients managed in a community setting (N=62)	$2,916	$3,064	$2,016	34.2	$2,990	$2,587	$403	13.5
Patients managed in a hospital setting (N=38)	$3,030	$3,250	$2,730	16.0	$3,139	$2,899	$240	7.7

5.3.9 Analysis of Differences (Control – Test) for PBS expenditure

In the estimate of costs as outlined above, no compensation is made for any changes in Control that may have occurred after intervention as in most cases, other than for Male patients and Cardiac patients no significant changes were observed when ancova analysis was used to test slopes of the combined before and after segments. However for Female Control patients and for diabetic Control patients (Figure 26), there was a highly significant (P<0.001) **increase** in slope after the start of intervention which cannot be explained. This increase in PBS expenditure over one year was estimated as $265 for Female patients and $696 for Diabetic patients. The reduction in PBS costs for these two Test patient groups ***relative to their controls*** thus increases to $446 and $1,054 respectively.

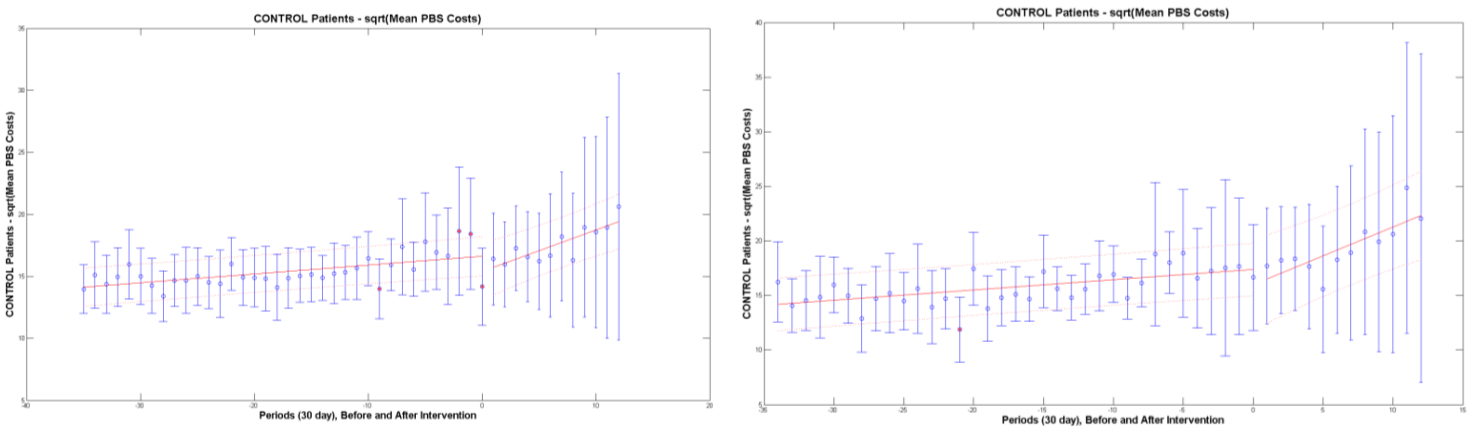


Figure 26 sqrt(30 day PBS Expenditure) for (A) Female Patients (N=33) and (B) Diabetic Patients (N=20)

However the effect of changes in PBS expenditure by Controls can also be accounted for by using the linear regression equations developed for differences between Control and Test expenditure, using similar methods as outlined above. Since no transform was applied to difference data, there is no need to calculate areas, as the mean of end points at start of intervention and one year later will provide the same answer. The results are shown below in Table 47.

Table 47 Estimates of PBS savings one year after the intervention, using differences (Control-Test)

PATIENT COHORT	Difference Year 0	Projected Difference at Year 1	Projected Average Difference	Average Difference after Intervention	Change in Control-Test After Intervention
All patients (N=100)	$896	$1,398	$1,147	$1,192	$44
Male patients only (N=67)	$830	$1,283	$1,056	$222	-$834
Female patients only (N=33)	$998	$1,470	$1,234	$2,295	$1,062
Patients with Cardiac disease as their primary diagnosis (N=50)	$947	$1,407	$1,177	$49	-$1,128
Patients with Respiratory disease as their primary diagnosis (N=30)	$344	$513	$428	$989	$561
Patients with Diabetes as their primary diagnosis (N=20)	$917	$1,551	$1,234	$3,267	$2,033
Patients managed in a community setting (N=62)	-$22	$76	$27	$222	$195
Patients managed in a hospital setting (N=38)	$2,252	$3,334	$2,793	$2,027	-$766

The results of the intervention on PBS expenditure are considerably more difficult to interpret because a number of Control patient cohorts showed a significant change in their PBS expenditure following the start of intervention as shown in Table 48.

Table 48 Comparison of PBS savings calculated from Test patients alone and from Differences (Control-Test)
Savings are shown as positive values and increases are shown as negative values

	ALL (N=100)	MALES (N=67)	FEMALES (N=33)	CARDIAC (N=50)	RESPIRATORY (N=30)	DIABETES (N=20)	Community Monitored (N=62)	Hospital Monitored (N=38)
Savings Using Test Patients Only	$354	$477	$181	$308	$303	$358	$403	$240
Savings Using Controls Only*	$260	$590	-$265	$642	-$23	-$696	$278	$740
Net Savings relative to Controls	$94	-$113	$446	-$334	$326	$1,054	$125	-$500
From Differences	$ 44	-$834	$1,062	-$1,128	$561	$2,033	$195	-$ 766
Average Difference (Fall in Test relative to Controls)	$69	-$474	$754	-$731	$444	$1,544	$160	-$633

* Assuming that all changes in Control after intervention were statistically significant

The relative savings calculated from differences (row 4) broadly match those calculated from Test patients relative to their controls (row 3). A negative value in row 5 of the Table above means that there was an **increase** in the PBS expenditure of Test patients relative to their Controls. This was observed Male patients, Cardiac patients and those being monitored in a hospital environment where the fall in PBS expenditure was greater for Controls than for Test patients. We have no explanation for these observations.

An increase in the slope of (Control-Test) differences after the intervention means either that PBS costs for Controls have increased, PBS costs for diabetic patients have decreased, or that both have occurred simultaneously. An increase in slope and a reduction in the intercept can be interpreted to indicate that the effect of the intervention is only observed after a significant time delay.

From Tables 38-45 we note that for Control patients there was a marginally significant increase ($P=0.046$) in the overall rate of PBS expenditure after intervention, and a highly significant increase ($P<0.001$) both for Female patients and Diabetic patients. In addition, although there was no significant difference in slope for male patients and those suffering from cardiac disease, before and after intervention, anocova analysis of the segment before intervention to the combined before + after segment did show a significant change ($P=0.0044$ and $P=0.0222$ respectively), associated with a shift downwards in the intercept, but no significant change in slope.

These effects of the intervention on Control patient data are difficult to explain, other than to note that Female patients (N=33) and Diabetic patients (N=20) are relatively small cohorts. This cannot be said of male patients (N=67) and cardiac patients (N=50), but we note that 68% of patients with cardiac conditions were male.

Similarly there were significant increases in slopes of Differences overall ($P<0.008$), as well as for Female patients ($P<0.001$) and Diabetic patients ($P<0.001$).This is consistent with an increase in PBS costs of Control patients as well as a decrease in PBS expenditure of equivalent Test patient cohort.

5.4 Analysis of Hospital Data – Number of admissions and length of stay

Hospital Data was intended to be sourced for all Test and Control patients selected from hospital lists at each of the six test sites. However the majority of Test and Control patients in VIC and NSW and a significant number from QLD were not selected from hospital lists and their hospital data were thus not available for analysis. The final selection of 53 Test and 64 Control patients for which hospital data was available is shown in Table 49 below;

Table 49 Selection of Test and Control patients for analysis of hospital admissions and LOS

	TAS		ACT		VIC		NSW		QLD		TOTAL	
	Hospital Based				Community Based							
Eligible Patients in Hospital Lists	210		520		282		230		187		1429	
	T	C	T	C	T	C	T	C	T	C	T	C
Patients Selected from Hospital Lists	29	56	16	22	0	1	7	4	19	27	71	110
Patients selected from outside Hospital List	-	4	-	1	26	48	10	8	7	2	43	63
All Patients Selected	29	60	16	23	26	49	17	12	26	29	114	173
Patients withdrawn	7	-	2	-	1	-	6	-	2	-	18	-
Patients died	4	7	1	3	2	2	-	-	1	2	8	14
Patients matched for PBS/MBS Analysis	25	55	13	19	25	35	14	8	23	20	100	137
Patients matched for analysis of hospital admission and LOS	25	52	13	19	13	13	12	3	23	20	86	107
Patients Rejected for analysis of hospital admission and LOS	2	18	1	3	13	13	12	3	5	6	33	43
Final patients matched for analysis of hospital admission and LOS	23	34	12	16	-	-	-	-	18	14	53	64

Of the 53 Test Patients selected, 29 suffered from Heart Disease, 21 suffered from Respiratory disease and 3 were diabetics. The average age was 70.8±8.7 years, not significantly different from the larger cohort.

For the available Test and Control patients for which data was available, all admissions involving at least one overnight stay were counted and summed over time intervals of 100 days before and after admission. The time period of 100 days was selected rather than the 30 day intervals selected for PBS and MBS expenditure as hospital events are much less frequent and would generate a large number of zero entries over any particular 30 day interval. Hospital admission and Length of Stay (LOS) data was normally distributed and did not require any transformation prior to analysis.

The time course of changes in the number of admissions and LOS were analysed in a manner similar to that used for PBS and MBS expenditure.

5.4.1 Linear regression analysis of number of admissions

Linear regression was carried out as before, using the *fit* command in the MATLAB statistics toolbox. Outliers, marked in red were excluded from the linear regression. The command *predobs* was used to plot 95% Prediction Intervals as dotted red lines. Note that prediction intervals indicate a 95% probability that a future observation at x will fall within

its boundaries. Standard goodness of fit measures, including SSE – sum of squares due to error, R^2 – the coefficient of determination, the R^2 value adjusted for degree of freedom and the stdError – fit standard error or root mean square error are also available. These are used together with one–way analysis of covariance (anocova) to determine whether the slopes of the BEFORE and AFTER portions of the linear regression lines are different (Figure 27).

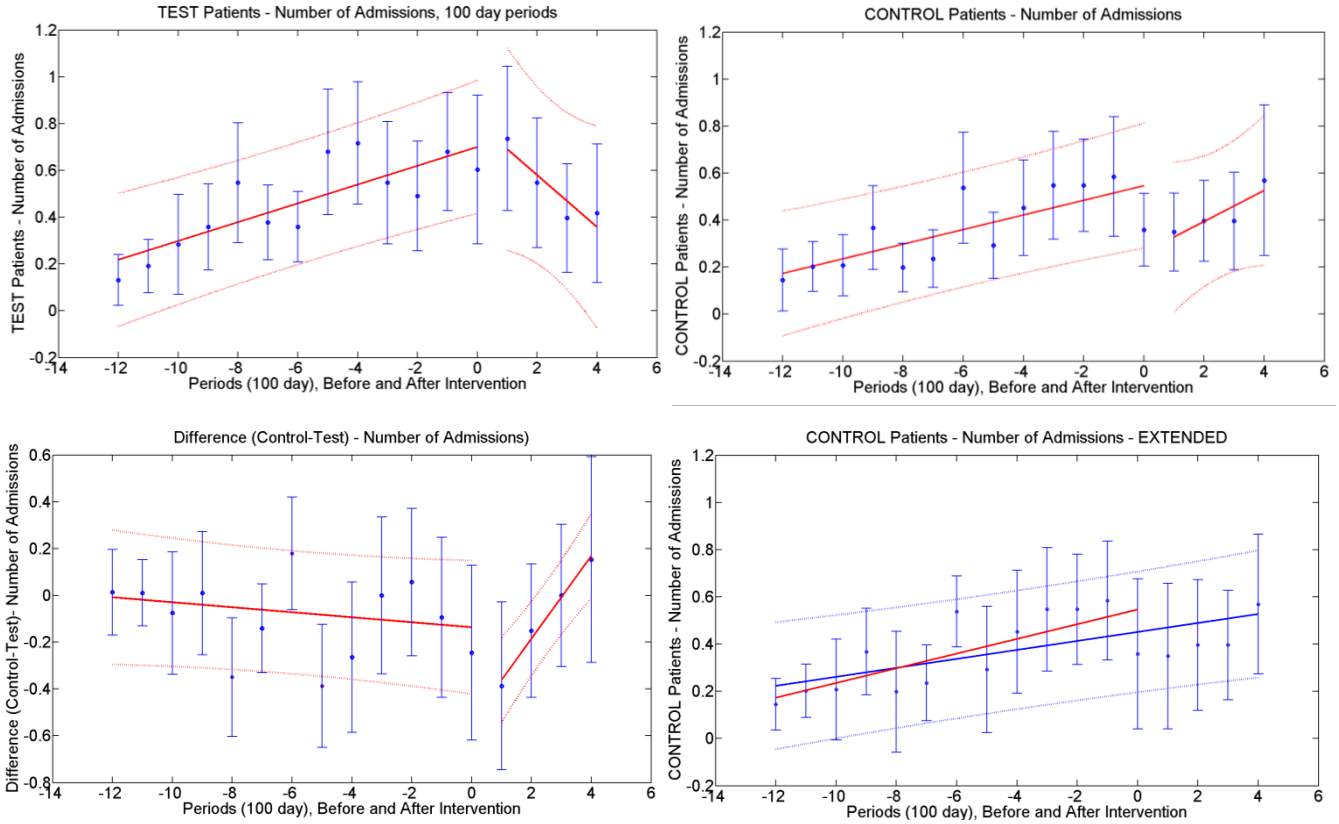


Figure 27 Fit of linear regression lines for Number of Hospital admissions over 100 day intervals before and after intervention

As before, if the Control patients were exactly matched against PBS expenditure, the BEFORE part of the linear fit of Differences would have a zero slope and an intercept very close to zero. A close look at the plot of differences shows that the slope is in fact negative and the intercept at the point of commencement of telemonitoring is almost exactly 0.5 admissions/annum. This indicates that the number of admissions was greater for Test patients over the period prior to intervention and just at the start of intervention.

For the plots shown above the linear regression fits and the results of the *anocova* analysis are given in tabular form in Table 50 below. Significant differences are indicated by * <0.05, ** < 0.01 and ***<0.001.

Table 50 Results of regression analysis of Number of Hospital Admissions for Before and After number of admissions

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.0311	0.0661	0.4576	0.5463	0.2624
	(0.0137, 0.0485)	(-0.0432, 0.1754)		(0.423, 0.6696)	(-0.0368, 0.5617)
TEST	0.0402	-0.1109	0.0094**	0.6998	0.8011
	(0.0215, 0.0588)	(-0.2592, 0.0374)		(0.5678, 0.8318)	(0.3949, 1.207)
P	0.4429	0.0145*			
DIFF (Control-Test)	-0.0107	0.177	0.0018**	-0.1361	-0.5387
	(-0.0295, 0.0082)	(0.1146, 0.2393)		(-0.2727, 0.0005)	(-0.7095, -0.3678)

5.4.2 Impact of telemonitoring on number of admissions

The linear regression analysis shown in Table 51 shows that the change in slope Before and After intervention was significant only for Test patients (P=0.0094) and for Difference data (P=0.0018), but was not significant for Control patients. Additional confirmation that there was no significant difference (P=0.2342) for Controls was from the *ancova* analysis of Control data before and the combined Before and After data. Similarly there were no significant differences in slope for Test and Control patients before (P=0.6629), but the differences in slope were significant (P=0.0145) after intervention.

Assuming that the reference point is used as the start of intervention it is easy to calculate that on average the predicted rate of admission would fall by 53% and the total number of admissions over one year would be reduced by almost one admission per annum.

Table 51 Results of intervention on number and rate of hospital admissions per annum using simplifying assumptions

Rate of Admissions at start of Intervention (N/annum)	Predicted Rate at Year +1 (N/annum)	Estimated Rate at Year +1 (N/annum)	% Change in Rate	Predicted Number Admissions in Year after Intervention (N/annum)	Actual Number Admissions in Year after Intervention (N/annum)	Reduction in Number Admissions over one year (N/annum)	% Change in Number Admissions over one year
2.55	3.09	1.45	53.2%	2.82	1.82	1.00	35.7%

However as was discussed previously, the best estimate of the impact of intervention may be shown diagrammatically as shown below in Figure 28.

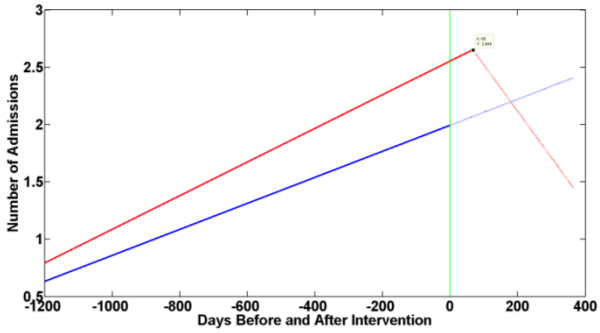


Figure 28 Estimate of impact of intervention on number of admissions per annum.

Note: Red line is for Test patients and blue line is for Control Patients. Solid lines are for response Before intervention and dotted lines represent response After Intervention. As the slopes of Controls before and after were not significant, the Control After response is represented as a continuation of the Before response.

In the above figure the intercept at which the rate of annual admissions begins to change is 67 days. It is reasonable to assume that it takes a little over two months before the impact of intervention of the rate of admission begins to take effect. From these graphical estimate the following data may be easily derived.

Table 52 Estimated impact of Intervention on number of admissions per annum

Rate of Admissions at start of Intervention (N/annum)	Predicted Rate at Year +1 (N/annum)	Estimated Rate at Year +1 (N/annum)	% Change in Rate	Predicted Number Admissions in Year after Intervention (N/annum)	Actual Number Admissions in Year after Intervention (N/annum)	Reduction in Number Admissions over one year (N/annum)	% Change in Number Admissions over one year
2.55	3.09	1.45	53.2%	2.82	2.15	0.67	23.8%

It is therefore likely that the effect of the intervention was to reduce the rate of admission by 53% resulting in an average reduction in hospital admissions following intervention of between 0.67 and 1.0 admissions per annum (seeTable 52).

5.4.3 Analysis of differences (Control – Test) for number of admissions

In the estimate of the effect of intervention on the number of admissions carried out above, no compensation is made for any changes in Control that may have occurred after intervention as no significant differences were noted in Control patients before and after intervention, and no significant changes were observed when ancova analysis was used to test slopes of the combined before and after segments.

However the effect of changes in Number of Admissions for Control patients can be accounted for by using the linear regression equations developed for differences between Control and Test expenditure, using similar methods as outlined above. Since no transform was applied to difference data, there is no need to calculate areas, as the mean of end points at start of intervention and one year later will provide the same answer. A more accurate result can then be calculated using the intercept between the Before and After data as shown in Figure 29.

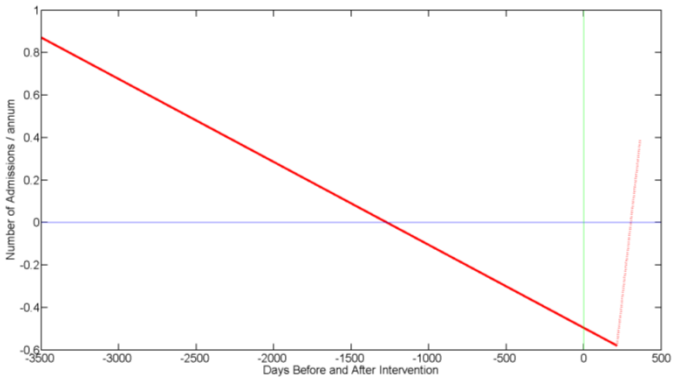


Figure 29 Linear regression of differences for Number of admissions/annum

The data above in Figure 29 shows that the first effect of the intervention is observed 214 days after the start. The results from the analysis of the linear regression for differences are shown in Table 53.

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Table 53 Estimates of Number of admissions one year after the intervention, using differences (Control-Test)

PATIENT COHORT (Differences)	Difference Year 0 (days)	Projected Difference at Year 1 (days)	Difference at Year 1 after intervention (days)	Projected Average Difference (days)	Average Difference after Intervention	Change in Control-Test After Intervention
All patients (N=53)	-0.50	-0.64	0.39	-0.57	-0.35	0.22

The results obtained from differences are lower than obtained directly from Test data in part because the intercept occurs later at 214 days. However the difference data also shows that after one year of intervention the rate of admission for Test patients relative to Controls is 1.03 admission/annum less than that predicted without the intervention.

5.4.4 Linear regression analysis of Length of Stay (LOS)

Length of Stay (LOS) was analysed in a similar manner to number of admissions. Linear regression was carried out as before, using the fit command in the MATLAB statistics toolbox. Outliers, marked in red were excluded from the linear regression. The command predobs was used to plot 95% Prediction Intervals as dotted red lines as shown in

Figure 30. Note that prediction intervals indicate a 95% probability that a future observation at x will fall within its boundaries. Standard goodness of fit measures, including SSE – sum of squares due to error, R^2 – the coefficient of determination, the R^2 value adjusted for degree of freedom and the stdError – fit standard error or root mean square error are also available. These are used together with one–way analysis of covariance (anocova) to determine whether the slopes of the BEFORE and AFTER portions of the linear regression lines are different.

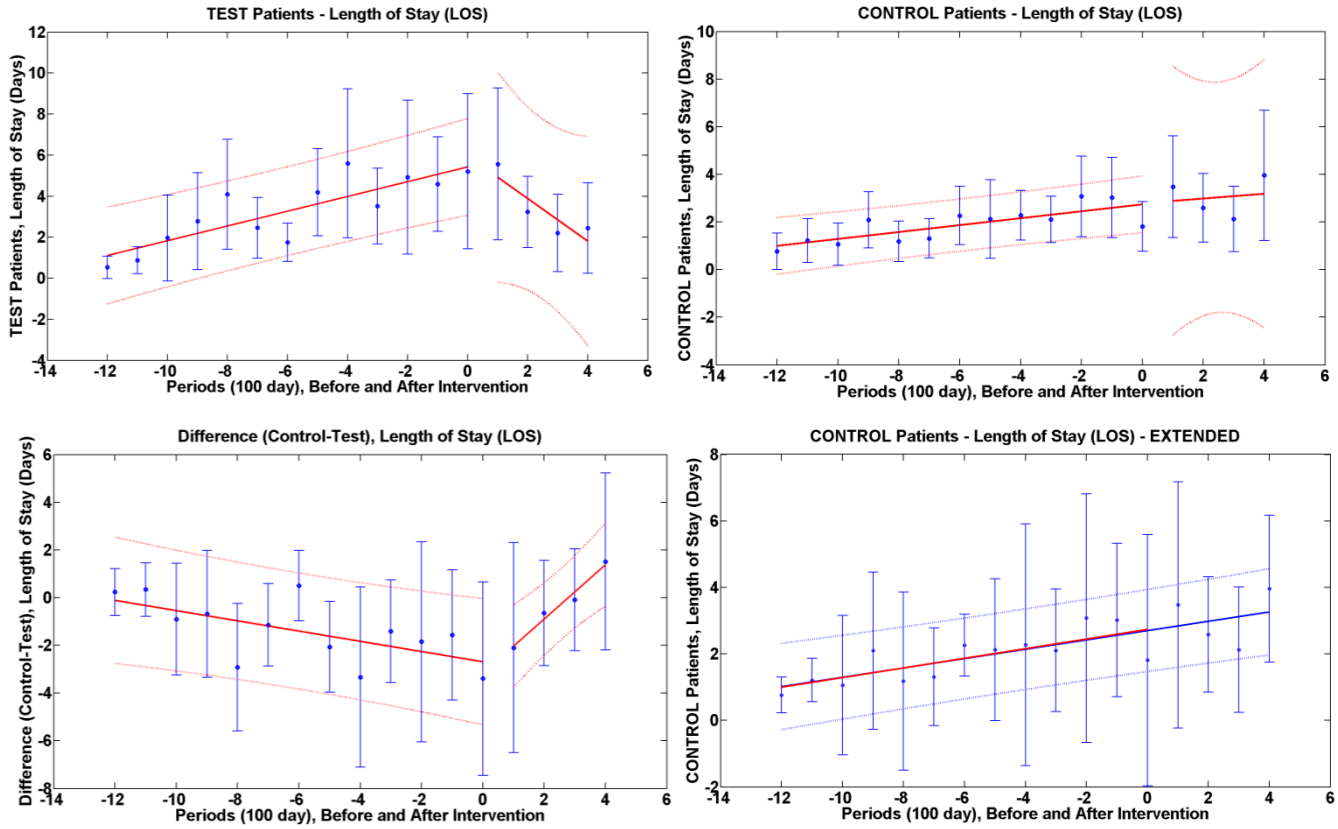


Figure 30 Fit of linear regression lines for Length of Stay (LOS) over 100 day intervals before and after intervention

The graphical data shown above and supported by the results of linear regression given in Table 54 below indicate that Test patients were considerably more likely to be admitted to hospital than their controls.

Table 54 Results of regression analysis of Length of Stay (LOS) for Before and After intervention

	BEFORE	AFTER		BEFORE	AFTER
	Slope	Slope	Sig	Intercept	Intercept
CONTROL	0.1452	0.1	0.869	2.739	2.785
	(0.0669, 0.2235)	(-1.836, 2.036)		(2.186, 3.293)	(-2.516, 8.086)
TEST	0.3597	-1.038	0.006**	5.424	5.957
	(0.2049, 0.5145)	(-2.791, 0.7141)		(4.329, 6.518)	(1.158, 10.76)
P	0.0125*	0.1339			
DIFF	-0.2145	1.138	<0.01**	-2.685	-3.172
	(- 0.3883, -0.0407)	(0.5418, 1.735)		(-3.914,-1.455)	(-4.806, -1.539)

5.4.5 Impact of intervention on Length of Stay (LOS)

Following the start of intervention, Test patients experienced a significant (P=0.006) reduction in their rate of hospital stays relative to their controls (P=0.869). In addition there was a significant difference (P=0.0125) in slopes for Test and Control patients before intervention, with Test patients showing an average length of stay of 19.8 days as against 10.0 days for controls at the start of intervention. This would suggest that Test patients were considerably more ill than their Controls.

As both number of admissions and length of stay were analysed without any transformation, the impact of telemonitoring can be readily analysed from the regression analysis shown in Table 55 . Assuming that the start of intervention is used as the reference point is used as it is easy to calculate that on average the predicted rate of length of stay would fall by almost 76%, and the total length of stay over one year would be reduced by approximately 9.3 days per annum.

Table 55 Results of intervention on length of stay (LOS) per annum using simplifying assumptions

Rate of LOS at start of Intervention (days)	Estimated Rate of LOS one year after, without intervention (days)	Estimated Rate of LOS one year after intervention (days)	% Change in Rate of LOS	Predicted LOS over one year without Intervention (days)	Estimated LOS in Year after Intervention (days)	Estimated reduction in LOS over one year (days)	% Change in LOS over one year
19.8	24.6	6.0	75.7%	22.2	12.9	9.3	41.9%

However as was discussed previously, the best estimate of the impact of intervention may be shown in Figure 31 below, where the intercept between the response before intervention and after intervention is calculated as 38 days.

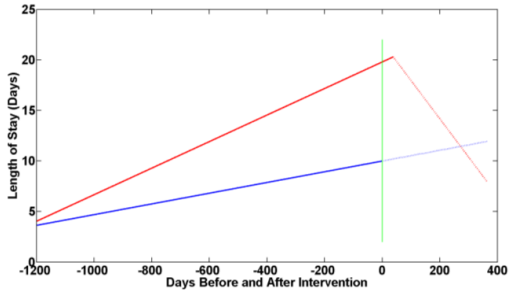


Figure 31 Estimate of impact of intervention on LOS per annum.

Note: Red line is for Test patients and blue line is for Control Patients. Solid lines are for response Before intervention and dotted lines represent response After Intervention. As the slopes of Controls before and after were not significant, the Control After response is represented as a continuation of the Before response.

Taking this intercept into consideration, the effect of intervention on the average length of stay is shown below in Table 56.

Table 56 Results of intervention on length of stay (LOS) per annum

Rate of LOS at start of Intervention (days)	Predicted Rate of LOS without intervention Year +1 (days)	Estimated Rate of LOS with Intervention Year +1 (days)	% Change in Rate of LOS	Predicted LOS over one year without Intervention (days)	Estimated LOS in year after Intervention (days)	Estimated reduction in LOS over one year (days)	% Change in LOS over one year after intervention
19.8	24.6	7.9	67.9%	22.2	14.7	7.5	33.8%

The effect of the telemonitoring intervention on Length of Stay may thus be estimated as an average reduction of between 7.5 and 9.3 days over the year following the start of the intervention. Note however that after one year of intervention the average expected LOS had fallen by almost 68% from the predicted value of 24.6 to 7.9 days.

5.4.6 Analysis of differences (Control – Test) for Length of Stay

In the analysis of the effect of intervention on length of stay (LOS) carried out above, no compensation is made for any changes in Control that may have occurred after intervention as no significant differences were noted in Control patients before and after intervention, and no significant changes were observed when *anocova* analysis was used to test slopes of the combined before and after segments.

However the effect of changes in LOS for Control patients can be accounted for by using the linear regression equations developed for differences between Control and Test expenditure, using similar methods as outlined above. Since no transform was applied to difference data, there is no need to calculate areas, as the mean of end points at start of intervention and one year later will provide the same answer. A more accurate result can then be calculated using the intercept between the Before and After data as shown in Figure 32 below.

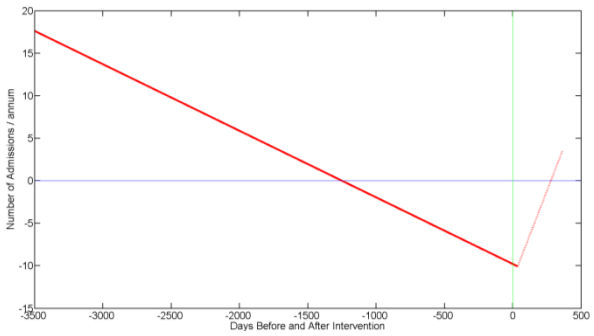


Figure 32 Linear regression of differences for LOS/annum

Figure 32 above shows that the first effect of the intervention is observed 36 days after the start. The results from the analysis of the linear regression for differences are shown below in Table 57.

Table 57 Estimates of Number of admissions one year after the intervention, using differences (Control-Test)

PATIENT COHORT (Differences)	Difference Year 0 (days/annum)	Projected Difference after one year (days/annum)	Estimated Difference one year after intervention (days/annum)	Projected Average Difference without intervention (days/annum)	Average Difference after one year of Intervention (days/annum)	Change in Control-Test After Intervention (days/annum)
All patients (N=53)	-9.8	-12.7	3.6	-11.2	-3.9	7.3

The results obtained from differences is very close to the estimated reduction in LOS over one year of 7.5 days obtained from Test patient data before and after intervention. The difference data also shows that after one year of intervention the rate of LOS for Test patients relative to Controls is 14.3 days/annum, comparable to the 16.7 days/annum obtained from Test patients alone.

5.5 Effect of telemonitoring intervention on Mortality

The simplest death rate that is commonly calculated is the crude death rate (CDR), defined as the total number of deaths divided by the population. Although it does relate the number of events to the population, the crude rate does not take into account the age distribution of the population. As such, it is not an appropriate measure for comparing differences between population groups or for assessing change in mortality over time.

To compare mortality between two groups the effect of the population's age distribution must be taken into account. A better measure is therefore, the age-specific death rate (ASDRs), defined as the ratio of the number of deaths in a given age group to the population of that age group.

Another commonly used measure is the Adjusted Death Rate (ADR). However in our case the ADR is not an appropriate measure as we do not have a standard national reference population for our specific patient cohort, and rates based on small numbers of deaths will exhibit a large amount of random variation.

As a result we have chosen to use age specific death rates (ASDRs) to compare Test patients to their controls and to a reference data base of eligible patients derived from hospital lists. This master register (MR) file of 1429 patients was formed by searching the hospital records in each Local Health District in each state and Territory that participated in the trial, for patients who satisfied our clinical criteria for admission into the trial. Hence all patients on this master register were eligible for participation in the trial. Deaths of patients in this master file were subsequently cross checked against the records of the Births, Deaths and Marriages (BDM) registers in each State and Territory. These data are presumed to be complete and accurate.

5.5.1 Mortality calculations based on comparative crude death rates

Crude death rates were calculated on the core patient group of 100 Test patients and 137 Control patients from the start of the project in March 2013 to the completion of the project on the 31st of December 2014.

However as not all Test and Control patients were sourced from the Master Register, mortality data was only available for 57 Test patients and 77 Control patients on the master list of 1429 patients. Mortality data for the remaining 43 Test patients and 60 Control patients were checked against the Ryerson[10] Index of death notices and obituaries in Australian newspapers which contains 5,332,370 notices from 307 different Australian newspapers. Searching by name was carried out using computerised search algorithms and names were then matched against age and sex and whenever possible location, before being accepted.

Although these data was carefully checked, deaths of control patients may not have been always recorded through the publication of death notices, and these data must be regarded as being less reliable than the mortality data sourced from the master register and cross referenced with the BDM register. Deaths of Test patients however, are accurately recorded as these patients were being monitored and were in regular contact with their care coordinators.

Mortality figures were calculated for the incomplete cohort of Test and Control patients identified in the Master Register matched against BDM data for the total cohort of 1429 candidates eligible for participation in the clinical trial, and the complete cohort of 100 Test and 137 Control patients matched against the Master Registry and the Ryerson Index of Death Notices. The results are shown in Table 58.

Table 58 Comparative Mortality data using different data sources

	Source BDM Master	Source BDM Master Register			Source BDM Master Register + Ryerson Index		
	All	Test	Control	Control (Matched)*	Test	Control	Control (Matched)*
Number (N)	1429	57	77	57	100	137	100
Number of Deaths	251	5	13	9	8	16	9.5
Crude Death Rate	17. 6%	8.8%	16.9%	15.8%	8.00%	11.7%	9.5
% Reduction in Deaths relative to controls	50.1%		48.0%	44.5%		31.5%	15.8%

* Test patients can have either one or two matched controls. If both matched controls die, this is counted as 1 death. If only one of the two matched controls dies, this is counted as 0.5 deaths. If a Test patient has only one Control and that Control dies, that is counted as 1 death.

These data show that Control patients selected from hospital lists have a very similar crude death rate as the patients in the Master Registry of eligible patients. For Test and Control patients selected only from the Master file, test patients have a 50.1% reduced mortality relative to the cohort of 1429 patients, a 48% reduction in mortality relative to the cohort of Control patients and a 44.5% reduction relative to their matched Controls.

However when the mortality of the control group is calculated with the addition of the 60 Control patients whose mortality figures were derived with reference to the Ryerson Index the reduction in mortality relative to controls falls to 31.5% and 15.8% respectively. This is strongly suggestive of two possibilities. Firstly that Control patients not selected from hospital lists were less ill and less likely to pass away from their condition or secondly, that a number may have passed away but their death notices were never published.

It may therefore be more productive to compare age specific death rates of Test patients against the much larger master database of 1429 patients.

[10] http://www.ryersonindex.org/

5.5.2 Age specific Death Rates of Test patients relative to the BDM database

The age of eligible patients in the Master Database on the 1st January 2014 was 73.4±10.8 years, significantly higher (two tailed t-test, unequal variance, P=0.012) from the age distribution of 100 Test patients (71.0±8.7 years). The age distribution for eligible patients in the Master directory is given below in Table 59 and Figure 33.

Table 59 Age Distribution in Master Registry

	AGE DISTRIBUTION					
	50-60	60-70	70-80	80-90	90-100	TOTAL
ACT	56	121	161	143	39	520
NSW	39	56	66	55	14	230
QLD	30	43	44	63	9	189
TAS	25	37	82	55	10	209
VIC	30	53	88	98	12	281
	180	310	441	414	84	1429

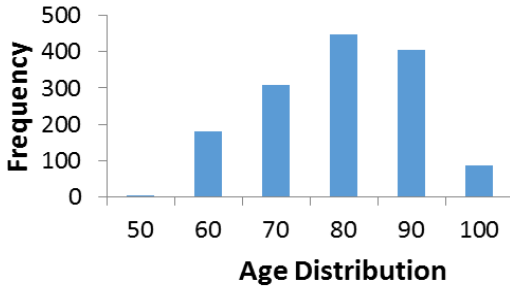


Figure 33 Age distribution in Master Registry

Table 60 Age adjusted distribution of Deaths over the period of the trial

	DEATHS					
	50-60	60-70	70-80	80-90	90-100	TOTAL
ACT	3	12	14	32	17	78
NSW	5	15	16	15	8	59
QLD	2	3	4	9	3	21
TAS	4	10	19	12	4	49
VIC	3	6	7	23	5	44
	17	46	60	91	37	251

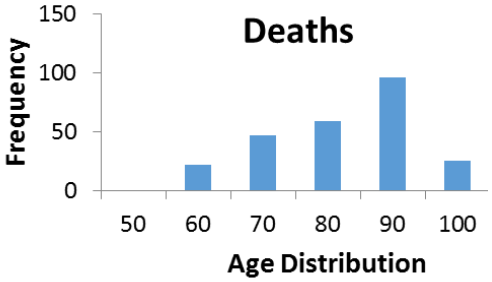


Figure 34 Age adjusted death rates in Master Registry

Table 61 Age adjusted deaths of Test patients relative to BDM master

	Age Distribution					
	50-60	60-70	70-80	80-90	90-100	N
Deaths in BDM Master	180	310	441	414	84	1429
Age Specific Death Rate	9.4%	14.8%	13.6%	22.0%	44.0%	17.6%*
Weights	0.126	0.217	0.309	0.290	0.059	1.0
Test Patient by Age	41	31	14	13	1	100
Age Specific Deaths	1	2	4	1	0	8
Expected Deaths	3.85	4.59	1.9	2.86	0.44	13.64
Deaths Saved	2.85	2.59	-2.1	1.86	0.44	5.64

* Crude Death Rate

Using age adjusted death rates (Table 61; Figure 34) calculated from the Master Register of eligible patients, 13.64 deaths were expected but only eight were recorded. This represents a saving of 5.64 lives, a reduction of 41.3%. This is in good agreement with the reduction of 48.0% and 44.5% calculated relative to matched controls.

5.6 Test patient self-reported measures at follow-up

In this section changes in self-reported measures from entry to follow up are analysed and reported. Patients were enrolled at different time and follow-up data collection continued until the end of December 2014. Some of the test patients did not necessarily always follow the recommended schedule for answering questionnaires and some of them answered more frequently than required. The following data analysis and report strategies are adopted:

- Questionnarie results at entry, 3 months, 6 months, 9 months and 12 months time points are included for each test patients
- Only questionnaires that are fully completed both at entry and the particular follow-up time points are accepted
- Only patients who have been monitored for more than 3 months are included.

As a result of the questionnaire compliance and our data analysis strategies, the total numbers of test patients (N) reported in each time points in each questionnaire vary. Wilcoxon signed ranks test are used to examine the within group differences between the baseline and available follow-up data for the K10, heiQ, and Morisky questionnaires. Results of baseline and follow-up of EQ-5D 5 dimension questions are compared and reported in a descriptive form.

All statistical tests are two-tailed, and a p value < 0.05 is accepted as indicating statistically significant differences. Statistical analysis is performed using SPSS 17.0 and Microsoft Excel.

Table 62 Kessler 10 results at baseline and follow-up

K10	N	Entry Median (SD)	Follow-up Median (SD)	P Value
Entry vs. 3 months	37	16 (8.20)	15 (9.13)	P=.036
Entry vs. 6 months	51	17 (8.86)	15 (9.18)	P=.003
Entry vs. 9 months	39	17 (7.87)	15 (8.32)	P=.070
Entry vs. 12 months	27	17 (9.10)	14 (9.80)	P=.035

The results in Table 62 compare baseline with follow-up for the K10 anxiety and depression questionnaire. Based on the available cases for entry and individual follow-ups, our results showed that test patients were significantly improved at the 3 months, 6 months and 12 months' time points assessments (p=.036, p=.03 and p=.035). It appears that telemonitoring produced improvement in test patients anxiety and depression.

Table 63 EQ5D results on baseline and follow-up (proportion of levels 1,2 and 3 answers)

EQ5D		B	3M	B	6M	B	9M	B	12M
		N=55		N=51		N=40		N=28	
Mobility	level 1 (no problem)	0.35	0.31	0.41	0.27	0.54	0.34	0.50	0.25
	level 2 (some problems)	0.65	0.69	0.57	0.71	0.46	0.66	0.50	0.75
	level 3 (extreme problems)	0.00	0.00	0.02	0.02	0.00	0.00	0.00	0.00
Self-care	level 1 (no problem)	0.65	0.56	0.59	0.61	0.71	0.66	0.68	0.71
	level 2 (some problems)	0.33	0.44	0.37	0.37	0.27	0.32	0.21	0.25
	level 3 (extreme problems)	0.02	0.00	0.04	0.02	0.02	0.02	0.11	0.04
Usual activities	level 1 (no problem)	0.27	0.31	0.22	0.27	0.30	0.33	0.30	0.33
	level 2 (some problems)	0.73	0.60	0.75	0.63	0.68	0.55	0.63	0.52
	level 3 (extreme problems)	0.00	0.09	0.04	0.10	0.03	0.13	0.07	0.15
Pain/discomfort	level 1 (no problem)	0.22	0.33	0.20	0.29	0.34	0.32	0.25	0.29
	level 2 (some problems)	0.67	0.49	0.69	0.53	0.54	0.61	0.61	0.57
	level 3 (extreme problems)	0.11	0.18	0.12	0.18	0.12	0.07	0.14	0.14
Anxiety/Depression	level 1 (no problem)	0.55	0.56	0.55	0.59	0.59	0.66	0.64	0.71
	level 2 (some problems)	0.44	0.36	0.39	0.35	0.41	0.29	0.32	0.21
	level 3 (extreme problems)	0.02	0.07	0.06	0.06	0.00	0.05	0.04	0.07

Note: B-baseline, M-months

EQ5D results (Table 63) show that the proportions of patients whose reponses were “no problem” increased slightly in the measures of Anxiety/Depression, Pain/Disconfort and Usual activities in all follow-up time points. Patients reported slightly more problems in Mobility and Self-care measures. The finding of Anxiety and depression is consistent with the result of K10.

Table 64 HeiQ results at baseline and follow-up

HeiQ	N	Entry Mean (SD)	Follow-up Mean (SD)	P Value
Self monitoring and insight				
Entry vs. 3 months	21	2.94 (0.32)	3.11 (0.29)	0.022
Entry vs. 6 months	46	3.05 (0.38)	3.09 (0.24)	0.661
Entry vs. 9 months	32	2.98 (0.25)	3.04 (0.25)	0.323
Entry vs. 12 months	19	3.09 (0.31)	3.10 (0.33)	0.977
Health service navigation				
Entry vs. 3 months	21	3.11 (0.41)	3.18 (0.36)	0.449
Entry vs. 6 months	46	3.24 (0.49)	3.17 (0.34)	0.312
Entry vs. 9 months	32	3.08 (0.35)	3.20 (0.37)	0.100
Entry vs. 12 months	19	3.28 (0.45)	3.17 (0.35)	0.305
Social integration and support				
Entry vs. 3 months	21	3.06 (0.43)	3.17 (0.36)	0.284
Entry vs. 6 months	46	3.05 (0.59)	3.08 (0.42)	0.856
Entry vs. 9 months	32	2.94 (0.57)	3.00 (0.40)	0.861
Entry vs. 12 months	19	2.95 (0.58)	2.97 (0.56)	0.833

HeiQ measures (self monitoring and insight, health services navigation and social isolation) for test patients were stable with slight increases over the monitoring period (Table 64). No statistical significance was observed except in 3 month Self monitoring and insight (P = 0.022).

Table 65 Morisky Medication Adherence results at baseline and follow-up

Morisky Medication Adherence	N	Entry Median (SD)	Follow-up Median (SD)	P Value
Entry vs. 3 months	6	8.00 (1.31)	8.00 (1.70)	0.157
Entry vs. 6 months	29	8.00 (1.09)	8.00 (1.03)	0.937
Entry vs. 9 months	18	7.00 (1.11)	7.50(0.97)	0.446
Entry vs. 12 months	18	8.00 (0.99)	8.00 (1.14)	0.623

Morisky medication adherence measures for test patients were stable with a slight decrease in 9 month time point (Table 65). No statistical significance was observed in all time points.

5.7 Implementing a high definition WebRTC teleconferencing system

This substantial body of work is described in detail in Appendix 8.5. Video conferencing for patients in this Telehealth Trial was initially made available through the Telemedcare telehealth device in-build video conferencing capability as discussed in the Appendix. However, to fulfil the requirement of delivering video conferencing at high definition (1280x720 pixels) 25fps, a selection process was carried out to determine an appropriate tablet suitable for this purpose considering user aspects appropriate for an elderly patient. The Samsung Galaxy Note 8 inch and Note 10 inch tables were selected both with front cameras capable of capturing video at greater than 720p (1280x720 pixels) for further assessment.

Initial testing demonstrated that neither the 8 inch nor the 10 inch tablet can send 720p at 25fps video using the front camera, but can receive and display 720p video at 30fps. This down scaling of upstream video is an Android operating system/Chrome feature which can't be controlled. These conclusions were confirmed by two external organisations Attend Anywhere and Medtech Global, both of whom are experienced in providing video conferencing services.

Following the result of this initial testing, additional research was undertaken to find an appropriate video conferencing platform to deliver this service via the tablet.

After reviewing several available platforms, WebRTC (Web Real-Time Communication) was selected, together with the new 2014 version of the Samsung Galaxy Note 10 inch tablet. Using WebRTC, a standards-based video conferencing system was developed and tested for the Telehealth Trial.

Laboratory testing was performed of the developed video conferencing system to identify whether the system can support two way HD quality (i.e., 720p 25 frames per second) video conferencing between patient and clinical nurse coordinator using Samsung Galaxy Note 10" tablet.

We subsequently undertook a small scale pilot of video conferencing in 2014 using the Samsung tablet with Test patients. Two sites (VIC and TAS) and 4 patients participated in the pilot. Patients answered a questionnaire developed by CSIRO after using the tablets for one month. The CCCs at VIC and TAS also made comments on their experience of using the video conferencing to communicate with their patients.

Table 66 Patients' responses to the video conferencing questionnaire

ITEM	Mean scores (0 - strongly disagree, 5 - strongly agree) (N=4)
The video conferencing tool was easy to use	3.75
I felt comfortable holding the video conferencing tool during the consultations	4.25
I was satisfied with the size of the video	3.5
The video conferencing tool worked well all the time	2.67
I felt comfortable communicating with my telemonitoring nurse by using the video conferencing tool	4.33
The video quality was good	3.33
The audio quality was good	3.00
Talking to the nurse during a video conferencing consultation was as satisfying as talking in person	4.00
The video conferencing tool made it easier for me to communicate with my telemonitoring nurse	3.00
The video conferencing consultation can enhance the existing telemonitoring service	4.25
I was able to explain my situation well enough during a video conferencing consultation	4.00
Overall, I was satisfied with my recent video conferencing consultations with my telemonitoring nurse	3.33
I prefer the video conferencing consultations to talk to my telemonitoring nurse more than the usual telephone consultations	3.67
I would use the mobile video conferencing tool to talk to my telemonitoring nurse again	4.00

The questionnaire results (Table 66) showed that the overall responses from the patients were positive in terms of being able to communicate with the nurse and explaining their health status. They believed that video conferencing could enhance the telemonitoring service. They felt that the video conferencing tool was easy to use. However they found that the tool did not work well all the time. They indicated that they would like to use the mobile video conferencing tool to talk to their telemonitoring nurse in the future if possible.

The feedback from CCCs was also positive. We asked questions about what they liked and what they did not like about the video conferencing tool. They believe the ability of being able to "see" each other enhanced their rapport with patients:

- Videoconferencing at its most basic level adds to the therapeutic relationship between a patient and clinician.
- It can increase a patient's feeling of safety as they are not 'assuming' that somebody is checking their readings via the telemonitoring service, instead they 'know' that they are being reviewed and can readily discuss their readings and feelings with a clinician.
- The patient does not have to leave their own home for a basic consultation, which saves the pressure on community resources and friends/families.
- Patients who live alone and with limited support or ability to mobilise in the community may feel a great deal more supported being reviewed in their homes without the need to access transport and the time required in a medical practice for basic monitoring.
- Patients could discharge from hospital early, and continue to be monitored from their home for a set period of time, saving huge costs of hospital stay just for purpose of monitoring.
- People are being monitored in their own setting, while they are eating their own diet and exercising (or not) at their normal rate.
- Ideal to review medications or medication administration, injection technique.

They reported on some issues, including regular educations initially required, network connection problem, unnecessary functions and icons on the interface and operational difficulties for patients with fine motor problems. They would like to see a longer trial of video conferencing if possible to addressing the issues.

The CCCs at TAS made the following comments:

"From a clinician's perspective video conferencing enhances the ability to review and assess a patient. Body language is an important aspect of physical assessment as you can actually view a person's work of breathing, skin colour, emotions, personal grooming. It gives additional information about how a person is on any given day, which is easier to disguise with a quick telephone call. When you have this assessment it needs to be acted on which enhances management of a patient.

I personally found that although the video conferencing trial was short, I developed a great rapport with the patients who trialled this tool, and in just a few sessions had found out a great deal about how they live. They too, developed a rapport with me and with this comes trust.

I was able to video conference from several locations, using the lap top and dongle, although there were some limitations due to internet coverage. I did not have to be in a particular office or suburb. This increased flexibility from my perspective.

I believe the outcomes could be enhanced if patients understood they didn't have to use the videoconference at set times only, but could use telemonitoring and videoconferencing at the times they feel unwell, as more can be gained for the clinician to capture these moments."

5.8 Demonstration of telehealth report upload to PCEHR

The primary objective was to demonstrate how PCEHR connectivity could be achieved by the project and to deliver a vital signs monitoring reports to the PCEHR's Software Vendor Test (SVT) environment. A second objective was to describe telehealth/PCEHR integration approaches for production environments.

The test environment developed for the integration of the CSIRO Telehealth project with the PCEHR was as follows;

- The trial participant uses the TMC device in their home. The device sends vital signs and other data to TMC's servers.
- On a periodic basis TMC sends vital signs monitoring reports to CSIRO's project server.
- CSIRO software, acting in the role of a PCEHR Clinical Information System within the Software Vendor Test (SVT) environment, packages the vital signs monitoring report into an Event Summary XML document, then uploads the XML document to the PCEHR via the Business-to-business (B2B) gateway.
- Study team members, acting as patients, demonstrate how patients view vital signs monitoring reports as Event Summary records using the PCEHR consumer portal.
- Study team members, acting as members of the patient's care team, demonstrate how health care providers view vital signs monitoring reports as Event Summary records using the PCEHR provider portal.

This schema was successfully implemented as a test environment as described in Appendix 8.6.

Based on this experience, and our understanding of the PCEHR architecture and operational environments, PCEHR integration for telehealth vendors such as TMC is viable. Vendors will need to choose the most appropriate PCEHR system role from a number of possible alternatives (Clinical Information System or a Contract Service Provider).

An enhancement to the PCEHR identified by this study and in the PCEHR review[11] is the development of a new clinical document type for clinical measurements that would allow clinical measurements to be inserted directly to Electronic Health Records and GP management systems. The PCEHR integration work conducted for this study would have utilised a clinical measurements document type in preference to Event Summary, had it been available, as a more appropriate means of storing vital signs monitoring data.

5.9 Development of a risk stratification system for telehealth

This project is described in greater detail in Appendix 8.7 and has been published in a special edition of the Journal of Intelligent Systems, 2016; 25(1):37-53.

This project represents a preliminary attempt to risk stratify chronically ill patients on a daily basis to identify patients who are ill but stable, those who are showing an early exacerbation of their condition and most importantly, those who are demonstrating an acute exacerbation of their chronic condition that if unattended could lead to an unscheduled hospital admission.

Accordingly a decision support system was developed for two levels of mathematical capability. Nurses with a statistical background are provided with in-depth information allowing them to detect changes in mean, mean square error (and hence variation), and correlations using a variation on dynamic principle components. Less mathematically inclined nurses are offered information about trends, change points, and a simpler multivariate view of a patient's well-being involving parallel coordinate plots.

[11] http://www.health.gov.au/internet/main/publishing.nsf/Content/PCEHR-Review

Five CCC's were asked to provide feedback on the prototype decision support system. Feedback was requested from each CCC after they had received one training session of about 30 min on the overview plot, trend plots, change points, and parallel coordinate plots.

The feedback from two nurses was that they have some value but are not looked at because of time constraints. Another said, "*Personally I would not use them as they are on a different portal – they need to be integrated into the portal we use for managing our patients*." In NSW and ACT, the CCC had not had enough experience with the decision support system to comment – most test patients had not been monitored that long, and they were not at the stage where they could effectively use the decision support and evaluate its value.

At-home telemonitoring offers the opportunity to track the patients' conditions on a daily basis and, should early evidence of an exacerbation be observed, to orchestrate the most appropriate and timely response to avoid an unscheduled hospitalisation. In our study, one CCC monitors up to 25 patients, which is approximately one-third of a full-time patient monitoring load. The CCCs were all experienced nurses but have not received any significant additional training on how to interpret the longitudinal patients' record, and typically use their own clinical experience and judgement to determine when and how to intervene.

The question of whether this "close to the patient coal face" model is the best way to monitor patients' health status is still unresolved. An alternative model that is being considered is the establishment of specialised call centres staffed by highly trained clinicians who are very experienced at identifying early signs of an exacerbation of a patient's health status and have the resources and the authority to communicate their concerns to the patient's carers, whether they may be a GP or a community nurse.

In an environment where a regional call centre may be monitoring tens of thousands of patients, our proposed decision support system could become an indispensable tool for more cost-effective and better management of a chronically ill population.

5.10 Discussion of results

Like all complex clinical trials this project has suffered from numerous setbacks. Table 10 provides a summary of the evolution of patient demographics as the trial progressed. Amongst some of the major issues that impacted on the analysis are the following;

- We recruited and consented 114 Test Patients and 173 Control patients, but of these only 71 Test patients and 110 Control patients were from the hospital lists provided. This caused some considerable difficulty in the reliable assessment of mortality and the analysis of hospital admissions and length of stay.
- Of the 114 Test patients consented 14 had missing data in their DHS records and had to be removed from further analysis. Similarly of the 173 Test patients consented, only 137 patients had complete DHS data. No explanation was available from the DHS as to why some patients had missing data in their DHS records.
- Test patients were recruited and initiated telemonitoring over a long period of time so that whilst the average number of days that patients were monitored was 276 days there was a considerable spread from < 100 days to >500 days. The period for analysis of the effect of telemonitoring was thus limited to 12 months as patient numbers rapidly fall and the data spread increases for periods > 12 months.
- For some patients consented early in the trial, signed consent was provided only through to June 2014. When the trial duration was extended to the end of December 2014, new consent forms for the extended period were not signed and as result DHS data for these patients was only made available through to June 2014.

Test and Control patients were generally well matched in primary diagnosis and SEIFA index across sites (Figure 9). However on receipt of DHS data at the end of the trial it was often observed that MBS and PBS expenditure was NOT well matched at the start of telemonitoring. Since we believe that MBS expenditure is a good proxy for the level of severity of a patient's chronic condition, it would be of interest to re-analyse the data available with matched controls being matched on MBS expenditure over the previous six months, as well as the other criteria described in Table 4.

Data was analysed using three different methods designed to identify the time dependent impacts of telemonitoring on MBS and PBS expenditure as well as number of admissions to hospital and length of stay, and age dependent mortality. Method 1, based on linear regression and ANCOVA analysis of Test and Control patients as well as Differences (Control – Test) was applied to overall MBS and PBS data as well as data for Male and Female patients, and patients selected on the basis of their primary diagnosis. Additional data segmentation was carried out to differentiate patients being monitored in Hospital settings and those being monitored in Community settings. Linear regression modelling was then used to provide estimates of the time course of changes in RATES of MBS and PBS expenditure and Hospitalisation and LOS, and through simple integration, estimates of SAVINGS made over the year following the start of telemonitoring.

Method 2 was a BACI linear mixed effects modelling approach which also investigated the possible impact of seasonal variations, gender and site specific differences. Because of the significant "smearing" of start dates for telemonitoring, and relatively small numbers, this analysis provides primarily a qualitative analysis of the impact of telemonitoring at each site.

Method 3 concentrates on the cumulative sum of differences of average 30 day costs. This method cannot provide absolute estimates of cost savings but a change in slope, and the time at which this occurs, provides strong visual confirmation of the impact of telemonitoring over time. This method was applied primarily to important elements of MBS costs, namely GP costs, specialist costs, laboratory costs, cost of procedures, number of GP visits, number of specialist visits and number of procedures.

Impact of telemonitoring on MBS costs

Overall expenditure on MBS items was $2,405 pa with Test patients spending on average $480 more than Control patients (Table 33). There was a clear drop in MBS costs over time for Test patients following the intervention, whilst there was no significant change for Controls. There was a 46.3% drop in the rate of MBS expenditure in the year following the start of intervention, representing a saving of $611 (Table 34) over that year. Generally savings were greater for patients with cardiac conditions $804 and those managed in community settings ($648). Savings were least for patients with chronic respiratory conditions ($409). These results were broadly corroborated by the analysis of differences (Table 36) and in the BACI lme analysis.

BACI lme analysis shown in Section 8.3.3 shows a marked decrease in MBS costs in TAS, QLD and NSW and smaller decreases in BIC. Reductions in MBS costs over the last eight months of the trial were between 12% and 30% for test patients and between -7% and 6% for Control patients.

The slope of the CUMSUM plot showed a gradual change of slope for GP costs and a dramatic change in slope of Specialist costs and of procedures. Laboratory costs began to fall only towards the very end of the trial in late 2014. Hence we can conclude that MBS expenditure fell the most in NSW (30%) and ACT (25%) and least in VIC, and that these savings were primarily made through modest falls in the number and cost of GP visits and significant falls in the number and costs of specialist visits and procedures carried out. Laboratory costs began to fall only in the last two months of the trial.

Impact of telemonitoring on PBS costs

It is well known[12] that polypharmacy is common with the elderly chronically ill person, with those aged 65-74 years typically taking > 6 medications. Our PBS data indicates that the median number of PBS entries recorded in the database were 68, 76, 82 and 80 per annum for the years 2011 – 2014 respectively. These represent an average of 6-7 scripts being filled per month, completely consistent with the published data on chronically ill patients.

However the spread noticed in the PBS data was considerable, ranging from as few as zero entries to as many as 400 entries per annum. Whilst the upper number may be conceivable, it is hard to believe that chronically ill patients were either not filling scripts at all, or very few. Accordingly outliers were identified using the simple Tukey rules on quartiles,

[12] http://www.nps.org.au/__data/assets/pdf_file/0003/15780/news13_polypharmacy_1200.pdf

where patients with entries exceeding ±1.5 IQR from the median value were rejected. Nonetheless the remaining PBS data still showed significantly greater variability than MBS data, with on occasion runs of zero entries for period ranging from 3-9 months. We cannot explain these missing data.

Overall expenditure on PBS items was $2,984 pa with Test patients spending on average $328 pa ***less*** than Control patients (Table 45). PBS results however were far less conclusive probably because of the large spread of monthly costs observed in the Department of Human Services databases. There was none-the-less an overall 25.5% drop in the rate of PBS expenditure in the year following the start of intervention, representing a saving of $354 (Table 46) over that year. Generally savings were greater for male patients ($477) and least for female patients ($181).

Analysis of differences (Table 47) however showed ***no*** overall change in PBS expenditure ($44 pa), with large ***increases*** recorded for males ($834 pa) and cardiac patients ($1,128 pa) and large ***reductions*** relative to controls recorded for Female patients ($1062pa) and Diabetic patients ($2,033pa). The cohort of Male patients and Cardiac patients overlap considerably and both demonstrated inexplicable ***drops*** in PBS expenditure following the intervention. Diabetic patients and to a lesser extent Female patients achieved large savings relative to controls as a result of an inexplicable ***increase*** in the rate of PBS expenditure after the intervention.

These inconclusive results are supported by the BACI lme analysis carried out in Section 8.3.4.

Much more pronounced seasonal variations were observed at all sites, but no significant differences in before and after PBS costs were observed, other than for a modest fall in the ACT and a more significant fall in NSW. Cumulative sum of differences analysis was not performed on PBS data.

Impact of telemonitoring on hospital admissions and length of stay (LOS)

Hospital data was only analysed for 53 Test patients and 64 matched Control patients for whom hospital data in Hospital Roundtable format was available from the Local Health District. Because of these reduced numbers, analysis was only carried out on the total cohort. Of the 53 Test patients selected, 29 suffered from Heart Disease, 21 suffered from Respiratory disease and 3 were diabetics.

Based on their rate of admission at the start of intervention (2.55 admissions pa) Test patients were predicted to have 3.09 admissions pa one year after the intervention. However one year after the start of telemonitoring, their rate of admission fell to 1.45 pa, a reduction of more than 53%. Over one year of the telemonitoring intervention, this represents a reduction of between 0.67 and 1.0 admissions pa. The effect of the telemonitoring on rate of admission to hospital begins to become visible only after two months.

Analysis of differences gave a similar result, but the impact of telemonitoring on admissions only becomes evident after approximately seven months. The Difference data also shows that after one year of intervention the rate of admission for Test patients relative to Controls (Table 53), is 1.03 admission/annum less than that predicted without the intervention. This is in good agreement with the data derived from Test patients alone (Table 51).
The linear regression analysis provides robust evidence that there was no change in LOS for control patients whilst there was a significant fall in LOS in the year following the telemonitoring intervention (Figure 21 and Table 54). Test patients at the start of telemonitoring had length of stays of approximately 19.8 days, which after one year were projected to increase to 24.6 days. Telemonitoring reduced the projected rate of LOS after one year (24.6 days) to a rate of LOS only 6.0 days pa, a reduction of almost 76%. This impact begins a little over one month from the start of telemonitoring, significantly earlier than the impact on number of admissions. This suggests that whilst admissions may not be initially reduced, length of stay is reduced. Over the year following the telemonitoring intervention this leads to a saving of between 7.5 and 9.3 days in length of stay.

As there was no change in the LOS trajectory of Control patients it is not surprising that the analysis of differences leads to almost identical results. Initial impact of the intervention becoming evident a little over one month from the start of telemonitoring, and leads to a saving of 7.5 days over the year.

Effect of telemonitoring on mortality

Mortality was calculated most reliably for 57 Test patients and 77 Control patients on the master list of 1429 patients. We do not consider the Ryerson Index of death notices a reliable alternative and as a result we recommend ignoring the mortality data which includes deaths identified only from death notices.

The results shown in Table 58 show that the crude death rate for the whole master file of 1429 patients was 17.6%, matching closely the 15.8% recorded for our control patients. Since the crude death rate for our Test patients was 8.8% the % reduction in mortality is 48% for Control patients as a whole, and 44.5% when Controls are matched to Test patients.

Analysis of age specific death rates in the Master record of 1429 patients then permits an estimate of the number of deaths expected in each age group for Test patients to be made. This was 13.64 deaths. Since only 8 deaths were recorded among our Test patients, this represents a reduction in mortality of 41.3%.

Test patient self-reported measures at follow-up

These results were analysed from follow up questionnaires administered at 3, 6, 9 and 12 months to a subset of the total Test patient cohort represented by 37, 51, 39 and 27 patients respectively. Results indicate that anxiety and depression measures (K10 Questionnaire) were significantly improved at 3, 6 and 12 months, but failed to demonstrate significance at the 0.05 level at 9 months.

Results for the EQ5D Quality of life questionnaire were broadly consistent with K10 results for Anxiety and Depression but patients reported slightly more problems in Mobility and Self-care measures. HeiQ measures (self monitoring and insight, health services navigation and social isolation) for test patients were stable with slight increases over the monitoring period (Table 64). No statistical significance was observed except at 3 month Self monitoring and insight ($P = 0.022$). Morisky medication adherence measures for test patients were stable with a slight decrease in 9 month time point (Table 65). No statistical significance was observed in all time points.

6. Conclusions

Test patients and Control patients were statistically well matched and did not demonstrate any statistically significant differences. There were no significant differences between age, gender or BMI of Test and Control patients at baseline. In the Test patient cohort 67 % were male and 33% female, with these figures more closely matched (55% males and 45% females), for the Control patient group. There were no statistical differences observed between Test and Control patients either with respect to the SEIFA status or their primary disease diagnosis.

However on analysis of MBS data and PBS data it became evident that Test patients had faster rates of growth of MBS expenditure over time and considerably higher MBS costs than Control patients at start of telemonitoring. Interestingly, for PBS costs Control patients had a higher rate of increase over time than Test patients and at start of telemonitoring had higher PBS expenditure.

Results presented in Chapter 5 suggest that telemonitoring is well accepted by patients who comply well with the scheduled measurement protocols. Patients almost universally expressed strong support for the service and reported better understanding and self-management of their chronic conditions. Engagement with GPs was a significant problem for the trial with poor uptake of the opportunity for GPs to view patient data on-line and reported difficulties by CCCs in communicating with GPs when changes in the patients' condition warranted a timely intervention.

The TAS and ACT sites represent one model where patients received normal care in the community but were monitored by a team of specialist nurses based in hospital settings. The NSW, QLD and VIC sites represent another model of care whereby patients were monitored by nurses operating in community settings without necessarily the backing and support of a regional hospital. Community based telemonitoring models appeared to generally deliver better economic results than hospital based models.

The project encountered a number of unexpected external difficulties in the identification, recruitment and consenting of Test patients. These had a significant impact on the outcomes of the study. A brief summary is provided below;

1. Roll out of the NBN was much slower and patchier than expected at every site other than TAS, and particularly impacted the sites in the Nepean Blue Mountain area and Townsville.
2. Connection of telehealth services via fibre to the node was deemed unacceptable by the previous Government thus making it impossible to connect any patients in the Canberra ACT area until late 2013 when the incoming government relaxed the requirement to connect patients ONLY to NBN internet services.
3. Although the NH&MRC stated that Ethics approval was required from only one nationally accredited HREC committee, every site other than TAS required new Ethics applications and site specific approvals to be submitted to local HREC committees before the project could proceed. In some cases the requirements of local HREC committees were in conflict with the CSIRO HREC approval and these conflicts were on occasion slow to resolve. These issues contributed in many cases to an additional delay in the rollout of the project of 2-3 months.
4. Selection of patients was intended to be made from lists of eligible patients made available by local hospitals. This was adhered to well in TAS, ACT and QLD but poorly in NSW and not at all in VIC, where our local site, the Djerriwarrh Health Services and local Melton - Bacchus Marsh hospital was unable to generate patient lists. These difficulties led to considerable uncertainty and data wastage in the final data analysis phase of the project.
5. Hospital data was difficult to source. Neither Melton-Bacchus Marsh local hospital nor the Nepean Blue Mountains were able to provide any hospital data despite strenuous efforts. Cost of admission data was only available from Townsville-Mackay Hospital (QLD).
6. A high number of refusals to participate as either Test patients or Control patients. This made the task of identifying and consenting patients much more protracted and time consuming.
7. Local political and administrative difficulties in local health districts led to long delays in identifying the clinical hosts for the project. These were related in one case, to massive organisational changes taking place in the Townsville Health District following the election of the new state government in Queensland, and in another,

the inability of the Connected Care program at the Nepean Blue Mountains LHD to host the project. Both these circumstances required the identification of alternative hosts for the project, which in both cases were the local Medicare Local organisations.

8. Significant delays in the negotiation of the Contract with the Commonwealth and even longer delays in signing service agreements with each of the six original clinical sites and two industry partners.
9. All patients for the project had to be newly identified and consented, none were readily available from any of the participating clinical partners. The complex recruitment processes imposed by the CSIRO HREC or the local HRECs may have led in part to a high rate of refusal. This made the recruitment of patients a far more complex and lengthy process than was originally expected.
10. The difficulties in recruiting Test patients and the necessity to have Test patients monitored for at least six months meant that all the effort was focused on that task to the detriment and delay in also recruiting Control patients, which were recruited at a later date.

Notwithstanding these difficulties, the CSIRO National Telehealth Project has provided a large amount of valuable data on the impact of introducing telemonitoring services at five different locations each with a different model of care for the management of chronic disease in the community. Together these service models can be considered representative of the Australian healthcare system.

Positive impacts of telemonitoring after one year include;

- 46.3% reductions in rate of MBS expenditure
- 25.5% reduction in rate of PBS expenditure
- 53.2% reduction in the rate of admission to hospital
- 75.7% reduction in the rate of length of stay
- > 40% reduction in mortality
- > 60% user adherence to measurement protocols
- > 50% user adherence to questionnaire administration
- > 83% user acceptance and use of telemonitoring technology
- > 89% of clinicians would recommend telemonitoring services to other patients

There was a high level of satisfaction with the telehealth service and the ease of use of the telemonitoring technology. A majority (87.5%) reported that they were satisfied with the telemonitoring service (Table 18). Their overall experience with telehealth nurses was positive in terms of the time and support they received from the CCCs. However only 12.2% of patients' GPs reviewed the telemonitoring results during patients' visits and only 34.7% patients agreed that telemonitoring improved their communications with GPs. A majority (73.5%) were satisfied with their internet connections.

As shown in Table 18, test patients found that telemonitoring had improved their knowledge about their conditions (69.4%) and symptoms to watch for (77.6%). They reported that they had become more involved in monitoring their health conditions (79.6%) and improved their self-care (71.4%) as a result of telemonitoring. A small number (12.2%) felt that seeing their vital signs every day and talking to telehealth nurses made them anxious or worried. A large majority (89.8%) of them responded that they would recommend telemonitoring service to other people.

Compliance with the measurement protocols scheduled for each patient was generally high with patients carrying out their scheduled measurements on a daily basis almost 63% of the time. A strong correlation was found between the level of involvement of the CCC and patient compliance. The higher the CCC engagement with the patient and the monitoring of patient data, the higher was the level of compliance from the patient.

Clinical Care Coordinators generally viewed every patients record daily and tracked time spent on every patient using the CSIRO WEB portal.

All CCCs, POs and GPs we interviewed believed that the home telemonitoring would have potential positive impact on the early intervention for chronic disease patients. The TAS PO has offered her opinions and her experiences on the benefits of telehealth monitoring in Appendix 8.8. Some CCCs and POs (e.g. TAS, VIC) and GPs (e.g.,QLD) found that their patients have improved knowledge about their chronic conditions and have been able to learn the measurements which are important to their chronic condition and discuss these with clinicians.

The data shown in Figure 13 suggests that on average, CCCs accessed the TMC Clinician Web Portal twice a day and spend on average a total of between 30 and 40 minutes a day reviewing patient data. The plots shown in

Figure 14 indicate the hospital based sites of TAS and the ACT were logging in to the CSIRO portal on average 1.4 times a day. For the community based sites, CCCs were logging in on average just less than once a day.

GPs were required to provide consent for the participation of their patients (only the Test patients). At that time they were given the opportunity of viewing patient data directly on screen, or to receive PDF reports on their patients' longitudinal records either by e-mail, fax or the post. Only 16% chose to have the option of viewing their patient's records online. Majority of GPs interviewed pointed out that telemonitoring would be more useful in rural settings. One of the physicians who worked in a hospital believed that it could play an important role in early discharge of patients from hospital.

GP engagement with the project was however one of the more disappointing aspects of the projects. Obtaining their consent could take months, thus imposing delays on the project and CCCs frequently reported great difficulties in making contact with the patient's GP when exacerbation of their patient's chronic condition was becoming evident.

The return on investment from such a national initiative would be in the order of 5:1 by reducing demand on hospital inpatient and outpatient services, reduced visits to GPs, reduced visits from community nurses and an overall reduced demand on increasingly scarce clinical resources. This could be achieved with an improvement in patient self-management, high levels of patient satisfaction and a perceived improvement in patient quality of life and health outcomes.

However to achieve these outcomes greater cooperation between State and Federal funding agencies will be required to establish policy frameworks and targeted funding models to scale up telehealth services nationally. In addition system level organisational changes and changes in local governance and workplace cultures will need to be actively promoted as the introduction of new models of care always succeed or fail at the operational and patient coal face.

6.1 Cost of Delivering Telehealth Services

Data shown in Figure 13 suggests that on average, CCCs accessed the TMC Clinician Web Portal twice a day and spent on average a total of between 30 and 40 minutes a day reviewing patient data. Thus a CCC working full time and responsible ONLY for monitoring patient data could manage a theoretical maximum of 240-320 patients a day. With additional time required to manage complex cases, communicate with GPs and carers and generally coordinate the patient's care, the realistic figure is likely to be closer to 100 patients. Data provided by one site for the monitoring of 25 patients is presented in Table 67 as follows;

Table 67 Cost of Clinical Care Coordination

Nurse	Annual Cost including OHs	Role	Time spent Hours(/week)	Cost per annum
1	$78,970	Clinical Care Coordination and Handover	10	$36,793
2	$103,808	Clinical Care Coordination and Handover	3	$13,495
3	$92,199	Clinical Care Coordination and Handover	1	$2,766
		TOTAL	14	$36,793

These costs suggest that a CCC would cost approximately $100,000 pa ($55.55 / hour), including overheads. Since in our trial 14 hours a week were spent monitoring 25 patients, each patient required 33.6 minutes per week of attention.

These costs convert to $6.22 per patient per day and suggest that a single nurse working fulltime could manage 68 patients. Other sites reported somewhat lower costs.

Given that this is a trial and not an established service it is likely that improved procedures and processes as well as increased efficiency and the use of predictive analytics tools to automatically risk stratify patients, would bring the monitoring cost per patient per day to approximately $4.00/day. This would allow a single nurse to monitor ~100 patients. We note that the Veterans Administration in the USA uses one care coordinator for 150 patients.

Estimating potential return on investment of telemonitoring service.

A typical telemonitoring system based on Tablet with three Bluetooth measurement devices costs approximately $1,324 (Costs provided by Telemedcare). Ignoring setting up costs of the service.

• Capital cost averaging $1324 amortised over 4 years at 7% interest		$35 / month
• Internet costs (3/4G data costs, 10MB monthly plan)		$5 /month
• Hosting, maintenance and Web services @ $70 / month		$70 / month
• Nurse coordination (100 patients / clinical care coordinator, $4 /day / patient)		$120 / month
	TOTAL	$230 / month
ESTIMATE OF ANNUAL COST	**$2,760 pa**	
• Savings in MBS and PBS costs (approximate, from CSIRO trial data)		$1,000 pa
• Reduced LOS, averaging 7.5 bed days @ $2,051 / day		$15,383 pa
Reduced demand on community nurses (Reduction of one visit / week @ $60 /visit)		$2,880 pa
ESTIMATE OF ANNUAL SAVINGS	**$19,263**	

RETURN ON INVESTMENT	**5.98**
Without involvement of community nurse	4.9

Notes:

1. Based on 48 weeks a year, 9:00 – 5:00 monitoring
2. Monitoring three vital signs + clinical questionnaires
3. Assumes that normal care is GP with/without Community nurse
4. Cost of bed day = $2051 (Queensland Health's 2012 -2013 Average patient cost - hospital and health care activity based costing collection)

6.2 Health economics of telemonitoring

Data presented by the AIHW[1] based on the 2004-2005 National Health survey indicates that 22.9% of the 3.34 million Australians aged over 65[13] have three or more chronic conditions. If patients aged over 65 and suffering from chronic disease and multiple co-morbidities have more hospital admissions and length of stay, then over 750,000 Australians aged over 65 would be good candidates for at home telemonitoring.

Conservatively reducing this figure for conditions such as cancer and neuromuscular disorders not commonly amenable to home monitoring, suggests that approximately 500,000 people in Australia would benefit from at home telemonitoring. If a critical mass of patients to achieve economies of scale were to be in the order of 10,000 patients, then fifty (50) telemonitoring centres would be needed nationally, each funded at a level of approximately $40m each,

[13] http://www.abs.gov.au/Ausstats/abs@.nsf/mf/3235.0

at a total cost of $2.0b. With means testing and cost sharing the Commonwealth investment could be reduced to the order of $1b annually.

If one hospital admission for a chronically ill patient, at an average cost of $6,000 could be avoided, cost savings of the order of $3b per annum could be achieved, a return on investment (ROI) of between 2 and 3. Additional savings would also be made from a far more efficient use of existing clinical resources including a 2-3 fold increase in case load for each community nurse and a reduction in patient visits to their GP.

A well-regulated telehealth market exceeding $2b per annum would be sure to attract private sector competition and investments into telehealth.

The health economics of implementing a telemonitoring services nationally has been analysed and a number of service models proposed. At this early stage of the evolution of telemonitoring services we recommend that monitoring and clinical triage continue to be carried out as close to the coal face as possible to the provision of hands-on care to chronically ill patients.

The necessity to align those who pay with those who benefit in achieving as high a Return on Investment as possible suggests that one reimbursement model might be to have Local Health Districts take responsibility for implementing telemonitoring services and clinical triage call centres, with a significant performance based cross subsidy from the Commonwealth government. Clinical triage and monitoring services could then be made available for all chronically ill patients irrespective whether they are under the care of a GP, a community nurse employed by the LHD, or a community nurse employed by an NGO.

From a simple analysis of population health data we conclude that in order of 500,000 people aged over 65 with complex chronic conditions and multiple co-morbidities who are admitted to hospital at least once each year would benefit from at home telemonitoring of their vital signs and from on-going clinical monitoring and triage of their health status.

6.3 Organisational Change Management and Impact on Workplace Culture

Our experience throughout the trial has demonstrated convincingly that successful deployment of a de-novo telemonitoring service requires the following success factors to be in place;

1. Strong support and leadership from the health service management team and the formation of strong clinical governance for the service.
2. Strong alignment of workplace culture and values with the objectives of telemonitoring. This will often require the implementation of extensive training and education programs.
3. A clear “ownership” and engagement not only with the patient, but with the patient’s carers who may include relatives, neighbours, community nurses and GPs.
4. Support for telemonitoring services through automated risk stratification protocols that can identify with high probability patients who are demonstrating an exacerbation of their condition and may require immediate attention to avoid an unnecessary hospitalisation.
5. Clear governance protocols and lines of communication between the CCC and the patient’s care team, in particular the patient’s GP.
6. Funding models from state and federal jurisdictions which clearly align those who pay and those who benefit from the telemonitoring of chronically ill patients.

6.4 Benefits for patients and clinicians

There are many examples in our Data portal of exacerbations being avoided through the early identification of changes in the patient's vital signs and the timely orchestration of a clinical response from the patient's care giver. Two examples are provided below.

- Example 1

"*Our patient had only been monitoring for a couple of days when the CCC noticed exceptional peaks and lows in blood glucose measurements. She contacted the patient and recommended a visit to the emergency department. The client lives alone and was unsure whether the situation was serious enough to press her vital-call alarm. The intervention of the Clinical Coordinator prompted her to seek medical assistance. She has since had follow up visits to her GP, who has been sent reports of the patient's readings. The patient will be seeing a diabetic educator to bring her diabetes under control*".

- Example 2

"*I noted from measurements taken 18.2.14 that Pt XXX had a very slight decrease in SpO_2 (2% from baseline), drop in spirometry and increase in temp (though technically still afebrile) She had reported a change in how she was feeling and her cough in her COPD questionnaire. I messaged via the TMC Unit XXX and then decided to call her on 19.2.14. Though patient had commenced oral antibiotics the previous week (initialled by GP after I recommended she see him) she had not improved and had more cough. I then contacted Outpatient department to establish if her Respiratory Physician had a vacancy in his clinic that day and secured it for her. I contacted Pt with the appointment time and produced a report for the Consultant*".

Impact of telemonitoring on patients and clinicians;

- Normal care by patients' GPs and/or community nurses is greatly facilitated by the early warning of an exacerbation provided by at home telemonitoring
- Improved patient understanding of their condition and better patient self-management leads to a reduced demand on GP and nursing services
- Although GPs were generally not heavily involved with the project, a small number were able to identify significant benefits for their patients by the "early warning system" provided by the telemonitoring service that could identify an early exacerbation of the patient's condition and orchestrate an optimal response from the patients clinical carers to avoid unnecessary hospitalisation
- Savings are available to patients in reducing out of pocket expenses associated with GP and hospital visits as well as reduced travel costs and loss of income for those patients still in employment.
- Community nurses have the potential for significantly increasing their case load without increasing their workload by only visiting those patients who have an evident clinical need and are at risk of exacerbation of their condition. Visits to patients who are sick but stable can be reduced.
- As the population ages GPs are facing a large increase in chronically ill patients and many are already restricting their daily lists and refusing to accept new patients. There is evidence that visits to GPs from patients enrolled in a telemonitoring program can drop by as much as 50% [7-10] thus reducing the demand for GP services at a critical time when access to GPs is becoming rationed because of the increasing demand.
- Benefits to health service providers are becoming increasingly evident as we engage with health service providers on the development of sustainable business models for the continuation and indeed extension of the project. More efficient use of existing clinical staff and reduced travel time impact directly on budgets.
- The health workforce has grown to be the largest in Australia at a pace that is unsustainable and which may impact on the availability of personnel in other productive elements of the economy. More efficient use of existing staff through better patient management and increased case-loads will make a contribution to blunting the rate of increase of demand for staff, and the asynchronous nature of monitoring patient health status may encourage some of the 34,712 RNs not in the workforce to consider PT or FT re-entry into the profession.

Healthcare providers involved in the study were interviewed both individually and collectively through focus groups and their views have been systematically documented. GP communication forums and workshops were also organised at a number of test sites.

Results indicate that community nurses can easily identify the benefits of at home telemonitoring, such as previously unavailable longitudinal tracking of their patients' condition, reduced need to travel to visit patients, greater clinical preparedness when they visit patients, improved patient awareness of their condition and greater patient self-management.

Community nurses are generally, but not universally strong advocates of at home telemonitoring. It is also evident that before the benefits of home monitoring can be appreciated, existing workplace cultures must be recognised and dealt with cooperatively through education and training. It is likely that at some sites this need was underestimated.

Community nurses often have a very strong patient centric focus and develop close relationships with patients, and some express concerns that home telemonitoring will undermine the capacity of nurses to deliver focused, individualised care to patients. However, most nurses working with patients in the community begin to value and ultimately depend on the care coordination provided by the monitoring nurse and recognise their significant contribution to more cost effective and improved patient health outcomes.

GPs are as yet less engaged with telehealth with 17.9% not wishing to be engaged at all with the monitoring of the patient, and only 18.6% wishing to view patient data online. The remaining 63.5% preferred to receive reports on their patient condition via e-mail or fax. GPs were generally surprisingly poorly informed of the range and sophistication of telehealth services available and were generally unaware of the large international literature available on the subject. At least two GPs refused to provide consent for their patients to participate and refused to engage in any dialogue to explain their decision.

Whilst it is possible that a large GP practice in a rural or remote location may wish to undertake the clinical monitoring function for a cohort of their chronically ill patients, no remuneration exists at present to fund this service and GPs engagement with telehealth is primarily limited to being informed of an exacerbation of their patient's condition by the CCC and arranging for that patient to visit the surgery or on occasion to be transferred to hospital via ambulance. These services are typically remunerated via standard MBS Item numbers

6.5 Integration of Telemonitoring services into the healthcare sector

Evidence collected today from the trial as well as the international evidence strongly suggests that a monitoring service needs to be closely aligned with all the services which deliver care in the community and should have a geographic reach which is aligned to a local health district (LHD) or primary health network (PHN).

Within such an entity, primary care is typically delivered through GPs, and community nurses employed by the LHD, as well as the private not for profit aged care sector and private providers. At this stage in the development of telehealth services, any of these care providers may be capable of providing a telehealth monitoring and triage service in their area if properly resourced and trained to deliver a high quality service.

Monitoring services operating close to the patient coal face may have many advantages. However possible difficulties include fragmentation and patchy and inconsistent levels of service reflecting the quality and training of staff available. To make this model work would require significant levels of government input to develop national governance models and licencing arrangements that ensure a consistently high level of service provided by as many as 31 monitoring centres nationally, possibly co-located with the 31 Primary Health Networks.

Health service organisations capable of providing a telehealth monitoring service include the Local Health Districts, Primary Care Networks, and not for profit and faith based health service providers who currently provide a large proportion of aged care services in the community.

An alternative more centralised model for the operation of monitoring centres, would be the establishment of state based or even national call centres, staffed by highly trained clinicians and supported by extensive ICT resources for automated risk stratification and decision support as well as detailed web based electronic health records of every patient being monitored, with data on their GP, their community nurse as well as family and community support networks.

Such a call centre would also be linked to major national initiatives such as the PCEHR, the NeHTA National eHealth Architecture, and the eHealth Interoperability Framework as well as the foundations established by the Department and Health and Aging such as the Health Identifiers Service, Secure Message Delivery and B2B Services allowing the development of sophisticated population based as well as individual predictive analytics.

6.6 Sustainability of telehealth enabled healthcare services

Discussions started in November 2014 with all sites regarding a continuation of the existing telemonitoring service for managing the chronically ill in the community. Two Medicare Local Organisations were facing imminent closure and were thus unable to plan an ongoing telehealth service. Anglican Retirement Villages in NSW agreed to extend their telemonitoring service to a total number of 40, and Djerriwarrh Health Services (VIC) has continued its telemonitoring service funded through internal cost efficiencies, but is seeking state Government funding to support an ongoing service. ACT Health will continue and intends to expand its existing telehealth service.

Telemedcare has partnered with Northern Australia Primary Health Limited (previously Townsville MacKay Primary Health Network) and the local GP Division, to submit a business case to Townsville Hospital to manage an increasing proportion of patients who are admitted frequently to the hospital for their chronic condition. The proposal starts with a preliminary cohort of 500 patients and increases to 2350 patients in the third year. This proposal has been accepted in principle by Townsville Hospital and a detailed submission is being prepared for funding under the recently announced $35m Queensland Health Innovation Fund.

This exciting proposal has the potential to provide the template for similar models to be deployed in all 31 Primary Health Networks in Australia.

6.6.1 Factors inhibiting sustainability of telehealth services

There are many factors that need to be considered in order to achieve sustainability of the existing services. Funding and governance are two key issues. Some funding mechanisms for telehealth already exist through the Consumer Directed Care program of the Commonwealth Department of Health. However these only apply to patients who are in receipt of Packages typically administered by an aged care service provider.

We recommend that additional research is undertaken to develop Aged Care Assessment protocols which take in consideration all aspects of the patient's needs and are able to allocate a range of services including at home telemonitoring to better manage the patient's condition in the community.

As stated earlier, the only organisation for which there is an optimal alignment of cost and benefit is the Local Health District, a State controlled entity funded primarily by the State but supported by the Commonwealth through various cost sharing arrangements. Local Health Districts have the clinical resources and the incentive to provide tele-monitoring services for their high cost chronically ill patients, but the evidence to date is that they lack the organisational management capability and technical expertise as well as governance structures to establish and maintain an effective telemonitoring service.

The most effective way of achieving sustainability in the provision of telemonitoring services is in our view to establish a National Office charged with responsibility for developing Governance Models, licensing and educational programs for the operation of telehealth service nationally and then to provide funding for eligible organisations, either public, not for profit or for profit, who can guarantee a population base of at least one hundred patients for the service based on a robust assessment of patient needs. This is a distributed model that should be considered as a starting point for promoting the development of sustainable models nationally.

An alternative model worthy of consideration is to have each State establish an organisation similar in function and purpose to the Ontario Telemedicine Network[14] (OTN) in Canada which provides policy input, technical and infrastructure support to local health districts in that state to establish telehealth services.

Another model based on a Private Public partnership arrangement, would be for the Commonwealth and State governments to use their extensive patient data bases to develop robust data analytical techniques to identify patients at risk of avoidable hospitalisation because of their chronic conditions, and then write tenders for public and private entities to deliver telemonitoring services at sufficient economies of scale to promote quality of services and deliver significant cost efficiencies.

6.6.2 Incentives for private sector investment into Telehealth

As previously discussed, there are numerous models for the deployment of telehealth nationally, providing that a market is formed that allows sufficient economies of scale to be achieved. One way to incentivise private investments into telehealth, would be for the Commonwealth and State governments to use their extensive patient data bases to develop robust data analytical techniques to identify patients at risk of avoidable hospitalisation because of their chronic conditions, and then write tenders for public and private entities to deliver telemonitoring services at sufficient economies of scale to promote quality of services and deliver significant cost efficiencies.

A very simple analysis of population demographics by age, chronic conditions and risk of hospitalisation suggests that approximately 500,000 – 750,000 people in Australia would benefit from at home telemonitoring. If a critical mass of patients to achieve economies of scale were to be in the order of 10,000 patients, then 50 telemonitoring centres would be needed nationally, each funded at a level of approximately $40m each, at a total cost of $2b. With means testing and cost sharing the Commonwealth investment could be reduced to the order of $1b annually.

If one hospital admission for a chronically ill patient, at an average cost of $6,000 could be avoided, cost savings of the order of $3b per annum could be achieved, a return on investment (ROI) of between 2 and 3. Addition savings would also be made from a far more efficient use of existing clinical resources including a 2-3 fold increase in case load for each community nurse and a reduction in patient visits to their GP.

A well-regulated telehealth market exceeding $2b per annum would be sure to attract private sector competition and investments into telehealth.

6.6.3 International evidence for wider adoption of Telemonitoring services

Whilst the market for telehealth services in Australia and to a lesser extent in Europe is still in its infancy, a recent visit to the American Telemedicine Association and a review of the program and the list of exhibitors provided clear evidence that a combination of changes in Government regulations and licencing as well as increased state and federal funding and other economic imperatives have led to quite widespread adoption of telehealth services in almost every state in the USA.

A number of lessons can be taken from the US experience of telehealth funding[15]. In 1997, the Balanced Budget Act mandated that Medicare reimburse for telemedicine services. However a number of constraints made the practical provision of services difficult. In 2000 Congress passed the Benefits Improvement Act (BIPA), which set a fee per visit to cover facility costs at 'originating sites' (where patient examination occurs); increased the number of eligible CPT codes; expanded eligible sites to include any rural area with professional shortages and expanded the definition of 'originating site' to include hospitals, rural health clinics and practitioners offices. These flexible reimbursement procedures incentivize health professionals and encourage the use of technology. Most providers bill as usual and do not use modifiers or specialized Current Procedural Terminology (CPT) codes. Service providers generally consider telemedicine

[14] https://otn.ca/en

[15] Naditz, A. Medicare's and Medicaid's New Reimbursement Policies for Telemedicine. Telemedicine and e-Health 14 (2008), 21-24.

services in the same way they would face-to-face medical practices and consider 'special coding' systems as generally being counter-productive.

Recently H.R. 5380, the Medicare Telehealth Parity Act of 2014, was introduced which improves telemedicine coverage in Medicare. H.R. 5380 creates a phased approach over four years to expand coverage of telemedicine-provided services and remove arbitrary barriers that limit access to services for Medicare beneficiaries. Included in these provisions are the gradual removal of geographic restrictions to patient care, and the addition of coverage for healthcare services that take place in other locations such as the home and walk-in retail health clinics.

The bill also proposes improvements for covered services such as services provided by diabetes educators, remote patient monitoring for chronic disease management, outpatient therapies, home telehealth, hospice, and home dialysis. The proposal authorizes the Government Accountability Office (GAO) to study the cost and clinical effectiveness of these changes.

The number of online medical consultations is expected to increase from less than one-tenth of 1% of the total for medical consultations today to 20% or more within the next 20 years. Hospitals, health systems, health plans, employers, and provider groups have rapidly been adopting telehealth for its ability to increase reach, better manage chronically ill patients, and produce better clinical outcomes.

As a result[16] Democrats and Republicans from both the House and the Senate came together in a bipartisan effort to introduce important legislation with significant positive impact for telemedicine. The *Creating Opportunities Now for Necessary and Effective Care Technologies CONNECT for Health* Act (S. 2484 in the Senate and H.R. 4442 in the House) will greatly expand providers' ability to leverage innovative telehealth healthcare technologies to increase access to healthcare for Medicare enrolees—and be appropriately paid for doing so.

But as the proliferation of these technologies has increased, Medicare policy has lagged significantly behind. The infrastructure for commercial and Medicaid payment for telehealth and remote patient monitoring has steadily improved, with states and health plans committing to reimburse providers who extend their care through technology. Only Medicare has remained stuck, requiring patients to drive to the care they need, rather benefiting from technologies that can bring the care to them. Up to this point, only rural Medicare enrolees could benefit from these innovative care models, and then only if they were willing to travel.

The Connect for Health Act will help providers transition from today's fee-for-service environment to the goals of alternative payment created by the Medicare Access and CHIP Reauthorization Act (MACRA). Providers making this transition will be able to use telehealth and remote patient monitoring without the current geographic barriers. Telehealth would become payable in alternative payment models without site restrictions, and become a part of the basic benefits package for Medicare Advantage. The bill will also significantly increase the number of approved locations and use cases for leveraging these technologies.

This announcement marks the most significant effort to embrace technology as a vital part of our health care ecosystem since EMRs. With 50 million Medicare enrolees, many coping with multiple chronic conditions, mobility issues, and significant wait times to access care, it's time to take off the handcuffs.

The USA is using a combination of changes in Government regulations and licencing as well as increased state and federal funding and other economic and market imperatives to drive widespread adoption of telehealth services in almost every state in the USA.

Clearly in this respect the USA is some years ahead of Australia in creating the legislative framework and the market condition for large scale national deployment of telehealth services in Australia.

[16] https://www.americanwell.com/new-bipartisan-legislation-promotes-telemedicine/

7. Financial

Project funding, expenditure and in-kind support is presented below. The income and expenditure presented in table below is for the Department of Health funding period which ended in September 2014.

Following the Department of Health funding period, CSIRO continued the trial to obtain at least 6 months telehealth monitoring data until end December 2014. Following the completion of this monitoring phase, data collection and analysis was undertaken to finalise the evaluation followed by preparation of this final report.

A financial report detailing statement of receipts and expenditure in respect to funds provided by Department of Health, clarifying all funding expenditure throughout the project funded period was prepared by an approved auditor at CSIRO and this audited report was submitted and approved in November 2014 by the Department of Health.

Table below summarises the audited income and expenditure statement as at 30 September 2014.

	LTD Total			
	Budget		Actuals	
	Dept. of Health and Ageing	CSIRO In-Kind	Dept. of Health and Ageing	CSIRO-In Kind
	$	$	$	$
Income				
Dept. of Health and Ageing	-	-	2,747,975	-
TOTAL REVENUE			2,747,975	
Expenses				
Staffing costs (GST exclusive)				
Project Officers each of four states (x4, 50% FTE, contribution to local data collection and project coordination)	375,000	-	435,043	-
Nurse Coordinators + associate overheads x6 (average of $150,000 pa per site, provided by clinical partners)	-	-	-	-
CSIRO 3 x Teams comprising Project Management, Data Management and Data Analysis (8.7 FTE in Overheads for 18 months)	1,566,035	758,892	1,567,276	775,490
Administrative costs (GST exclusive)	-	-	-	-
Travel and associated expenses	57,374	-	77,017	-
Vehicle running costs	-	-	-	-
Audit costs	-	-	-	-
Registration of IP	15,648	-	-	-
Operating Costs (including Staff training & development, internal audits and other overhead costs	62,590	-	57,403	-
Additional costs of premises	-	-	-	-
Stationary and printing	10,432	-	1,913	-
Asset costs (GST exclusive)	-	-	-	-
Equipment for nurse coordinators (computer terminals and printer)	20,863	-	20,742	-
Other Infrastructure Costs (GST exclusive)	-	-	-	-
TMC upfront fees for equipment	150,000	-	150,000	-
TMC monthly monitoring fees	382,500	-	382,500	-
TMC software, management and training support and discount on daily monitoring fee	-	-	-	-
iiNET installation to NBN	-	-	-	-
iiNET provision of modems	-	-	-	-
iiNET monthly rental	107,532	-	91,240	-
Total Expenses	2,747,975	758,892	2,783,134	775,490

From the above expenditure report the total expenditure (cash) of the project was $3,558,624. Therefore, compared to the original budget the project was $51,757 over spent which is <2% over budget.

As discussed above after the Department of Health funding period, CSIRO continued the telehealth trial until end December 2014 and completed the data collection, analysis and writing of this final report.
This extension of the project costed $344,000 which was funded by CSIRO.

Table below summarises the in-kind support provided by partner organisation for this project.

In Kind Support from Partner Organisations (exc. GST)	
Clinical service Providers	$792,237
Telemedcare	$315,789
Samsung Electronics	$58,500
Network Services Provider iiNet	$137,549
Total In-Kind	**$1,304,075**

Total project value is detailed below:

Expenditure until end Sep 2014	$3,558,624
Extension of the Project	$344,000
In-kind from all partners	$1,304,075
Total Project Cost	**$5,206,699**

8. Appendix

8.1 Data Architecture

This study had complex data management and organisational requirements by virtue of its operation in five different location in five different states and territories, each with their own Ethics requirements and with different hospital systems from which to source hospital data. In this section we describe a secure and effective service-oriented approach for securely managing telehealth services research data.

The data architecture and data integration services developed as part of this project made a considerable contribution to research and being in the public domain, warrant closer examination. A more detailed description had been published elsewhere [39].

- Data was collected in this study from many different sources, in multiple formats and with varying levels of automation, with some requiring considerable manual processing. A simplified diagram of data sources used in this study is shown schematically in Figure 7.
- Entry and Exit Questionnaires were administered online by POs when Test and Control patients were consented and were stored in Open Clinica[17], the world's first commercial open source clinical trial software for Electronic Data Capture (EDC) and Clinical Data Management (CDM).
- Periodic Questionnaires (daily, weekly or monthly) were scheduled on the TMC clinician website and were presented and administered directly on the patient telemonitoring system. The results were stored in the TMC servers.
- Patient vital signs were recorded as longitudinal records and original waveforms were recorded and stored in the TMC server for quality control and diagnostic purposes. All records were accessible to the clinicians via the TMC clinician portal.
- Hospital Data was sourced from the Patient Administration Systems of hospitals servicing the trial sites and was supplied in the format of the Hospital Roundtable[18]. This comprehensive data set was requested for the 4.5 year period of July 2010 through to 31st December 2014.
- PBS and MBS data were provided by the Department of Human Services following successful Ethical Clearance by the Department and on receipt of signed consent forms from all patients. Data was made available for the 4.5 year period of July 2010 through to 31st December 2014.
- HIE Data from focus groups and structured interviews were transcribed and annotated before storage in OPenClinica.
- Clinical events and user experiences were stored in the CSIRO portal. The portal also served as a means of communication between researchers and clinicians in the field and linking to a range of services.

Liferay[19], an open source enterprise portal written in Java and distributed under the GNU Lesser General Public License, was used to develop the CSIRO Telehealth Portal. Liferay provides content management, collaboration, and social networking functionalities, along with enterprise databases and document management solutions.

[17] https://www.openclinica.com/

[18] https://www.healthroundtable.org/

[19] https://www.liferay.com/products/liferay-portal/overview

Key services to users included a role based user authentication service, social network service to provide a common forum for all researchers and clinical participants as well as a range of data services such as activity logs, data analytics, patient data, access to TMC and access to OpenClinica and private documents as shown in Figure 35 below.

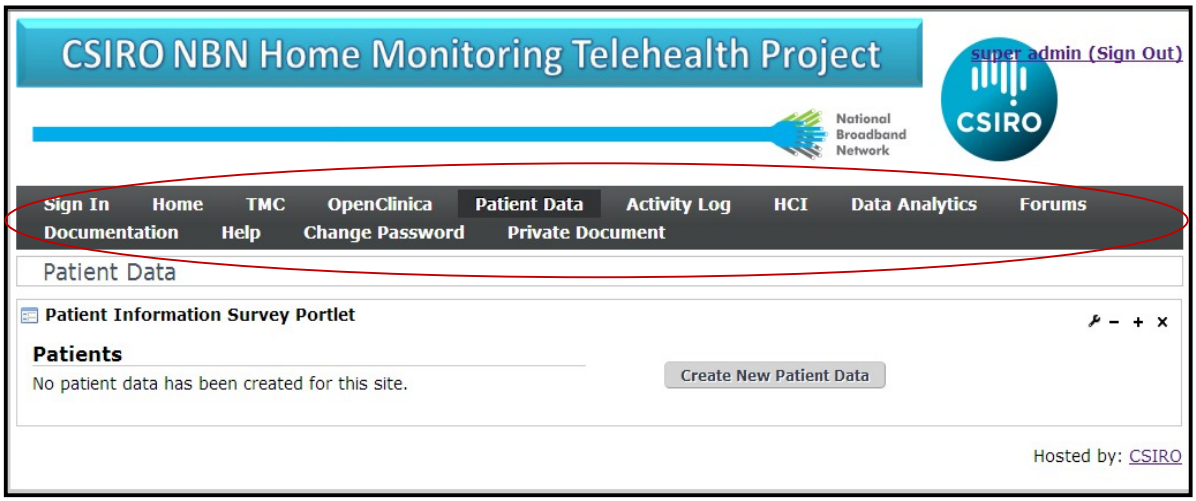


Figure 35 CSIRO Portal showing basic functionality and access to multiple services.

These data services were supported by three types of underlying data management systems. Data from services such as TMC and activity logs were stored in a MySQL database as linked data behind the enterprise firewall. Data containing patient personal information such as consent documents signed by patients, and patient personal data used for creating linked data also needed to be managed and stored securely. The document data was managed using Microsoft SharePoint, whereas a secure encrypted database was used to manage patient personal data. All patient personal attributes such as first name, surname, date of birth, contact details, emergency details, contact GP/nurses, etc. were encrypted using the AES (Advanced Encryption Standard) algorithm with a 128 bit key length.

A link file using a unique identifier for all patients was used to link data coming from various data sources. Since all patients were enrolled online using OpenClinica, the OpenClinica Identifier (OCID) was used as a unique identifier for all patients enrolled in the study.

There were two different mechanisms for creating link-file. In the first phase, the PO obtained the signed consent form from the patient and then enrolled the patients for the trial. The PO collected patients' general data (which was de-identified) and private data (which was identifiable) as part of the enrolment process. The PO then entered the de-identified general data into OpenClinica which assigned a unique identifier for the patient, the OpenClinica ID (OCID) which was used as a unique identifier for creating the link-file and linked data. The private part of the data was then stored in a secure encrypted database behind the CSIRO firewall along with the OCID. This process linked the private and public parts of the entry questionnaire through OCID. In the second phase, data coming from different sources, such as Hospitals or the DHS were also linked via the OCID.

Only the Project Director, the Project Manager and the Clinical Trial Coordinator had access to personalised patient data.

8.2 Data Integration

To integrate telehealth services with existing multi-disciplinary healthcare services, a cloud based telehealth system using SOA (Service-Oriented Architecture) concepts was designed, implemented and deployed.

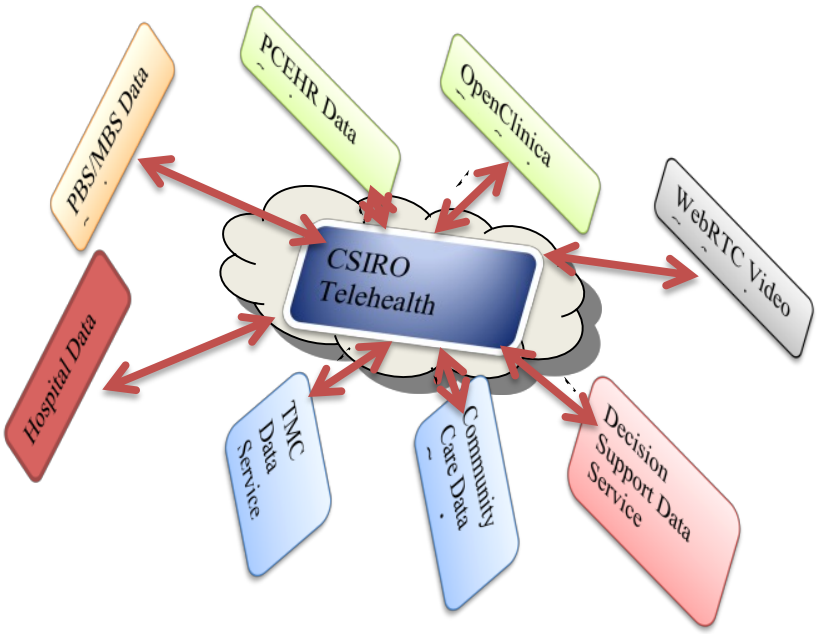


Figure 36 Data Integration schema developed by the CSIRO for the trial

The telehealth system was designed to work as a light-weight trusted third party service broker. The high level architectural view of the service broker is shown in Figure 36. The basic idea was that each service provider published its services with appropriate authentication and authorisation policies. The authentication and authorisation policies strictly followed the ethics clearance obtained from each service provider. The service broker could authenticate to access each service, and made the integrated service available to care team (i.e., CCC, general practitioner, etc.) and research team (i.e., data analysts) following the data access and retention policies as specified in the ethics clearance documents from different healthcare services.

The service broker provided a scalable solution as there was no defined limit to numbers and types of services. Furthermore, the interactions between existing healthcare services and the service broker occurred through messages. The messages were exchanged in XML format. Though the implementation did not use HL7 standard, we used XML messages with the view that it could be possible to make the system HL7 compliant.

The service broker was implemented as a cloud service. Hence, there was no performance issue as the system took the benefits of scalability, availability, and elasticity offered by cloud. Though the broker was designed to be implemented as a light weight service, the telehealth system in the current implementation for the project actually collected all data and integrated them. Some of the integration tasks could be off-loaded to other services (e.g., decision support service).

Australian Government
Department of Human Services

Department of Human Services
Information Services Branch

Approved Report Layout for Request ID MI1704
Requestor - Professor Branko Celler, CSIRO
For the period 01/01/2010 to 01/07/2014 (2nd extraction)

Medicare and PBS claims data for consenting participants of the "Home Monitoring of Chronic Disease for Aged Care Study"
Medicare and PBS items for consented participants listed in the data extraction file

MBS

Participant ID	Date of Service	Medicare Item Number	Item Description	Provider Charge	Schedule Fee	Benefit paid	Patient Out of pocket	Scrambled Ordering Provider Number	Scrambled Rendering Provider Number	Date of referral	Rendering Provider Postcode	Ordering Provider Postcode	Hospital Indicator
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Optional extra

Item Category
✓

PBS

Participant ID	Date of Supply	Date of Prescribing	PBS Item Code	Item Description	Patient Category	Patient Contribution	Net Benefit	Scrambled Prescriber Number	Pharmacy Postcode	Form Category
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Optional extras

ATC Code	ATC Name
✓	✓

8.2.2 Health Roundtable Format

The Health Roundtable

Inpatient Data Specifications

2013 July to 2014 June

Release Date 28/07/2014

Version: v1a

Data Submissions Due: 15th August 2014 (for inclusion in first round of reports)

For more information contact: Aman Dayal Aman.Dayal@healthroundtable.org

+61 (0) 430097930

We try to accept whatever data you have available; in whatever format you have to make it as simple as possible for each health service. We will let you know if we have trouble interpreting what you send us.

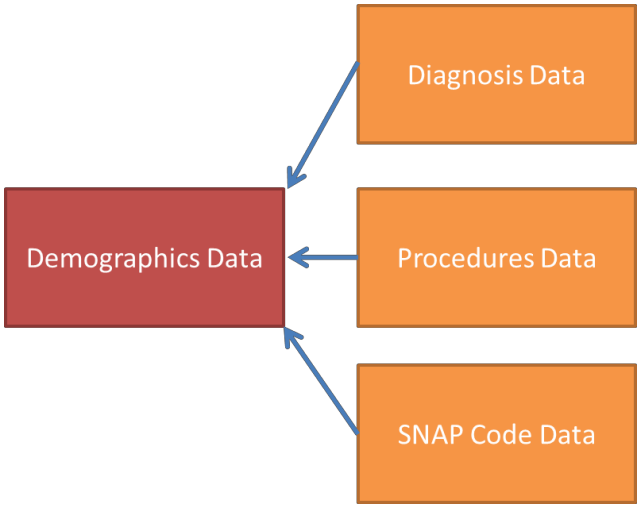
Change History:

1. v1a released, no changes from 2013 Jul-Dec data specs.

Table of Contents

Overview

Overview of the 4 tables requested



Data Specifications

Please supply the following information for each inpatient discharged from 01/07/2013 and 30/06/2014 inclusive. Please submit separate demographic, diagnosis, procedure, and snap code data tables.

Fields Coloured Thus are used by the National Efficient Price calculation

NOTE: Please supply the following information for each admitted episode, whether they are acute or non-acute/sub-acute.

Episode/Demographic Data Table

Field	Format	Possible Values
Hospital Identifier	A3	Any -- constant for all records in a hospital's data set. Use a different identifier for each facility to be analysed separately. (Please provide lookup table to explain the identifiers)
Sequence Number	N10	Start with 2013000001 increments by one for each episode discharged on/after 1 July 2013.
Unit Record Number	A10	Any unique **patient** identifier common to all episodes for that patient (encrypted identifiers are preferred, but they must refer to the same patient over time to enable analysis of readmission rates)
Episode Number	A15	Any unique **episode** identifier. This field is also used to link to clinical costing information. This should be a unique key field for each episode record.
Admission Type	A2	Hospital Defined Codes, to be used primarily to distinguish between Emergency and Elective admissions. If the admission could be put off for 24 hours without adverse effects to the patient the admission should be considered Elective. Direct admissions to wards should be coded based on the 24-hour rule.
Emergency Event ID	A30	If the patient was admitted via the ED this is the event identifier used in the ED system. Use the same encryption used in the HRT ED data submission if any is used.
Source of Referral	A1 (or hospital defined codes and table)	Indicates where the patient came from: 1=transferred from another hospital, 2=type change, 3=admission from leave, 4= other.
Admission Date	A10	Preferred format: dd/mm/yyyy
Admission Time	A8	Time from 00:00 to 23:59 (Seconds optional)
Separation Date	A10	Preferred format: dd/mm/yyyy
Separation Time	A8	Time from 00:00 to 23:59 (Seconds optional)
Birth Date	A10	Use the following format: dd/mm/yyyy
Age in Years on Admission Date	N3	Pad with blanks if not available. Valid values include 000 to 150

Field	Format	Possible Values
Age in Days	N3	Required if patient is less than 365 days old
Admission Weight * *< 1 month old*	N4	Weight in grams 0001-9000
Neonatal Linkage to Mother's Episode	A15	Hospital Episode Number of mother for newborns admitted (including stillbirths). Leave blank if not applicable or available.
Gender	A1	"M" or "1" = male "F" or "2" = female "X" or "3" = unknown
Intended LOS	N1	Required if MDC 10 Rehab or Aftercare DRGs 1-same day, 2-overnight, 0- not entered
Hours on Mechanical Ventilation	N4	Numeric data in hours 0-9999 – required for grouping in some cases
Acute LOS	N4	Numeric days.
ICU Hours	N5	Hours in ICU, rounded to nearest hour
Hospital in the Home (HIH)	N3	Numeric days. Number of whole days patient was in "Hospital in the Home" in this episode. Note these are subtracted from LOS so do not include HITH days after this episode ended. Do not include this value if you generate a new episode for HITH portion of stay.
Mental Health Legal Status	N1	1 = involuntary patient, 2 = non-involuntary (if blank, assume non-involuntary)
Leave Days	N3	Numeric days. Number of days patients were on leave during the inpatient episode. Note. These are subtracted from acute LOS.
Number of Psychiatric Care Days. (Number of Qualified Days for Neonates)	N3	Numeric Days. The number of days in psychiatric care. See METeOR identifier 270300.
	N3	Numeric Days. The Number of days a neonate is qualified as a separate admission to the mother for medical care. See METeOR identifier 270033, 269504, 327254.
Care Type	Hospital Defined (please supply explanatory table) Indicates whether a patient is under acute or non-acute care (eg Acute, rehab, palliative, etc). See http://meteor.aihw.gov.au/content/index.phtml/itemId/270174 for example.	

For NZ hospitals, this should be the 3-character Health Specialty Code (where more than one HSC is available for an episode, assign the discharge HSC). These will then be mapped by to Australian standard care types. No explanatory table is necessary in this case.

Field	Format	Possible Values
Separation Mode	N2	Standardised codes 01-09 (Commonwealth Definitions - See 3M Grouper code definitions)
DRG Assigned by Hospital	A4	Please provide DRG if already assigned by hospital – We will validate independently using Visasys DRG Grouper (Please indicate the DRG version you are using in the
Facility region identifier	N2	Region of facility. Region codes are: 01 = New South Wales 02 = Victoria 03 = Queensland 04 = South Australia 05 = Western Australia 06 = Tasmania 07 = Northern Territory 08 = Australian Capital Territory 09 = Other territories (Cocos (Keeling) Islands, Christmas Island and Jervis Bay Territory) 10 = New Zealand
Area of usual Residence	N5	**5 digits** = Statistical Local Area (Australia) or Domicile Code (NZ). Note as some PAS systems only allow 4 digits for this field health services are providing the 4 left most digits of the SLA. If this is the case can you let us know in a supporting document.
Episode Provider Contract Code	N1	1 = Service provided by this health service under contract from another public health service 2 = Service provided by this health service under contract from another private health service 3 = Service for this episode provided by another public health service 4 = Service for this episode provided by a private health service
Financial Class	A2	Hospital defined codes to indicate whether the patient's care is funded by the state hospital system ("Public" patient), or by any other means. Please supply codes along with the data. For NZ hospitals please use the Principal health service purchaser coding from the NMDS.
Funding Source	N2	Funding source for hospital patient, range 01 to 13 with 99 = Not Known [METeOR identifier: 339080]

Field	Format	Possible Values
Ethnic Origin	A4	Code indicating ethnic origin of patient For Australian Hospitals: 1. Aboriginal but not Torres Strait Islander Origin 2. Torres Strait Islander but not Aboriginal Origin) 3. Both Aboriginal and Torres Strait Islander Origin 4. Neither Aboriginal nor Torres Strait Islander Origin 5. Not stated / Inadequately defined For New Zealand Hospitals: Standard Ethnic Code Ethnic Group code: Ethnic Group code description 10 European nor further defined 11 NZ European 12 Other European 21 NZ Maori 30 Pacific Island not further defined 31 Samoan 32 Cook Island Maori 33 Tongan 34 Niuean 35 Tokelauan 36 Fijian
Discharge Unit	A10	Code indicating the name of the clinical unit that discharged the patient. (please provide a lookup table with the full text of the unit's name)
Discharge Ward	A20	Code indicating the name of the ward that the patient was discharged from.
Clinical Subunit Identifier	A10	Any unique identifier of the clinical service provider(s) responsible for discharge of the patient. It can be a clinician, or a group of clinical providers (eg clinician and associated registrars). This should be encrypted locally by your health service. Please do not send identifiers that could be recognisable to clinicians at other facilities.
Date of Death	A10	Preferred format: dd/mm/yyyy (If available) – date of death should be included even if not associated with this episode of care.

Field	Format	Possible Values
Hospital Identifier	A3	Must match the identifier used in the demographic file
Unit Record Number	A10	Must match the unit record numbers in the demographic
Episode Number	A15	Must match the episode number in the demographic file
Diagnosis Code (Including External Cause and Morphology codes)	A10 (no punctuation, left justified and null filled)	Alphanumeric ICD10 code, including External cause and Morphology codes. These codes must be listed in sequence as entered by coders to preserve links between codes. The first diagnosis in the sequence must be the principal diagnosis. We no longer require information on the Admission Diagnosis in the inpatient dataset. If you submit the admission diagnosis, please mark it with position zero (0). Make sure you are providing your external cause codes sequenced correctly with your diagnoses. See: http://meteor.aihw.gov.au/content/index.phtml/itemId/361926
Condition onset flag	N1 by 40 fields (one field preceding each diagnosis code)	1 = Condition with onset during the episode of admitted patient care 2 = Condition not noted as arising during the episode of admitted patient care 9 = Not reported
Diagnosis Position Number	N2 Sequenced as per Australian Coding	Sequence number of the diagnosis/external cause/morphology as entered by the coders.

Field	Format	Possible Values
Hospital Identifier	A3	Must match the identifier used in the demographic file
Unit Record Number	A10	Must match the unit record numbers in the demographic file
Episode Number	A15	Must match the episode number in the demographic file
Procedure Code	A10 (no punctuation, left justified and null filled)	Alphanumeric ICD10 codes using ACHI coding. The first procedure should be the principal procedure for the episode.
Procedure Position Number	N2 Sequenced as per Australian Coding Standards	Sequence number of the procedure as entered by the coders.
Procedure Date including investigational procedures (e.g cardiac cath lab) and vaginal deliveries	A10	Preferred format: dd/mm/yyyy Enter the date on which the procedure started, except for vaginal deliveries, please include date of birth in this field. (Required for the first procedure. Optional for all other procedures)
Procedure Start Time	A8	Time from 00:00 to 23:59 Patient entry into theatre is the preferred measure of start time. If this is unavailable please use the closest measure to this. For vaginal deliveries, please include time of birth in this field. (Required for the first procedure. Optional for all other procedures.)
Procedure Elapsed Time	N3	Time in minutes from patient's entry in theatre to patient's exit from theatre, if available, for each procedure. (Required for the first procedure. Optional for all other procedures. Where multiple procedures are performed in the same session, assign the full amount of time to the first procedure only. Do not count the patient's time in the same theatre session multiple times.)

SNAP Code Data Table

Multiple phases and SNAPv3 codes can exist for Palliative care episodes.

Field	Format	Possible Values
Hospital Identifier	A3	Must match the identifier used in the demographic file
Unit Record Number	A10	Must match the unit record numbers in the demographic file
Episode Number	A15	Must match the episode number in the demographic file
SNAPv3 Code	A4	The SNAPv3 code for this Episode if it's sub-acute ie rehab, palliative, GEM, psychogeriatric or maintenance care More info: http://meteor.aihw.gov.au/content/index.phtml/itemId/496405
PhaseStartDate	DateTime	Palliative care phase start date. The commencement date is the date on which an admitted palliative care patient commences a new palliative care phase type. Subsequent phase begin dates are equal to the previous phase end date. http://meteor.aihw.gov.au/content/index.phtml/itemId/445848
PhaseEndDate	DateTime	Palliative care phase end date. The end date is the date on which an admitted palliative care patient completes a palliative care phase type. http://meteor.aihw.gov.au/content/index.phtml/itemId/445598

8.3 Method 2: Detailed statistical analysis using BACI and lme models

The statistical analysis presented in the Results makes a number of simplifying assumptions, and does not analyse the impact on specific parameters such as number and cost of GP visits, number and costs of laboratory tests etc choosing instead to combine all these individual costs into a single overall total MBS cost.

8.3.1 BACI design and linear mixed effects models

Let y_{ijk} be the PBS/MBS/Hospital costs value per unit time period (month) at time k during period *i* (before or after the intervention), for patient *j* (control or intervention patient). The model for the response value is given by:

$$y_{ijk} = \mu + \alpha_i + \tau_{k(i)} + \beta_j + (\alpha\beta)_{ij} + \mathrm{e}_{ijk}$$

where:

- μ is the overall mean
- α_i is the effect of period (before and after)
- $\tau_{k(i)}$ is the repeated measures within periods (assumed to be a random effect)
- β_j is the effect on jth matched patients (intervention or control)
- $(\alpha\beta)_{ij}$ is the interaction between period and matched patient groups
- e_{ijk} is the random error term of the model that is assumed to be normally distributed with homogeneous variance.

Assumptions made:

- Log of cost plus one will be treated as normally distributed with log of the number of days in the month as the offset. Sometimes the square root transformation is used to stabilise the variance. We are hoping there are not too many zero cost periods or zero counts. If this fails we will use the zero adjusted inverse Gaussian distribution for the model – fitting them using the **gamlss** (package in R) using random() for including random effects (see Stasinopoulas et al. 2013).
- $\tau_{k(i)}$ is a random effect in the above model that is assumed to be normally distributed with mean zero and constant variance.
- The assumption in the previous dot point and the assumption for e_{ijk} in the model thus assumes that measurements made at the same time segments (e.g., on the same quarter) have the same correlation and homogeneous variances for all repeated measures.
- The above model treats the study as a fully-designed experiment with the appropriate randomisation. However, this is seldom the case because most impact studies are observational in nature.
- The assumption is that each measurement for the intervention patients is matched with a measurement for one or more control patients. This blocking is expected to control for the non-randomisation in the design. Some people have analysed the differences between these measurements which can greatly reduce the complexity of the analysis. If the matching process can only deliver one useful control then this will be the approach we will follow.
- The model above tests whether a significant change has occurred by testing the significance of the interaction term of the model for the before after indicator variables and the control-intervention indictor variable. For example if the coefficient for intervention patients and after intervention duration has lower insured costs that before the intervention after adjusting for controls, then the intervention has had a significant impact on costs (and hence the well-being of the patient). This just provides evidence for improvement in costs.
- The random effects terms and random error term are assumed to be uncorrelated in time.
- The control patient is generally selected to control for all covariates. In this study this means that control patients should be identical to the intervention patient in terms of age, gender, SEIFA index and major co-morbities.
- The samples are selected over time (therefore they are time series rather than repeated measures made at the same time). So it may seem unlikely that the model errors will be independently distributed but hospital costs are measures three months apart and this should be enough to for the assumption of independence to be valid.
- The assumption that all repeated measures have the same variance is unlikely to be true. If the gamlss package is used then this change in variance can be accounted for. Although theoretically longitudinal data structures can be modelled by random effects in gamlss (Rigby and Stasinopoulos, 2005) but at present no computationally feasible implementation for large sample sizes and complex models exists.

We may use measured variables on patients as covariates to improve the correlation between intervention and their controls thus making better inference. This only helps when the covariate is not impacted by the change, i.e., no interaction between the covariate and the before-and-after indicator variable.

In this study we used 4.5 years of data documenting monthly costs over that period that included a maximum intervention period of roughly 12 months.

The time varying aspect of the design needed to be considered because the cohort considered was very sick and their condition would change over time. Therefore the model that fitted is:

$$y_{ijk} = \mu + \alpha_i + \tau_{k(i)} + \beta_j + (\alpha\beta)_{ij} + (\alpha t)_{ik} + (\beta t)_{jk} + (\alpha\beta t)_{ijk}$$

where:

- μ is the overall mean
- α_i is the effect of period (before and after)
- $\tau_{k(i)}$ is the repeated measures within periods (assumed to be a random effect)
- β_j is the effect on *j*th matched patient (intervention or control)
- $(\alpha\beta)_{ij}$ is that the y-intercept term differs for each patient by period group
- $(\alpha t)_{ik}$is the interaction between period (before-after) and month
- $(\beta t)_{ijk}$is the interaction between matched patient groups (I & C) and month
- $(\alpha\beta t)_{ijk}$is the interaction between period (before-after), matched patient groups (I & C) and month

These models were fitted using the nlme package in R (Pinheiro, and Bates, 2000 and Pinheiro, Bates, DebRoy & Sarkar, 2011).

8.3.2 Power calculations

The power of the tests in the linear mixed model was not easy to compute. The power of a match paired t-test was estimated assuming a correlation of ρ and a standard deviation of σ for the differences in match scores, a decision boundary for a test of size κ departure between the match scores, and no autocorrelation with an effective sample size of 30.

The power calculations based on independent observations and the outcomes of the test are given in Table 68 below:

Taking:

$$d = \kappa/(\sigma\sqrt{2(1-\rho^2)}$$

Table 68 Power Calculations

Outcome measure all on the monthly scale	Effective sample size?	Assumed normal distribution	Shift amount (K)	Power
PBS Benefit	30	Log(PBS Benefit +1)	1	0.90
PBS Total cost	30	Log(PBS Total cost+1)	1	1.00
MBS out of hospital costs	30	Log(MBS out of hospital costs+1)	1	1.00
MBS in hospital costs	30	Log(MBS in hospital costs+1)	1	0.84
Number of hospital admissions	30	Square root the number of hospital admissions	0.5	0.99
Number of GP visits during working hours	30	Square root of number of GP visits during working hours	0.5	0.89
Number of GP visits outside of working hours	30	Square root of number of GP visits outside of working hours	0.1	0.50
Total number of GP visits	30	Square root of total number of GP visits	1	0.97
Total number of either Specialist, Psychiatric, Allied Health visits and Procedures	30	Square root of total number of either Specialist, Psychiatric, Allied Health visits and Procedures	1	0.77
Total number of Laboratory tests	30	Square root of total number of Laboratory tests	1	0.97
Number of Laboratory Tests	30	Square root of number of Laboratory Tests	1	0.96

The actual results were much more complicated than this because the differences between the outcome variables may be auto correlated. This was particularly true if the control patient and match test patient outcome measures had different time series trends. However prior to the study this was not thought of as an option. Testing of whether the matched differences were auto correlated had not been carried out as this was not expected to be a problem prior to doing the study. This however proved to be an issue when the data was subsequently analysed.

8.3.3 Final Linear Mixed Effects Models for MBS

Although we are carrying out a BACI design we wished to also estimate the temporal trend and the seasonal influence on the PBS scores. We fitted the models using the lmer function in the lme4 Package (Linear Mixed-Effects Models using 'Eigen' and S4(Bates, Maechler, Bolker, Walker, Christensen, Singmann, Dai,Grothendieck, 2015) [ctb] in R. (see https://cran.r-project.org/web/packages/lme4/lme4.pdf) These models attempted to model random effects as well as before and after effects for site specific behaviour as well as seasonal variations which were modelled as sine and cosine functions with fixed periods and variable gains.

MBS data was normalised by applying the *sqrt* function. The resultant fitted model was as follows:

```
Linear mixed model fit by REML ['lmerMod']
Formula: sqrt(1 + MBS.mcost) ~ Sex + time + Site * Before.After * TC +
    Before.After * TC * time + period.From + (cos(2 * pi * time/365.25) +
    sin(2 * pi * time/365.25)) + (1 | OCID) + (1 | period.From)
   Data: MBS

REML criterion at convergence: 81634.8

Scaled residuals:
    Min      1Q  Median      3Q     Max
-2.8949 -0.6529 -0.0537  0.5252  8.8885

Random effects:
 Groups      Name        Variance Std.Dev.
 period.From (Intercept)  0.00    0.000
 OCID        (Intercept)  9.56    3.092
 Residual                62.64    7.915
Number of obs: 11661, groups:  period.From, 1554; OCID, 99

Fixed effects:
                                 Estimate Std. Error t value
(Intercept)                     20.997630   3.751492   5.597
SexM                            -0.386103   0.353766  -1.091
time                            -0.005304   0.002096  -2.531
SiteTAS                          0.513259   1.422100   0.361
SiteVIC                          1.148710   1.440379   0.798
SiteQLD                          0.221124   1.468597   0.151
SiteARV                          2.945891   1.661437   1.773
Before.Afterbefore             -12.909972   3.661388  -3.526
TCC                             -1.627148   4.783918  -0.340
cos(2 * pi * time/365.25)       -0.106738   0.103674  -1.030
sin(2 * pi * time/365.25)       -0.161461   0.106141  -1.521
SiteTAS:Before.Afterbefore       1.160280   1.033905   1.122
SiteVIC:Before.Afterbefore      -0.272779   1.051010  -0.260
SiteQLD:Before.Afterbefore       0.854250   1.079519   0.791
SiteARV:Before.Afterbefore       0.578611   1.237747   0.467
SiteTAS:TCC                     -1.635062   1.215462  -1.345
SiteVIC:TCC                     -1.500712   1.262479  -1.189
SiteQLD:TCC                     -3.965552   1.327268  -2.988
SiteARV:TCC                     -4.875014   1.537341  -3.171
Before.Afterbefore:TCC           5.695121   4.809290   1.184
time:Before.Afterbefore          0.008837   0.002111   4.186
time:TCC                         0.003614   0.002748   1.315
SiteTAS:Before.Afterbefore:TCC   0.260020   1.322369   0.197
SiteVIC:Before.Afterbefore:TCC   0.847063   1.364968   0.621
SiteQLD:Before.Afterbefore:TCC   0.685571   1.426746   0.481
SiteARV:Before.Afterbefore:TCC  -0.905815   1.633601  -0.554
time:Before.Afterbefore:TCC     -0.004608   0.002775  -1.661
```

The significant interpretation of this model is as follows:

1. The overall time trend is significantly negative in terms of MBS costs which indicates a potentially positive result if this is driven by the intervention.
2. ARV has significantly higher MBS costs to ACT patients.
3. Before MBS costs are significantly lower than the after.
4. Seasonal influences are not independently significantly but are jointly just significant.
5. QLD control patients have significantly lower MBS costs than ACT control patients.
6. However on the other hand before MBS costs are significant lower before the intervention
7. The before period has a significantly higher rate of increase in MBS costs than the after period.
8. The before intervention control patients have a lower trend over time – this suggests that the intervention is significant and a clear indication that the intervention reduced MBS costs significantly.

TASMANIA

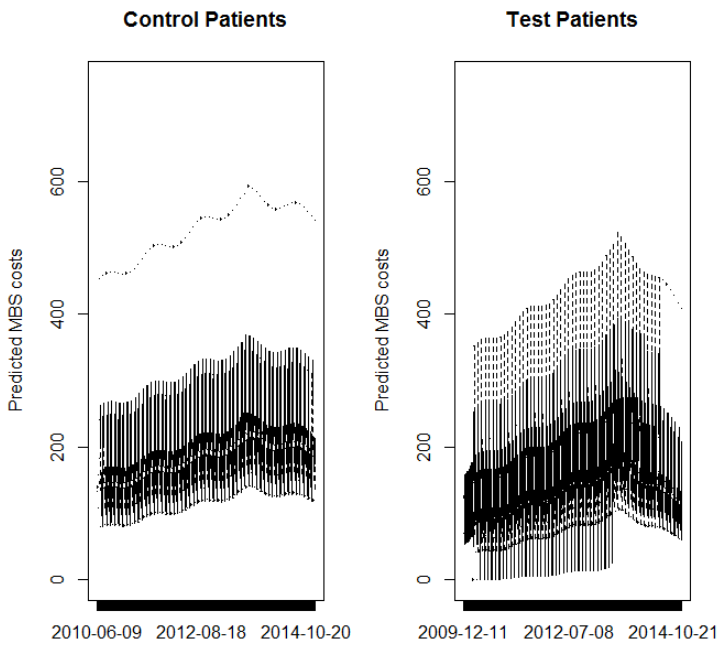


Figure 37 Time course of MBS costs for TAS patients

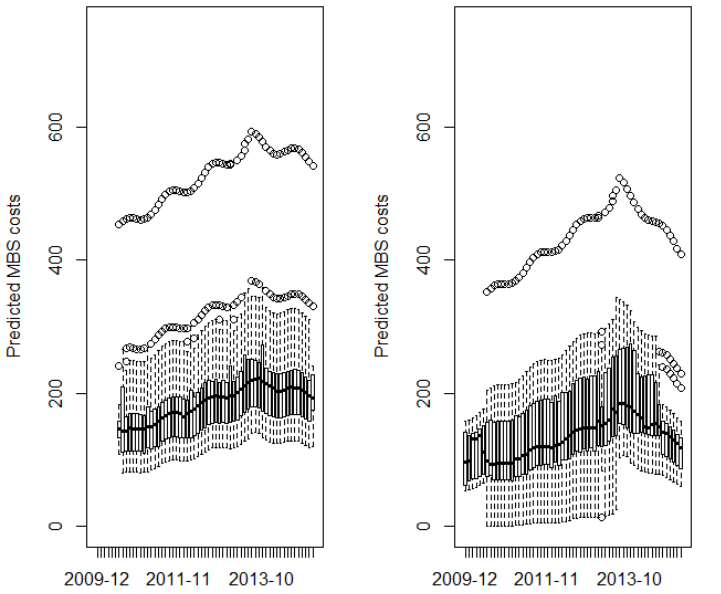


Figure 38 Time course of MBS costs for TAS patients with start month synchronised.

The plot above combines subjects whose start period was in the same month. This does not identify the exact start date but tidies up the visual image produced by the parallel boxplots in Figure 37. For example the trend change in the controls is clearer and the drop off in MBS costs for the test patients in the after period is clear in Figure 38.

The TAS Test patients at start the study period had an average cost of roughly about $ 118.40 per month on June 2010 which increased to an average cost of roughly $175.80 by April 2014 before reducing to an average cost of roughly $136.60 by December 2014.

The TAS Control patients at start the study period had an average cost of roughly about $170.80 per month on June 2010 which increased to an average cost of roughly 231.30 by April 2014 before reducing to an average cost of roughly $228.40 by December 2014.

VICTORIA

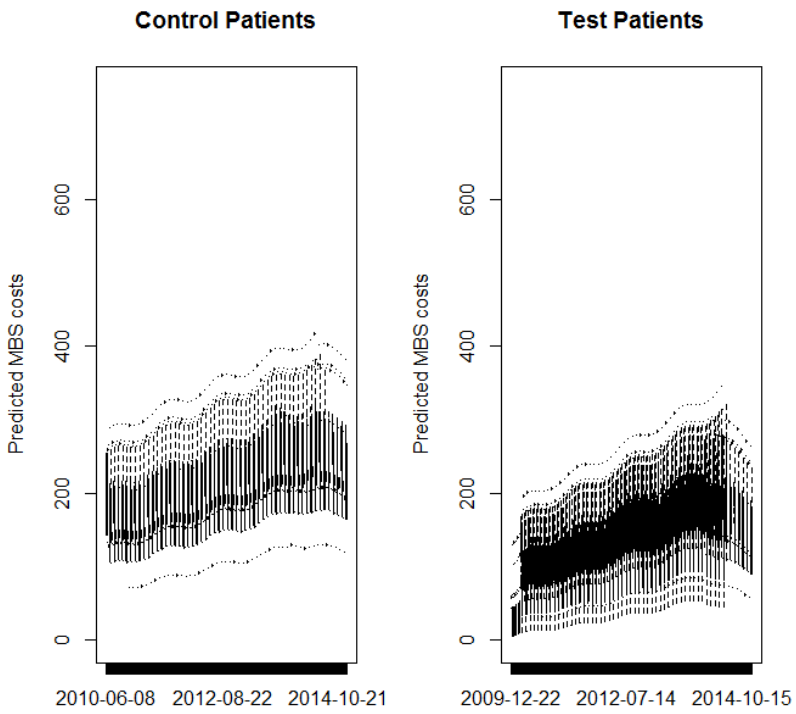


Figure 39 Time course of MBS costs for VIC patients

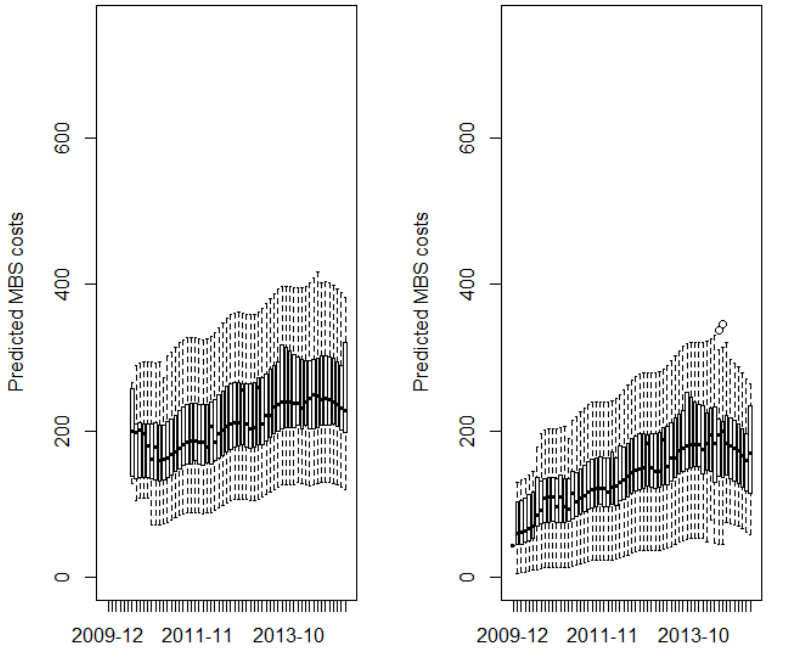


Figure 40 Time course of MBS costs for VIC patients with start month synchronised

The VIC (Figure 39, Figure 40) Test patients at start the study period had an average cost of roughly about $ 102.30 per month on June 2010 which increased to an average cost of roughly $188.90 by April 2014 before reducing to an average cost of roughly $166.50 by December 2014.

The VIC Control patients at start the study period had an average cost of roughly about $193.8 per month on June 2010 which increased to an average cost of roughly $259.9 by April 2014 before reducing slightly to an average cost of roughly $255.60 by December 2014.

QUEENSLAND

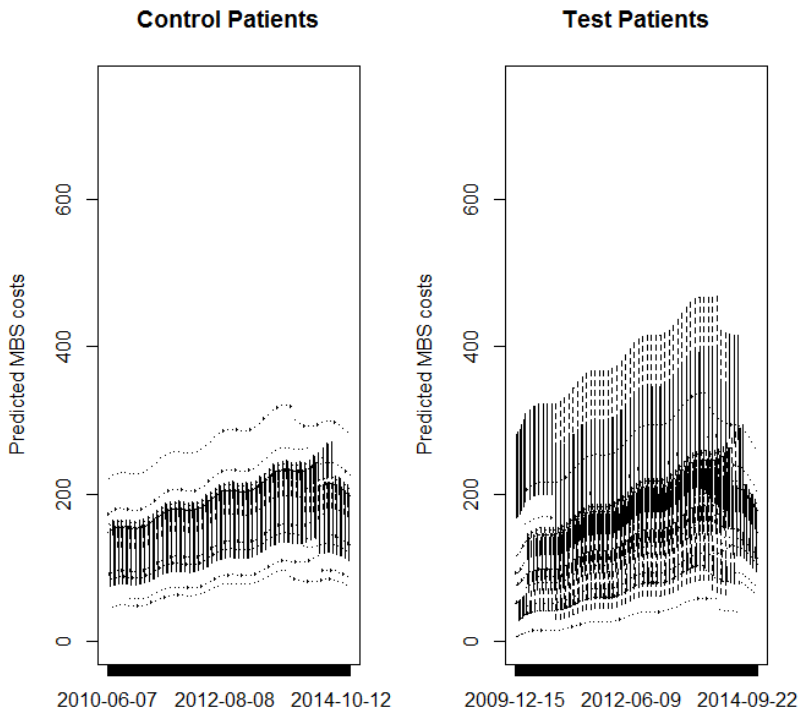


Figure 41: Predicted MBS costs for QLD patients

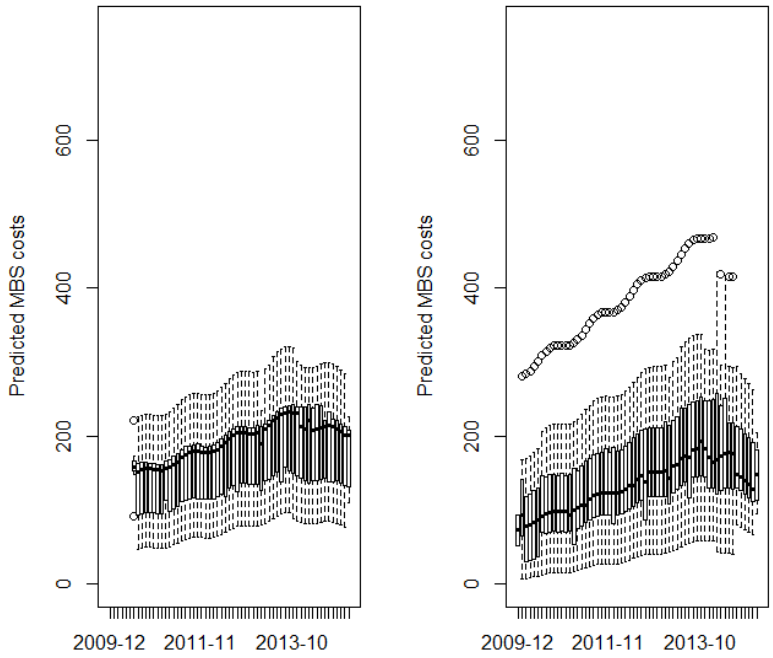


Figure 42 Time course of MBS costs for QLD patients with start month synchronised

The QLD (Figure 41, Figure 42) Test patients at start the study period had an average cost of roughly about $113.90 per month on June 2010 which increased to an average cost of roughly $ 179.00 by April 2014 before reducing to an average cost of roughly $148.00 by December 2014.

The QLD Control patients at start the study period had an average cost of roughly about $158.70 per month on June 2010 which increased to an average cost of roughly $194.90 by April 2014 before reducing slightly to an average cost of roughly $ 182.7 by December 2014.

NEW SOUTH WALES

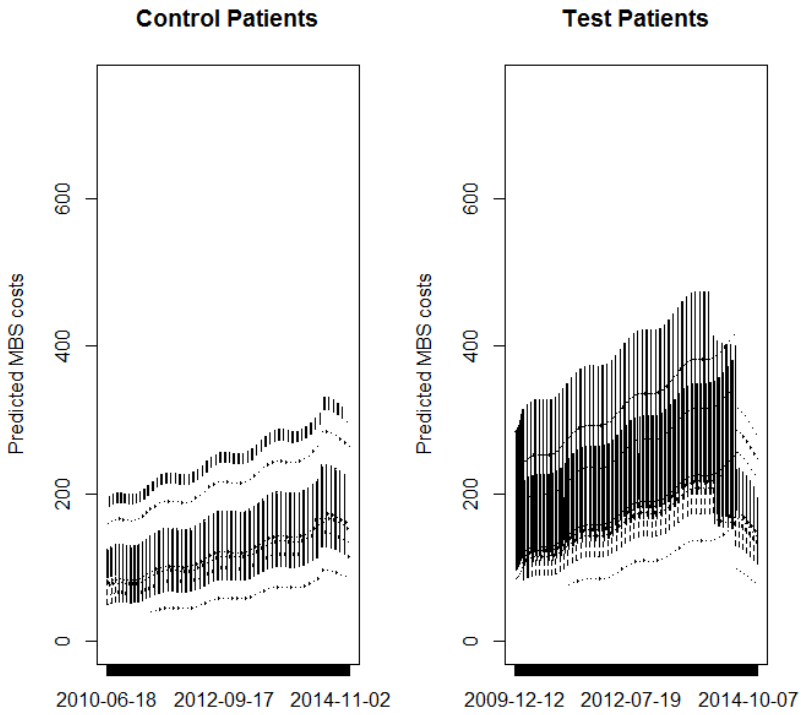


Figure 43 Predicted MBS costs for NSW patients

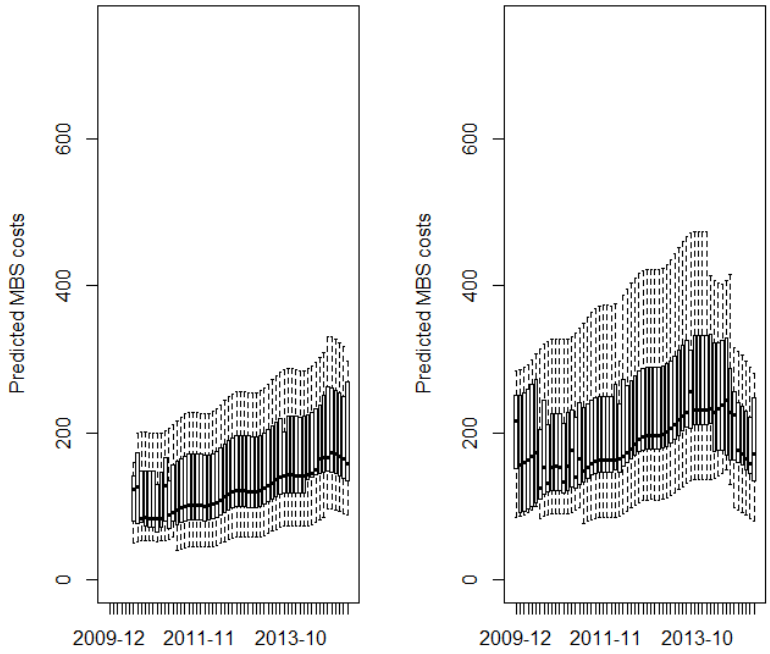


Figure 44 Time course of MBS costs for NSW patients with start month synchronised

The NSW (Figure 43, Figure 44) Test patients at start the study period had an average cost of roughly about $163.70 per month on June 2010 which increased to an average cost of roughly $260.40 by April 2014 before reducing to an average cost of roughly $181.90 by December 2014.

The NSW Control patients at start the study period had an average cost of roughly about $111.50 per month on June 2010 which increased to an average cost of roughly $ 180.50 by April 2014 before increasing slightly to an average cost of roughly $188.90 by December 2014.

AUSTRALIAN CAPITAL TERRITORY

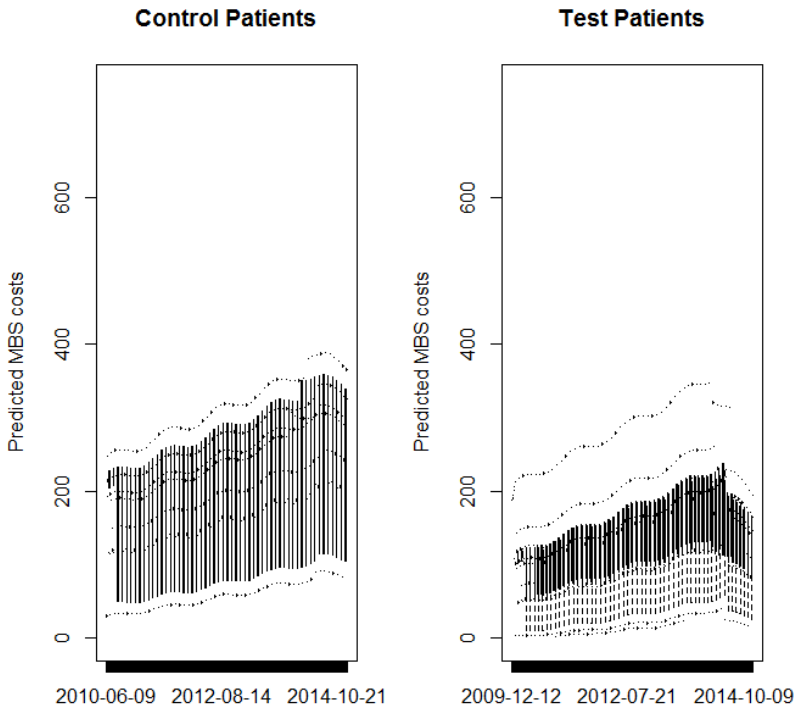


Figure 45 Figure 10: Predicted MBS costs for ACT patients

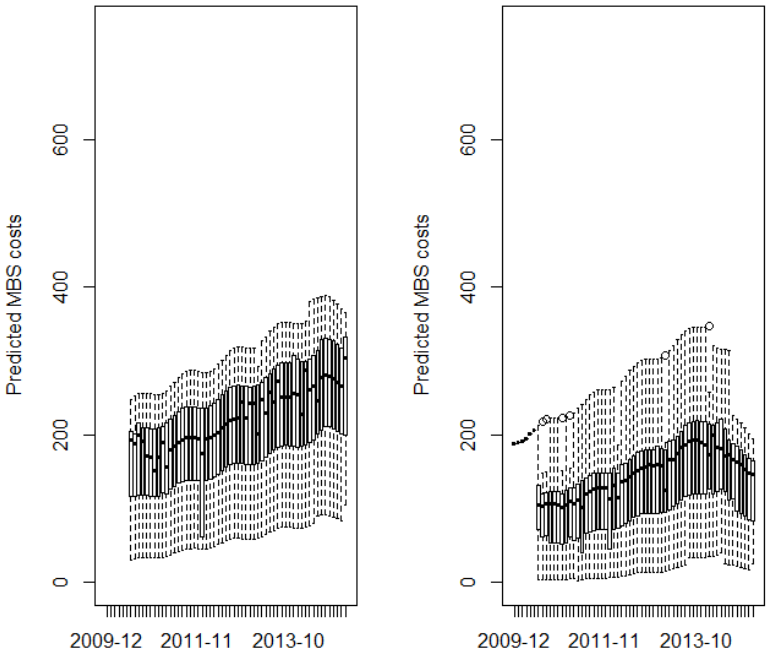


Figure 46 Time course of MBS costs for ACT patients with start month synchronised

The ACT Figure 45, Figure 46) Test patients at start the study period had an average cost of roughly about $100 per month on June 2010 which increased to an average cost of roughly $172.8 by April 2014 before reducing to an average cost of roughly $129.60 by December 2014.

The ACT Control patients at start the study period had an average cost of roughly about $ 159.30 per month on June 2010 which increased to an average cost of roughly $242.30 by April 2014 before increasing to an average cost of roughly $258.6 by December 2014.

8.3.4 Final Linear Mixed Effects Models for PBS

As before in our BACI design we wished to also estimate the temporal trend and the seasonal influence on the PBS scores. We fitted the models using the lmer function in the lme4 Package (Linear Mixed-Effects Models using 'Eigen' and S4(Bates, Maechler, Bolker, Walker, Christensen, Singmann, Dai,Grothendieck, 2015) [ctb] in R. (see https://cran.r-project.org/web/packages/lme4/lme4.pdf)
These models attempted to model random effects as well as before and after effects for site specific behaviour as well as seasonal variations which were modelled as sine and cosine functions with fixed periods and variable gains.

The resultant fitted model for the sqrt of PBS costs is as follows:

```
Linear mixed model fit by REML ['lmerMod']
Formula: sqrt(1 + PBS.mcost) ~ Sex + Before.After * TC * time + Before.After *
    TC * Site + period.From + (cos(2 * pi * time/365.25) + sin(2 *      pi *
time/365.25)) + (1 | OCID) + (1 | period.From)
   Data: PBS

REML criterion at convergence: 119725

Scaled residuals:
    Min      1Q  Median      3Q     Max
-3.4905 -0.5733 -0.0434  0.4820 12.1889

Random effects:
 Groups      Name        Variance Std.Dev.
 period.From (Intercept)  2.159   1.469
 OCID        (Intercept) 15.267   3.907
 Residual                43.491   6.595
Number of obs: 17950, groups:  period.From, 1554; OCID, 99

Fixed effects:
                                Estimate Std. Error t value
(Intercept)                    1.543e+01  3.374e+00   4.573
SexM                          -1.933e+00  2.536e-01  -7.623
Before.Afterbefore            -1.837e+00  3.209e+00  -0.572
TCC                            1.153e+01  3.543e+00   3.254
time                          -4.843e-04  1.846e-03  -0.262
SiteTAS                        3.124e+00  1.560e+00   2.003
SiteVIC                        2.646e+00  1.578e+00   1.677
SiteQLD                        9.799e-01  1.600e+00   0.612
SiteARV                        8.768e-01  1.797e+00   0.488
cos(2 * pi * time/365.25)      1.488e-01  9.187e-02   1.620
sin(2 * pi * time/365.25)     -5.023e-01  9.431e-02  -5.326
Before.Afterbefore:TCC        -1.219e+01  3.561e+00  -3.424
Before.Afterbefore:time        2.456e-03  1.868e-03   1.315
TCC:time                      -5.360e-03  2.034e-03  -2.635
Before.Afterbefore:SiteTAS    -1.651e+00  8.740e-01  -1.889
Before.Afterbefore:SiteVIC    -2.050e+00  8.910e-01  -2.301
Before.Afterbefore:SiteQLD    -8.087e-01  9.139e-01  -0.885
Before.Afterbefore:SiteARV    -8.068e-01  1.049e+00  -0.769
TCC:SiteTAS                   -1.923e+00  9.116e-01  -2.109
TCC:SiteVIC                   -1.362e+00  9.410e-01  -1.448
TCC:SiteQLD                   -4.194e+00  9.865e-01  -4.251
TCC:SiteARV                   -3.706e+00  1.141e+00  -3.249
Before.Afterbefore:TCC:time    6.038e-03  2.054e-03   2.940
Before.Afterbefore:TCC:SiteTAS 3.006e+00  9.904e-01   3.035
Before.Afterbefore:TCC:SiteVIC 2.624e+00  1.016e+00   2.583
Before.Afterbefore:TCC:SiteQLD 2.314e+00  1.059e+00   2.186
Before.Afterbefore:TCC:SiteARV 1.718e+00  1.210e+00   1.420
```

The significant interpretation of this model is as follows:

1. Males PBS costs are significantly lower for males relative to females (the most significant variable)
2. The control patients have significantly higher PBS costs after correcting for all other factors.
3. Tasmanian and Victorian patients have significantly higher PBS costs than ACT patients
4. There are significant seasonal influences on pharmaceutical costs (this is highly significant)
5. There is a significant interaction between the before-after indicator variable and the test-control indicator variable this indicates that the before control patients have a significantly lower PBS cost than other combinations – this provides some evidence that the intervention may have worked but must be contrasted with 8 below.
6. There is a significant interaction between time and control patients which means that the rate of increase in costs is significantly lower for the control patients compared to the test patients.
7. The before-after differences are significantly greater in Tasmania & Victoria than in other states.
8. The control patient PBS costs in states Tasmania, Queensland and ARV differ significantly to those on ACT patients.
9. The before intervention control patients have a higher trend over time – this suggests that the intervention albeit significant is complicated – on its own this suggests that the intervention has reduced the costs for controls after the intervention, but this needs to be balanced with the interpretation given in number 4.
10. The before and after control patient interaction influences differ significantly from state to state, and this suggests that the influence of the intervention is significant difference for Tasmania, Victoria and Queensland than ACT (the impact is lower at these sites relative to NSW).

TASMANIA

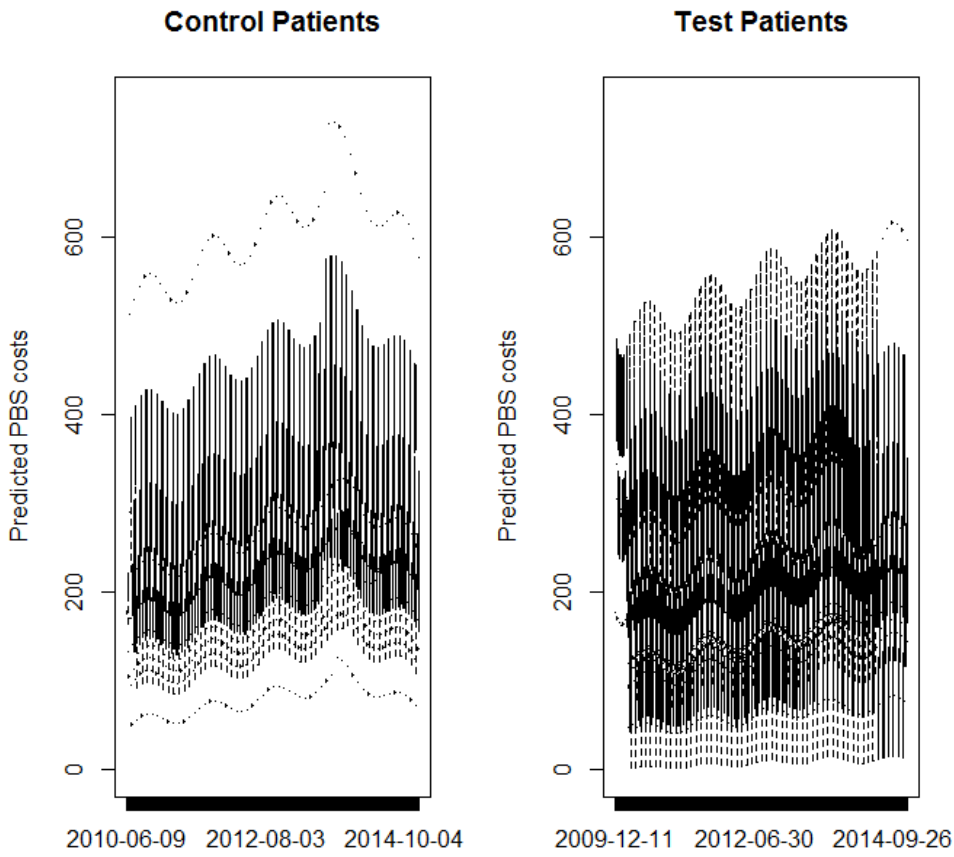


Figure 47 Predicted PBS costs for Tasmanian patients

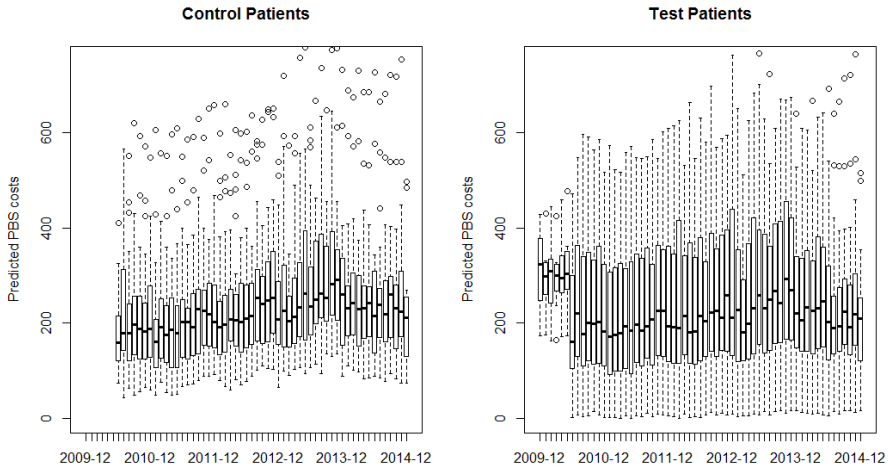


Figure 48 Time course of MBS costs for TAS patients with start month synchronised

For TAS patients PBS costs for both Test and Control patients were similar and did not change substantially after the intervention (Figure 47, Figure 48).

VICTORIA

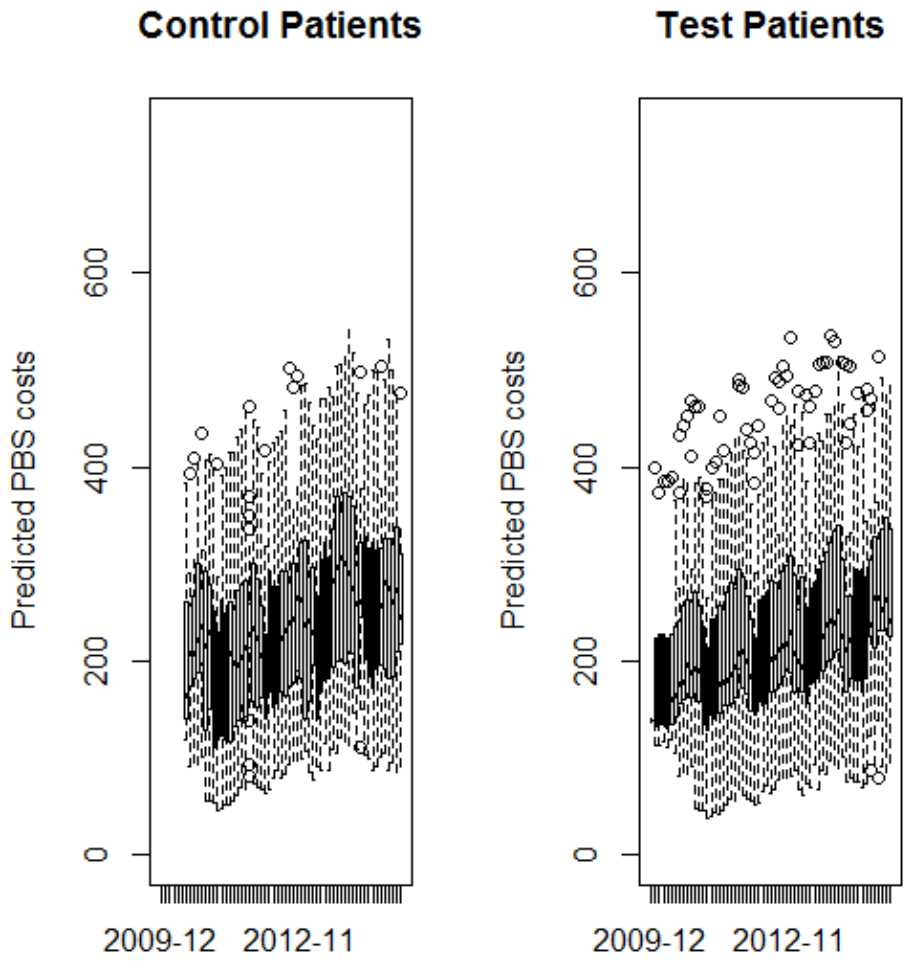


Figure 49 Predicted PBS costs for VIC patients

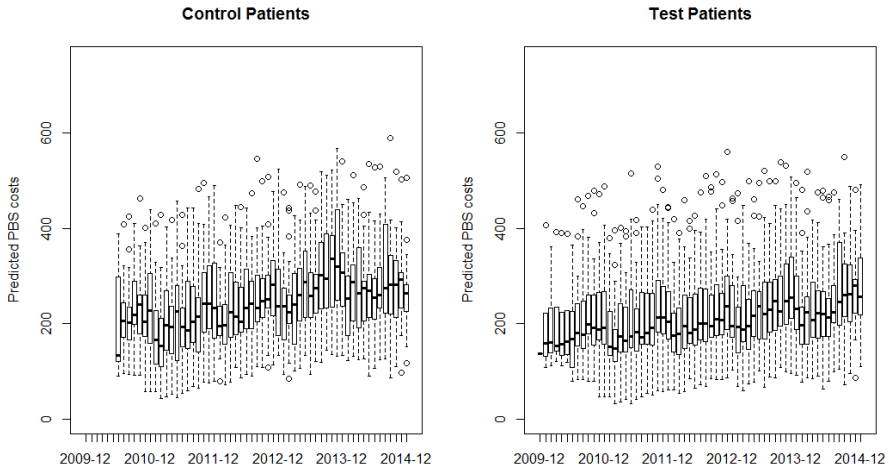


Figure 50 Time course of MBS costs for VIC patients with start month synchronised

These plots (Figure 49, Figure 50) indicate that there was no evidence of a benefit from the intervention in VIC.

QUEENSLAND

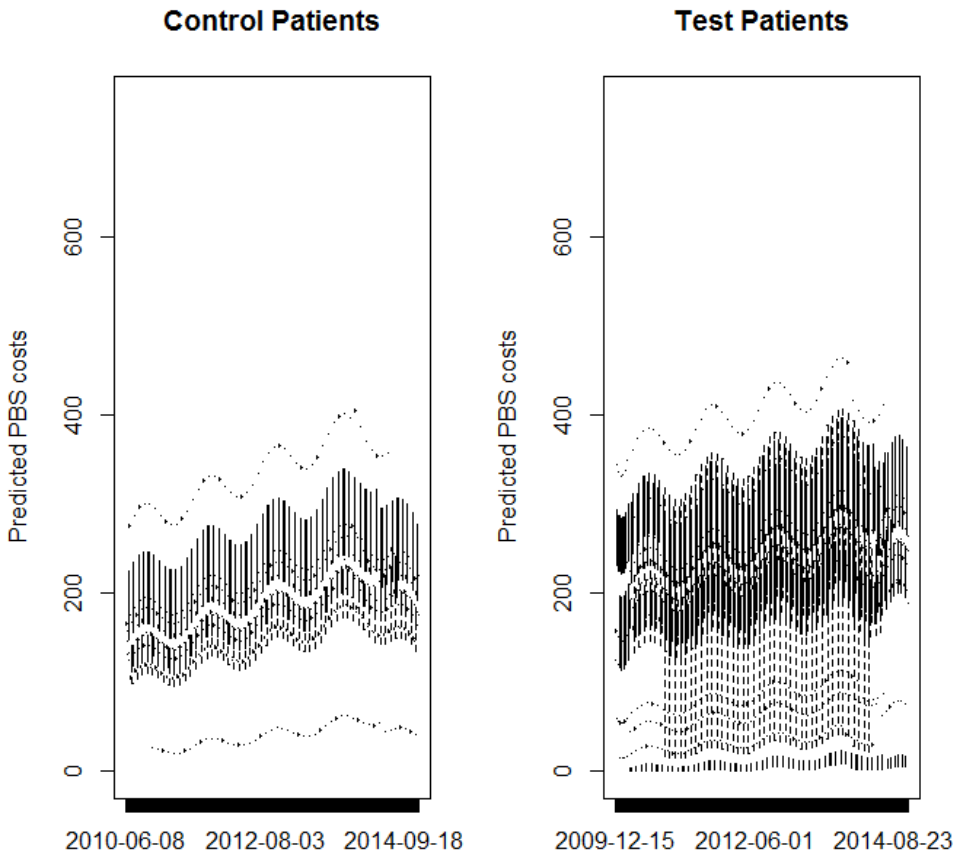


Figure 51 PBS Predicted costs for patients in QLD

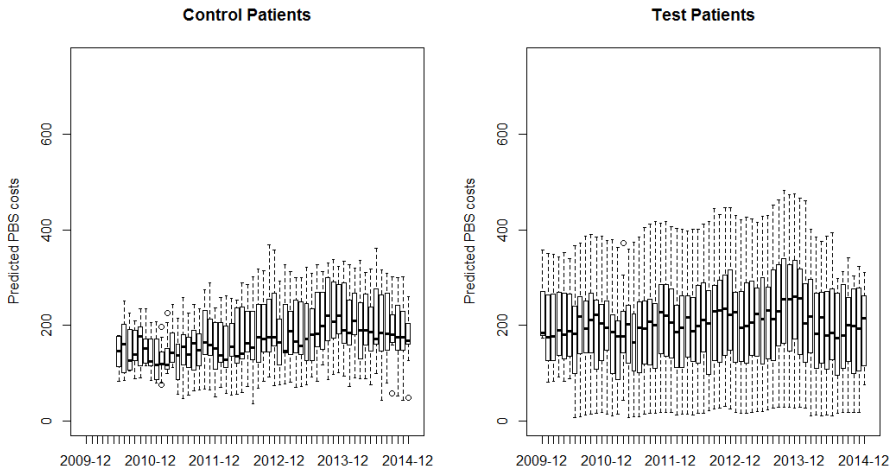


Figure 52 Time course of MBS costs for QLD patients with start month synchronised

There was no significant effect of the intervention on PBS costs in QLD as seen in Figure 51 and Figure 52.

AUSTRALIAN CAPITAL TERRITORY

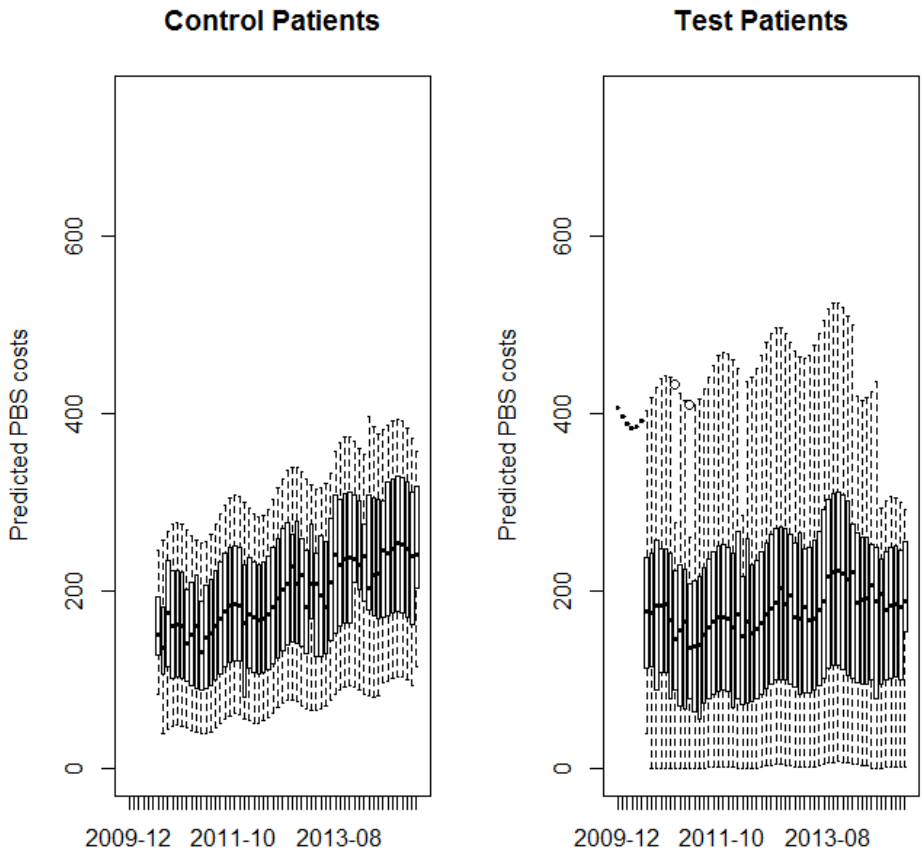


Figure 53 PBS Predicted costs for patients in ACT

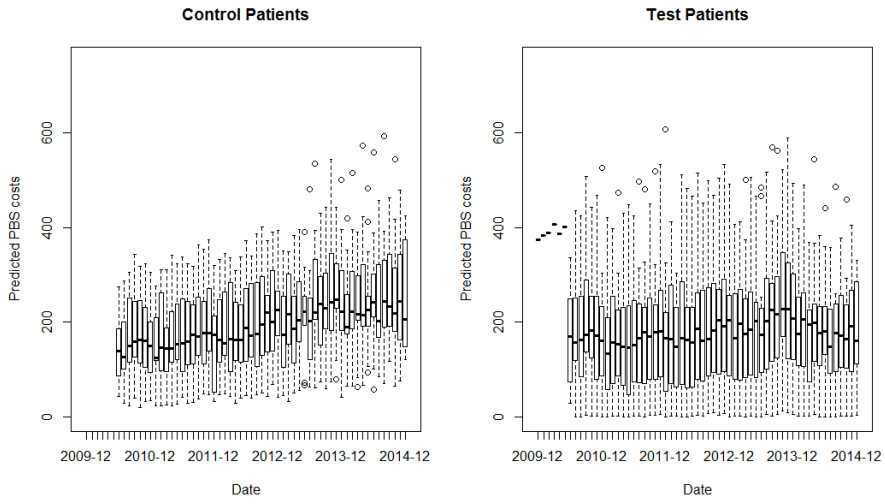


Figure 54 Time course of MBS costs for ACT patients with start month synchronised

The ACT patients differed for the Control patients from TAS, VIC and QLD where the PBS costs kept on rising as we would have anticipated prior to the study, and the Test patients cost dropped off after the start of the intervention (Figure 53, Figure 54). There was evidence of the Test patients benefitting from the intervention relative to their controls in ACT.

NEW SOUTH WALES

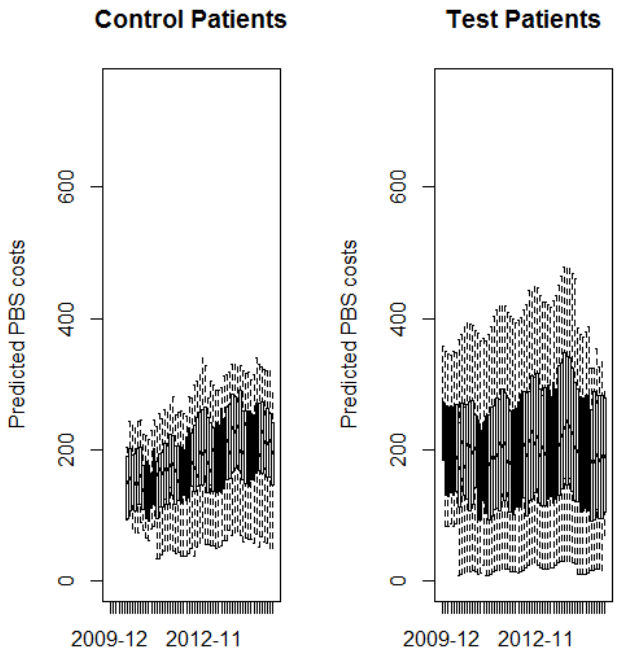


Figure 55 Predicted PBS costs for NSW patients

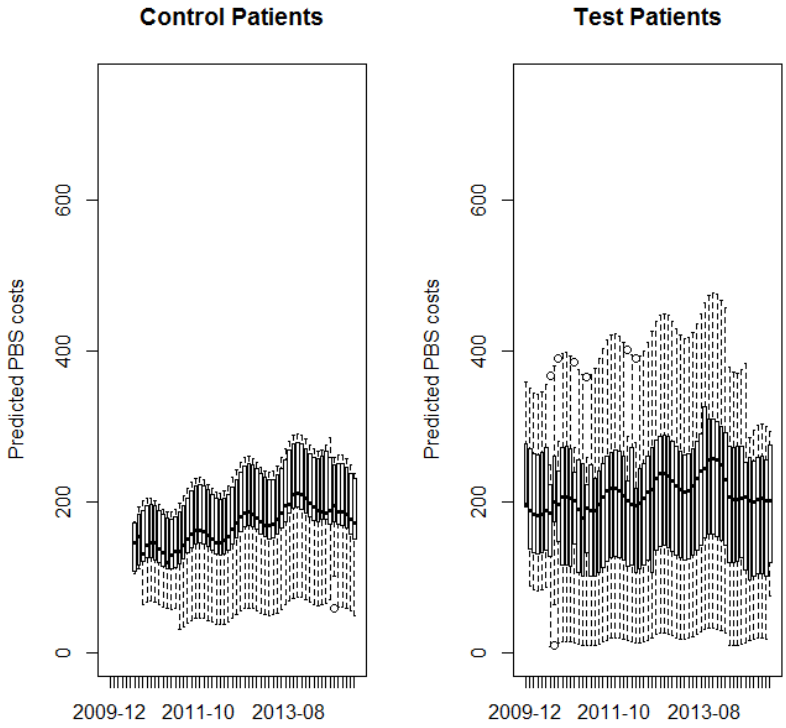


Figure 56 Time course of MBS costs for NSW patients with start month synchronised

These patients were similar to the TAS patients with a change in PBS cost trend for the Controls after the intervention, but the Test patient showed a drop off in PBS costs after the intervention period (Figure 55, Figure 56).

The conclusion with respect to the effect of the telemonitoring intervention on PBS costs from the five sites differ. In TAS, ACT and NSW there were signs of potential benefit but the message was far from clear, while in VIC and QLD there was no obvious benefit – in fact the Controls seemed to have reduced their costs more after the intervention period.

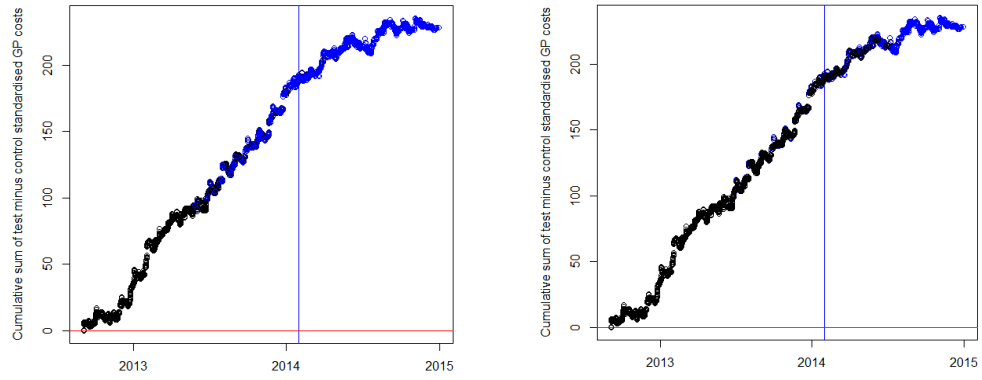
8.4 Method 3: Monitoring cumulative sum of differences in costs over time

In this analysis we took the average 30 day costs for the Control patients when there were two matches and then we examined the differences (Test-Controls) in the 30 day costs for each Test papient and their controls. If there was only one matched Control patient for a Test patient we took the differences between the matched Test and Control patients' 30 day costs. These differences should be randomly distributed around zero if there was no change in the cost distribution between the matched Test and Control patients' respective costs. These differences in 30 day averages remove the temporal trends of time and seasonal influences as well as any local influences in time – this is the major advantage of this approach besides its simplicity.

The first plot looks at the accumaltive sum of the differences between the matched costs for the Test patiets and the aveages costs of the Control patients. This plot can be interpreted in terms of the rate of change over time (slope of the CUSUM):

1. If the CUSUM tracks downwards then the test patient has lower costs than the controls. If it tracks upwards then the reverse is true.
2. If the CUSUM changes its trend over time (rate of change) and this corresponds to when the intervention started then this indicates a change that is likely to be a result of the intervention. If it reduces slope after the intervention then this suggests that the test patients have reduced their costs compared to what was expected. If the slope increases after the intervention then the test patients cost have increased and the intervention has had the oppositie effect to expected.
3. If the slope is increasing over time before the intervention date then the test patients appear to be deteriorating more than their controls with time as measured by their costs.

8.4.1 Cumulative sum of differences in in GP Costs over time



(a) Blue before circles plotted last. b) Blue before circles plotted first

Figure 57 CUSUM differences in matched test and control patients' GP costs

Figure 57 indicates the trend in the differences between the match Test and Controls GP costs. From the start of the study it is clear that the costs for the Test patients increased more before the intervention. Note that the blue circles indicate the differences after intervention and the black circles indicate those differences that occured before the intervention. We plotted the blue circles in Figure 57a and the black circles in Figure 57b, because some Test patients started their intervention in the same 30 day period. There is also evidence that the CUSUM reduced its slope after some patients started the intervention which provides some evidence that the intervention was successful in reducing GP costs. It is also clear that as

more and more Test patients start the intervention the slope of the line keeps reducing its gradient hence providing reasonable evidence that the intervention reduced GP costs mathematically.

Figure 57a is the same as Figure 57b but it illustrates those test patients that started the intervention later than most others, while Figure 57b illustrates those that started early. The blue vertical line indicates the median starting date of the intervention. In Figure 57a and Figure 57b we don't plot the full 'before' period to avoid this longer period dominating the graph.

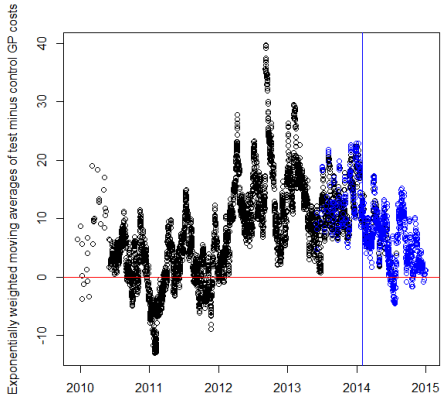


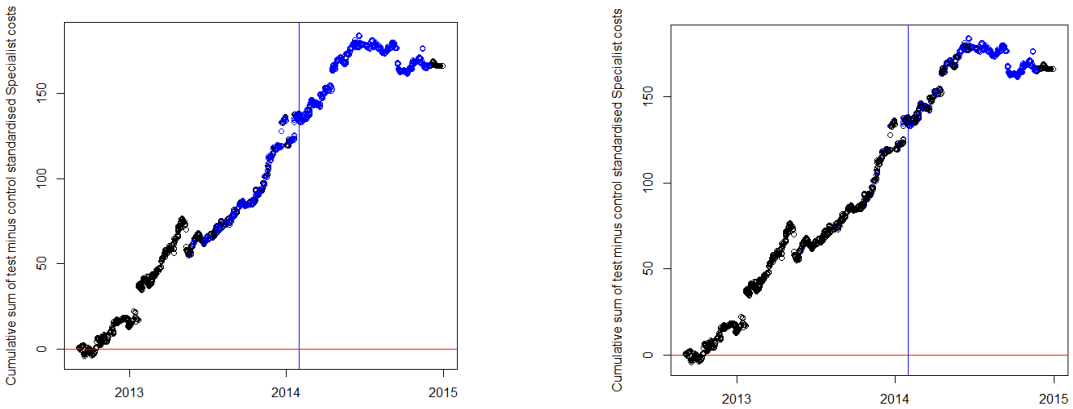
Figure 58 The EWMA of the matched differences in (average) 30 day costs between the test and control patients

Figure 58 is the exponentially weighted moving averages (EWMA) of the match differences in the non-overlapping 30 day period total GP costs. These are interpreted as follows:

1. If there is no difference in these costs then these differences should remain close to zero by following a random walk around zero.
2. If these differences trend away from zero then this estimates the local differences (in time) between the costs of the tests and controls.
3. The trends in these costs indicate the direction these costs are heading in over time, e.g., positive differences indicate that the local costs for test patients are higher than for control patients.

In Figure 58 the local average costs nearly always was greater for the Test patients than the Controls before the intervention. Figure 58 indicates that the Test patients GP costs trended up to on average $15 higher for the Test patients per 30 day by the beginning of 2013. After some Test patients had started the intervention this stablised at about an increase of $10 per 30 day, but after nearly all Test patients had moved to onto the intervention this was trending to about Test patients only paying on average $5 per 30 day indicating a potential gain on average of about $10 per 30 day period. There is some evidence that if the trial had lasted a little longer and this trend continued then there would be no difference in GP costs or even better the Test patients' GP costs would be lower than the Control patients' GP costs.

8.4.2 Cumulative sum of differences in specialist costs over time



(a) before circles plotted last (b) before circles plotted first

Figure 59 CUSUM differences in matched test and control patients' specialist costs

The fact that the cumulative sum of the matched differences in (average) specialist costs before the intervention increased at a rapid rate from the start in Figure 59 indicates that the specialist costs were higher for the Test patients than for the Control patients. The reduction in the slope after the intervention started indicates that this gap between the Test and Control costs closed a little after the intervention. When the cumulative sum starts trending downwards then the Test patients now have lower costs than the Control patients. So Figure 59 suggests that there was a continued improvement in the Test patients' specialist costs to the level at the end of the study where the Test patients had lower specialist costs (after starting with higher costs). This does suggest that we stopped the study too soon to realise the full benefit of the intervention (but this is a hunch rather than a fact – we can't explolate what would have happened beyond the end date of the trial).

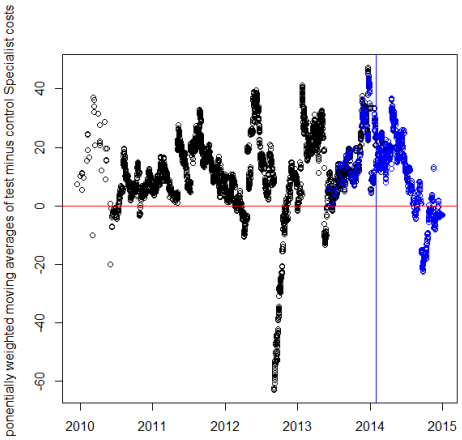


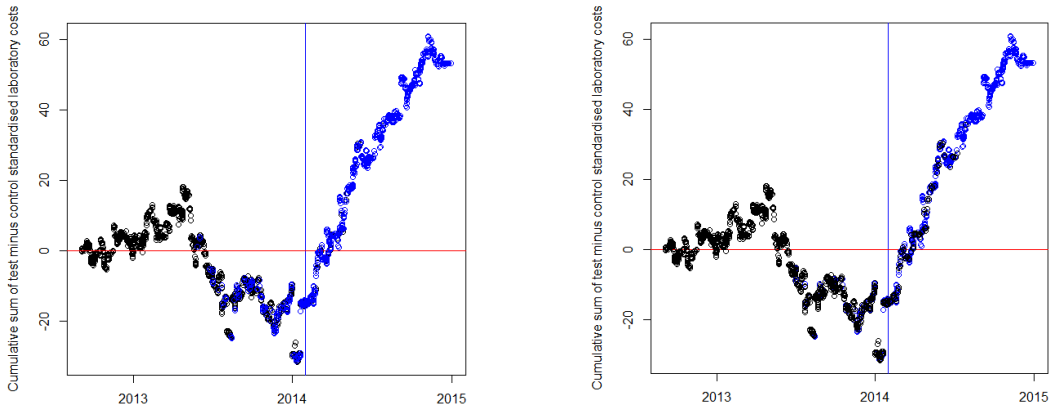
Figure 60 The EWMA of the matched differences in (average) 30 day specialist costs between the test and control patients

In Figure 60 it is clear that once nearly all Test patients have started the intervention then the trend in the cost differences started trending downwards which clearly suggests the intervention worked in reducing Test patients' specialist costs relative to their Control patients.

The figures above plot the times series trend in the EWMA smoothed specialist costs. These smoothed differences were on average mostly greater than zero before the intervention indicating that the Test patient generally had higher 30 day costs than the Control patients. These values trended upwards when these Test patient costs started increasing relative to the Control patients and trended downwards when they started decreasing. Note that towards the end of the study the Test patients' specialist costs

appeared to be lower on average than the Control patients. This suggests that the intervention may have had a long-term benefit for the patients in reducing specialist costs.

8.4.3 Cumulative sum of differences in laboratory costs over time



a) after circles plotted last (b) after circles plotted first

Figure 61 CUSUM differences in matched test and control patients' laboratory costs

Figure 61a. demonstrates that the laboratory costs for Test patients appeared to increase soon after the intervention, but these start reducing towards the end of the study. Unfortunately we can't tell whether this late reduction in laboratory costs were going to persist beyond the study period. This evidence suggests that although Test patient laboratory costs appeared to increase at the initial stages of the study, by the end of the study this trend was reversed.

Figure 61b. suggests that once the Test patients were almost all entered the after period (the intervention has started) then the (cumulative sum of the differences) CUSUM trend changed to a lower slope indicating that the relative costs started to reduce, with a change in direction later in the study period indicating that by the end of the study period the laboratory costs for Test patients were on average lower than the Control patients.

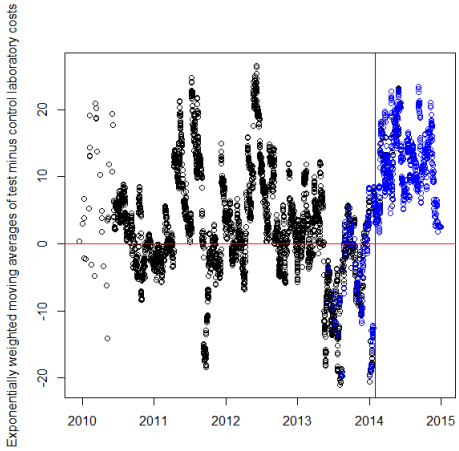
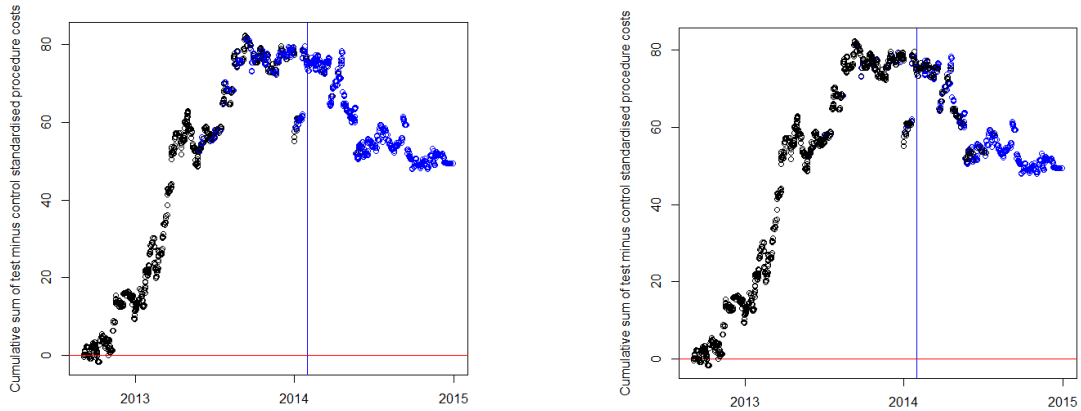


Figure 62 The time series trend in EWMA smoothed matched differences in (average) 30 day laboratory costs between the test and control patients

Figure 62 examines the time series trend in EWMA smoothed matched differences in laboratory costs. This indicates that before the intervention the Test patients generally had higher laboratory costs than the Control patients. There is evidence that after the intervention the test patients' laboratory costs trended higher more than the Control patients but towards the end of the study period this trend was downwards in the direction of lower differences in laboratory costs.

8.4.4 Cumulative sum of differences of procedure costs



(a) after circles plotted last (b) after circles plotted first

Figure 63 CUSUM differences in matched test and control patients' procedure costs

Figure 63 presents the time series plot of the CUSUM for the differences in procedure costs. There is strong evidence from Figure 63a. that before the intervention the Test patients' procedure costs were increasing at a rapid rate relative to the Control patients. This is evident by the increasing trend in the CUSUM for most of 2013. This trend starts turning around at the start of the intervention. By the time nearly all Test patients have started the intervention the trend in the CUSUM is downwards indicating that the Test patient procedure costs are now lower than the Control patients' procedure costs.

Figure 63b. makes the evidence of the change points in differences in procedure costs more evident and clearly providing more evidence on the reasons for change in the differences in procedure costs.

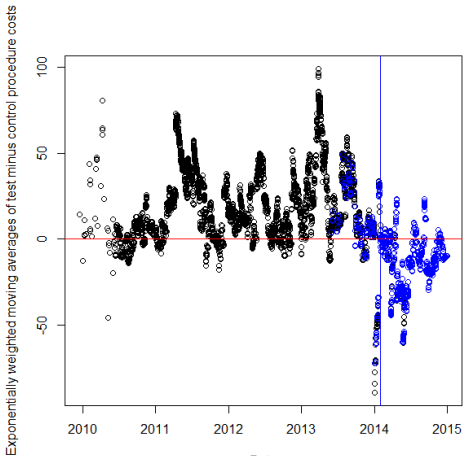
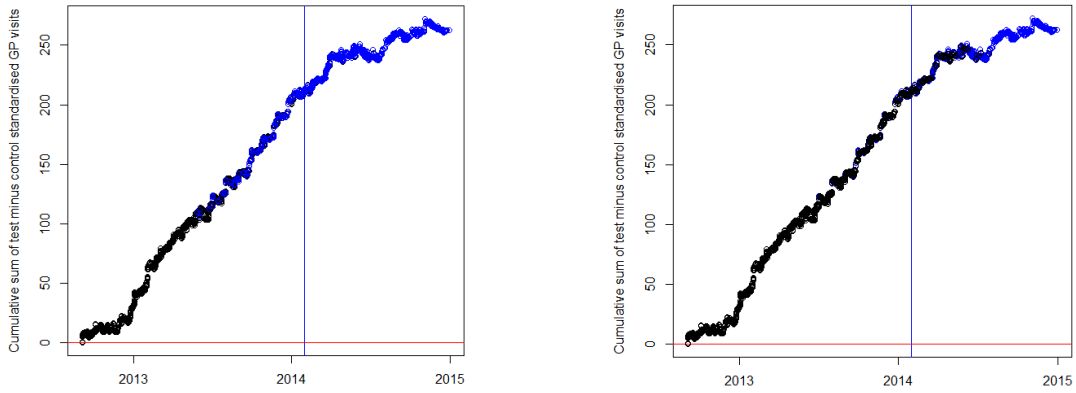


Figure 64 The EWMA of the matched differences in (average) 30 day procedure costs between the test and control patients

Figure 64 presents the time series trend for the EWMA smoothers 30 day differences in the procedure costs. Before the intervention these EWMA values are nearly always above zero indicating that the Test patient procedure costs were nearly always higher for the Test patient. However, after the intervention there is evidence that these EWMA differences trends below zero now suggesting that after the intervention the Test patient procedure costs were lower that their matched Control patient. This turn around appears to be due to the intervention.

8.4.5 Cumulative sum of differences of number of GP visits

The discussion for the number of GP visits, specialist consultations, laboratory tests and procedures will be commented on in less detail because these have already been appropriately analysed using the BACI design. However this analysis gives greater insight into the changing trends which are assumed to be linear in the BACI analysis.



(a) after circles plotted last (b) after circles plotted first

Figure 65 CUSUM differences in matched test and control patients' number of GP visits

Figure 65 presents the CUSUM of the matched differences in the number of GP visits. This indicates that the CUSUM starts with a slightly increasing trend in late 2012. The CUSUM increased noticeably in slope in early 2013 indicating an increase in the number of GP visits for the Test patients relative to the Control patients. However after the intervention there is evidence of this slope first reducing and then towards the end starting to reverse in trend. If this trend persisted in a downward trend after the end of the study period then it is clear that the number of GP visits would have reduced significantly for the Test patients relative to their Controls.

Figure 65b. illustrates the change points clearly correspond to the start of the intervention indicating that it has the desired impact on the number of GP visits.

Figure 66 presents the time series plot of the EWMA smoothed matched differences in GP number of visits in 30 day periods. This indicates an increase in the Test patient number of visits before the intervention date, but a change in this trend after the intervention started. It is clear that the differences were trending towards zero after the intervention which provides reasonable evidence that the intervention may have realized a significant result for the number of GP visits if the trial was run for a longer duration.

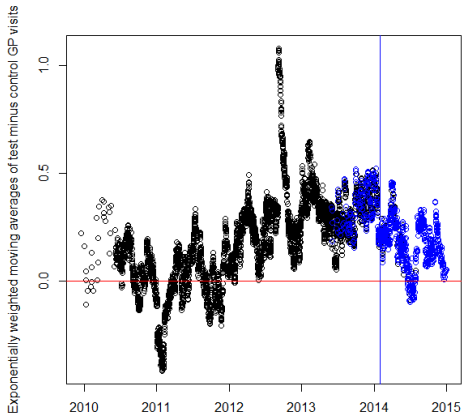
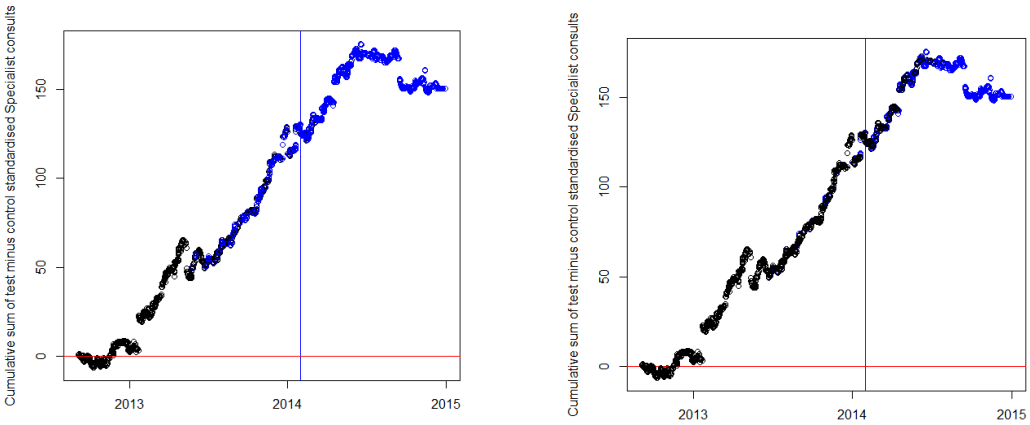


Figure 66 The EWMA of the matched differences in (average) 30 day number of GP visits between the test and control patients

8.4.6 Cumulative sum of differences of number of specialist consultations



(a) after circles plotted last (b) after circles plotted first

Figure 67 CUSUM differences in matched test and control patients' specialist consultations

Figure 67 provides the time series plots for the CUSUM matched differences in the number of specialist consultations. These plots indicate that the number of specialist consultations for the Test patients increased relative to the Control before the intervention. After the intervention there is evidence that after the intervention started the number of specialist visits for the Test patient started to reduce relative to the Control patients. The impact seemed to be delayed or at least the impact seemed to be longer term rather than immediate.

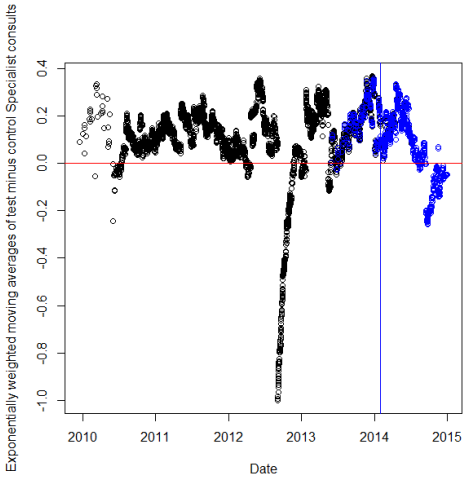
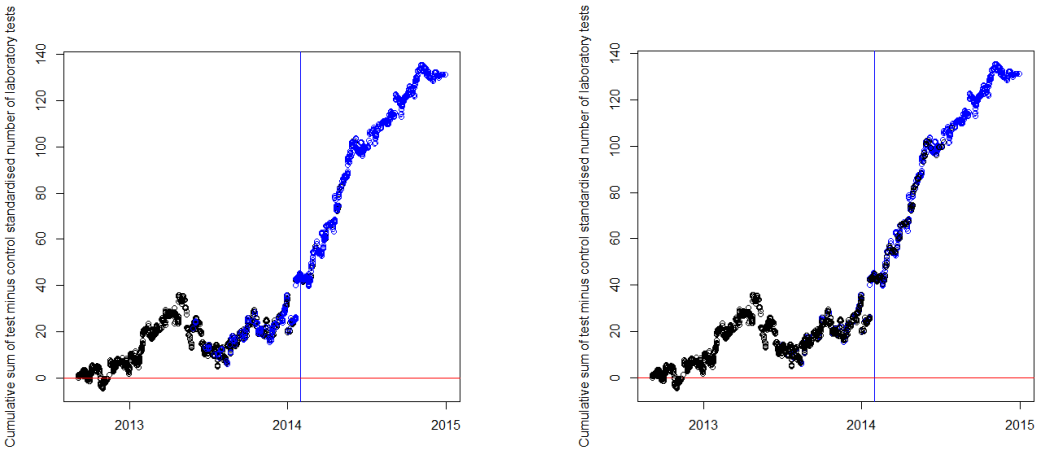


Figure 68 The EWMA of the matched differences in (average) 30 day specialist consultations between the test and control patients

The time series trend in the EWMA smoothed matched differences in the number of specialist visits in Figure 68 indicates that the number of specialist visits prior to the intervention was on average about 0.2 more per Test patient than Control patients, but after the intervention this appeared to trend down to less than zero (i.e., Control patients had more 30 day visits to the specialist than Test patients).

8.4.7 Cumulative sum of differences of number of laboratory tests



(a) after circles plotted last (b) after circles plotted first

Figure 69 CUSUM differences in matched test and control patients' number of laboratory tests

Figure 69 presents the time series plots of the CUSUM matched difference in the number of laboratory tests. This provides evidence that the number of laboratory tests increased dramatically in the Test patients relative the Control patients until near the end of the study where this trend is reversed. However the study appeared to not run long enough to fully realise this relative benefit.

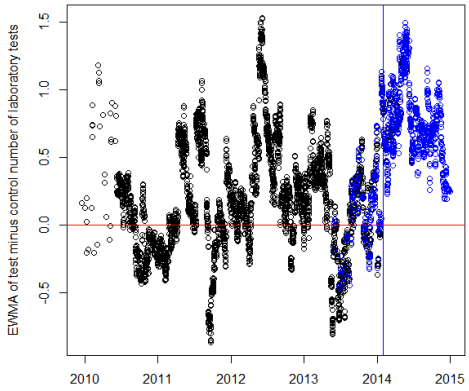
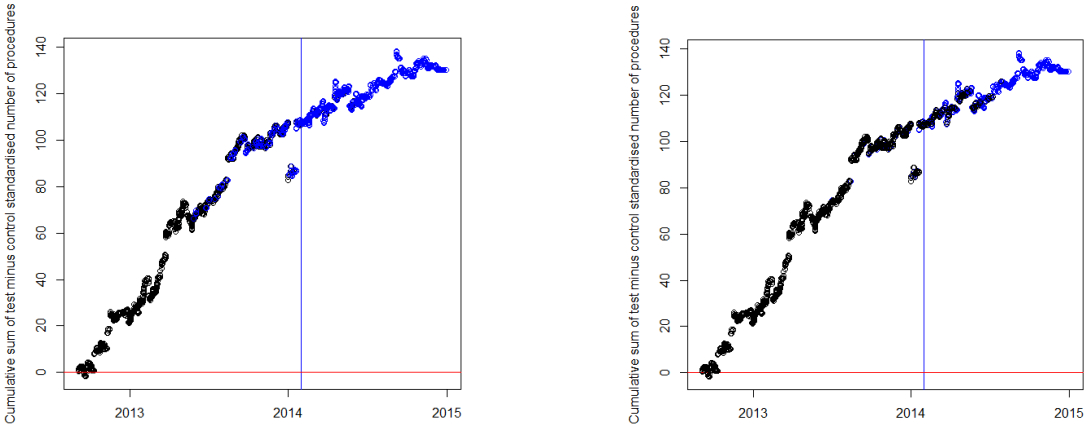


Figure 70 The EWMA of the matched differences in (average) 30 day number of laboratory tests between the test and control patients

Figure 70 provides similar evidence as Figure 69.

8.4.8 Cumulative sum of differences of number of procedures



(a) after circles plotted last (b) after circles plotted first

Figure 71 CUSUM differences in matched test and control patients' number of procedures

The time series trends in Figure 71 indicate an increase in the CUSUM over time, but the rate of this increase lowers with the start of the intervention. This indicates that the higher number of procedures in Test patients compared to Control patients persisted for the duration of the study, but the difference between these two groups was reduced by the intervention, suggesting a significant impact of the intervention.

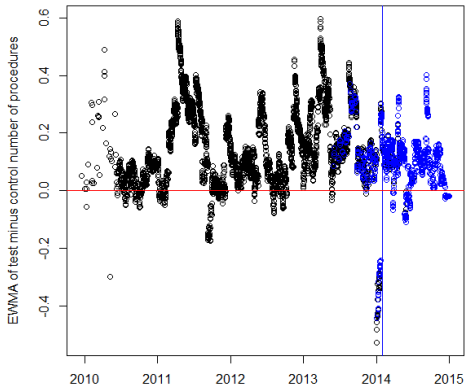


Figure 72 The EWMA of the matched differences in (average) 30 day number of procedures between the test and control patients

Figure 72Figure 72 confirms the information found in Figure 71.

8.5 Development of a WebRTC Video Conferencing Service

Video conferencing for patients in this Telehealth Trial was made available through the Telemedcare telehealth device in-build video conferencing capability as discussed below. However, to fulfil the requirement of delivering video conferencing at high definition at 720p (1280x720 pixels) 25fps, a selection process was carried out to determine an appropriate tablet suitable for this purpose considering user aspects appropriate for an elderly patient. The Samsung Galaxy Note 8 inch and Note 10 inch tables were selected both with front cameras capable of capturing video at greater than 720p (1280x720 pixels) for further assessment.

Initial testing demonstrated that neither the 8 inch nor the 10 inch tablet can send 720p at 25fps video using the front camera, but can receive and display 720p video at 30fps. This down scaling of upstream video is an Android operating system/Chrome feature which can't be controlled. These conclusions were confirmed by two external organisations Attend Anywhere and Medtech Global, both of whom are experienced in providing video conferencing services.

Following the result of this initial testing, additional research was undertaken to find an appropriate video conferencing platform to deliver this service via the tablet. After reviewing several available platforms, WebRCT (Web Real-Time Communication) was selected, together with the new 2014 version of the Samsung Galaxy Note 10 inch tablet. Using WebRCT a standards-based video conferencing system was developed and tested for the Telehealth Trial.

8.5.1 Telemedcare Video Conferencing

Video conferencing with a patient using Telemedcare telehealth device was quite simple and could be initiated by the CCC via their remote clinical monitoring software. CCCs who had this feature enabled were required to activate the video conference button on the screen after selecting the patient's name.

Below is a brief description of operations of this video conferencing feature:

The CCC is required to select a patient from their list to whom they want to video conference as shown in Figure 73 below.

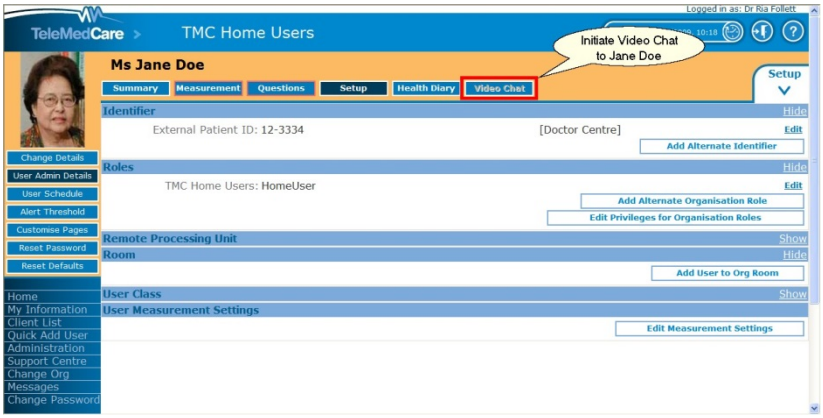
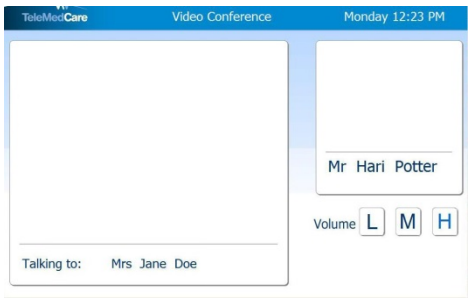


Figure 73 Selecting patients from the TMC Clinician interface

A 'video chat' button is visible near the top of the page; if the 'Video Chat' button is greyed out, the selected patient is not on line and the CCC cannot initiate the video chat. This may be due to the monitoring unit not being turned on, or the patient having disconnected the monitoring unit from an internet connection. If the patient is connected to the internet, the 'Video Chat' button on the clinician's web page will become enabled. The CCC can then initiate the video chat by selecting the video chat button.

Once video chat has been selected, a message will indicate that the video conference is starting up, and wait for the client to accept the conference on their remote unit.



If the patient does not want to accept the conference, he/she can reject this, and the conference clinician will receive the following message:

If the patient accepts the conference invitation, an image of the user who initiated the conference will appear on their health monitor. The CCC will also be able to view the person they have called, as well as seeing a small image of what is being sent.

The volume of the video chat can be adjusted to low, medium or high, as well as using the usual windows volume control.

When the conference is finished the user can press the disconnect button.

If the patient finishes the conference first by disconnecting, the following message is displayed.

NOTE: Video conferencing can only be initiated from the CCC (Carer/Clinician) on the web interface. The patient cannot initiate video calls to their clinician.

This video conferencing service was available for use but was not widely used because of frequent dropouts, particularly when the Clinician was behind a hospital firewall or the patient was not connected to the NBN.

8.5.2 WebRTC Prototype Implementation

In this section, a prototype implementation is used to illustrate how some of the design ideas described earlier have been realized in the video conferencing system using WebRTC.

Environment Setup:

Though the WebRTC is still at a draft stage, there are number of open source projects and commercial platforms available with the promise to assist in the fast and effective development of WebRTC based video conferencing applications with the minimum efforts from the developers. Among those, EasyRTC, a full-stack open source WebRTC toolkit that supports the building of secure WebRTC applications was selected. EasyRTC is a bundle of web applications, code snippets, client libraries and server components written and documented to work out of the box. EasyRTC APIs and JavaScripts are used to access the functions of WebRTC engines already implemented in many browsers. As the Chrome browser comes pre-installed in the Samsung Galaxy Notes, this was used. Node.js, which is a JavaScript based runtime platform, was used as a web server to develop our web applications.

Acquiring Audio and Video Streams:

In practice, the complexity of representing the video and audio streams and specifying the constraints of the media streams are all hidden from the developers. The following code snippets illustrate how easy it is to define a local stream (i.e., getting a video and audio stream from the local machine).

```
easyrtc.initMediaSource(
  function(){
    var selfVideo = document.getElementById("me");
    easyrtc.setVideoObjectSrc(selfVideo,easyrtc.getLocalStream());
   easyrtc.connect("VC test",connectSuccess,connectFailure);
  },
  connectFailure
);
```

It is important to note the call to easyrtc.getLocalStream and easyrtc.setVideoObjectSrc. The former gets a video and an audio stream from the local camera and microphone, once the call to easyrtc.initMediaSource succeeds. The latter ties a video tag to a media stream object. Invoking this method will cause the user's browser to ask for permission to access the requested local camera and microphone as seen in Figure 74. Once the permission button is clicked, the users see their own images on the screen.

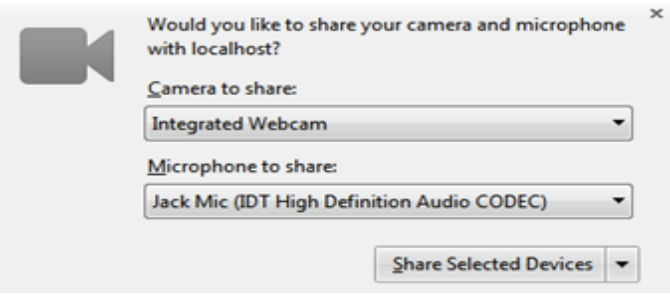


Figure 74 Browser asks for a permission to access the local camera and microphone

Obtaining a remote peer's media stream is also straightforward by using a callback method. The callback method ties the video tag to the incoming stream. When the remote peer hangs up, the callback clears the video tag.

```
easyrtc.setStreamAcceptor(
  function(callerEasyrtcid, stream) {
    var video = document.getElementById('caller');
    easyrtc.setVideoObjectSrc(video, stream);
  });
easyrtc.setOnStreamClosed(
  function (callerEasyrtcid) {
    easyrtc.setVideoObjectSrc(document.getElementById('caller'), "");
  });
```

In addition, EasyRTC provides a number of functions for developers to set up media constrains. For example, calling easyrtc.setVideoBandwidth() allows to set the bandwidth used to send and receive

Signalling and Peer Connection

A signalling process assists the finding of peers and establishing communication among peers by exchanging data through dedicated channels. The dedicated channel allows the privacy and security of the data from the interference of concurrently running processes. The implementation of signalling process can vary depending on the requirements of each application and the environment the application runs on. For example, if an application only requires communication among peers within the same network, it is relatively straightforward to obtain public IP addresses of the peers and make the connections. However, a signalling process becomes complex if peers' public IP addresses and port information are hidden away from peers as they are located behind their own private network. As a result, neither peer is directly reachable by each other. To initiate a session, one must first gather the possible IP addresses and port candidates for each peer, traverse the NATs, and then run the connectivity checks to find the ones that work.

The PeerConnection API in the WebRTC is responsible for managing the full life cycle of each peer-to-peer connection by encapsulating all the connection setup, management, and state within a single interface. However, before the application developer dives into the details of each configuration option of the API, one needs to understand the interactions among peers before choosing a right signalling process. Figure 75 illustrates our signalling requirements and interactions required between peers.

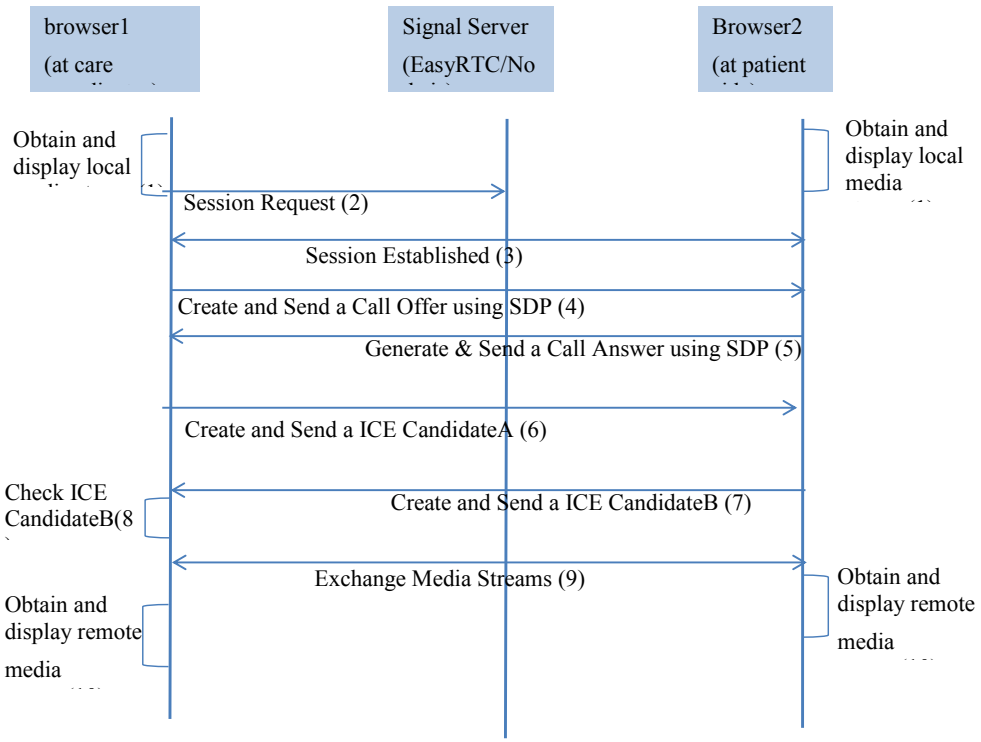


Figure 75 Signalling and Interactions

1. When a care coordinator clicks a "connect" button, the care coordinator's browser obtains and displays the local media stream.
2. (We then need assistance from a signal server to create a secure channel between the care coordinator's browser (browser 1) and the patient's browser (browser 2) which is requesting a particular video conferencing session.
3. A session is established.
4. The browser 1 uses Session Description Protocol (SDP) to describe the session profile which contains information such as types of media to be exchanged, codecs and their settings, and bandwidth information. The SDP is used to make an offer to the browser 2. At this stage, actual media itself is not attached to the offer.
5. Upon receiving the offer, the browser 2 creates an answer that it is willing to connect to the browser 1 and also sends its corresponding session profile using SDP. Now the browser 1 knows that the browser 2 is ready to run a peer to peer communication.
6. After getting an answer from the browser 2, browser 1 creates an Interactive Connectivity Establishment (ICE) agent (ICE A). The ICE agent gathers local IP address and port tuple and queries an external STUN server to retrieve the public IP and port tuple of the peer.
7. Upon receiving the ICE A, the browser 2 performs the same operation as browser 1 to create and send ICE agent (ICE B).
8. Browser 2 checks that the public address received in ICE B matches with the information received earlier (i.e., the browser 2 sends this information when the patient clicks video conference reservation request). At this point, if the browser 1 and browser 2 cannot establish a connection directly as P2P fashion, the TURN server is used as a proxy to relay traffic.
9. Browser 1 sends the media stream to browser 2. Likewise, browser 2 sends its local media streams to browser 1 after obtaining the public IP addresses and port number tuples from the ICE A received earlier.

At this stage, both browsers start displaying media contents and the video conferencing is in operation.

The above mentioned interactions clearly demonstrate a need for STUN/TURN servers and a signal server that can handle a small number of participants. EasyRTC supports a signalling server that fits our requirements. Though the interactions in our case look lengthy and intricate, the complexity is actually all wrapped together by the signalling process. All that was required was to define a STUN/TURN server and to add a few lines of JavaScript code.

The enabled STUN/TURN server enforces the EasyRTC to go through the external STUN/TURN server to get public IP addresses and ports of the peers that interact in our application. If this set up is omitted, the EasyRTC will only attempt the direct peer to peer connection within the same network using the local IP addresses. The following code excerpt illustrates how to specify STUN/TURN server in the code and direct the EasyRTC to use the configuration.

```
var onGetIceConfig = function(connectionObj, callback) {
        var myIceServers=[
                {url:'stun:stun.l.google.com:19302'},
                {url:'stun:stun1.l.google.com:19302'},
                {url:'stun:stun2.l.google.com:19302'},
                {url:'stun:stun3.l.google.com:19302'},
          {url:'turn:tele@telecare-demo-cdc.it.csiro.au:3478?transport=tcp',
                credential: 'test',
                username: 'test'}
    ];
}
easyrtc.on("getIceConfig", onGetIceConfig);
```

The following JavaScript is added to make peer to peer connections. With the STUN/TURN server enabled, EasyRTC makes a number of decisions on our behalf. In the background, it initializes the PeerConnection with a public STUN/TURN server for NAT traversal by creating ICE agents, requests audio and video streams with getUserMedia, and initiates a WebSocket connection to establish a session with its own EasyRTC signaling server and passes the media streams between the peers.

```
function performCall(easyrtcid) {
   easyrtc.call( easyrtcid,
      function(easyrtcid) {
         console.log("completed call to " + me);},
      function(errorMessage) {
         console.log("err:" + errorMessage);},
      function(accepted, peers) {
         console.log(
            (accepted?"accepted":"rejected")+ " by " + peers);});}
```

Chat Rooms:

Rooms are a compartmentalizing feature of EasyRTC that are used to create chat services. The chat service allows a care coordinator and a patient to exchange text messages in addition to the online meeting they are conducting. To create a chat service, both client and server codes need to be implemented. On the client side, first the client connects to a socket.io server to get a chat channel. Once connection is established, the client sends a chat message.

```
//connection to socket.io server
var chat = io.connect(window.location.protocol + '//' + window.location.host + '/appointments);
//sending a chat message
function sendChatMessage(val) {
//sending message to the server
chat.emit("chat message", {text: val });
}
```

Once the server receives the 'chat message' from the client, it will fire the 'chat message' in the current room to every joined participant.

```
var chat = socketServer.of('/appointments').on('connection', function(socket) {
        socket.on('subscribe', function(data) {
                socket.join(data.room);
          roomName = data.room;
    });

    socket.on('chat message', function(data) {
          chat.in(roomName).emit('chat message',
                    {'text' : txt, 'from' : userName , 'userId' : userId});
   });
});
```

Upon receiving the 'chat message' by clients from the server, the client parses the incoming data and displays the text in the chat log.

```
function initChatRoom(appointmentID)
{
        //join the chat room
    chat.emit("subscribe", {'room': appointmentID });
        //receive the chat message sent by the peer (sent via the server)
        chat.on("chat message", function(data) {
            chatlog.append(data.from + ": " + data.text + "\n");
    } );
}
```

8.5.3 Laboratory Test of WebRTC Video Conferencing System

Laboratory testing was performed of the developed video conferencing system to identify whether the system can support two way HD quality (i.e., 720p 25 frames per second) video conferencing between patient and clinical nurse coordinator using Samsung Galaxy Note 10" tablet.

In our test environment, the patient is upplied with a Samsung 10" tablet with a simple WebRTC video conferencing application installed. The patient is connected to local Wifi network with a capacity 27MB/s. The CCC is provided with a standard Dell laptop connected to 100MB/s LAN.

The basic statistics of the system were captured using a chrome browser provided tool chrome://webrtc-internals . The captured statistics are shown in the Figure 76 below.

Figure 76 Signalling and interaction data

The frame width, frame length and frame rate are shown in the boxed pictures above. It clearly shows that the frame width and frame length satisfy the HD quality (1280x720). However, the frame rate, although satisfying the HD image quality requirements, fluctuates during the video conference. There are a number of factors that may influence these fluctuation such as CPU performance, network congestion, etc. Identifying such factors was out of the scope of the test.

The sending and receiving frame width and height were also captured on screen as shown in Figure 77 below for a Samsung tablet. The local refers to the video captured by the patient side tablet camera, and the remote indicates the video received by the tablet from CCC. Both show that HD quality frames are correctly exchanged in our WebRTC based video conferencing system.

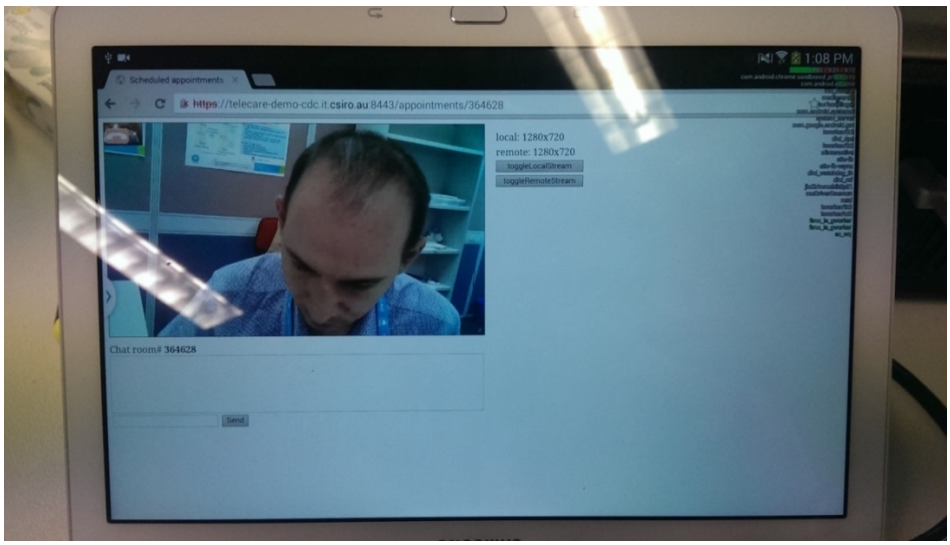


Figure 77 Demonstration of two way high definition 720p video conferencing

8.6 Implementation of telehealth report upload to PCEHR

An original stated project goal was to demonstrate connectivity to PCEHR developments in Greater Western Sydney with the support of the NSW Dept. of Health. However, this proved unachievable and in order to de-risk the project and given that MBS & PBS data was being supplied directly from Medicare, the project team de-prioritised, slipped and re-scoped PCEHR connectivity activities to later in the project schedule.

The re-scoped goals for PCEHR connectivity were;

- Describe how integration was achieved by the project and demonstrate the delivery of vital signs monitoring reports to the PCEHR's Software Vendor Test (SVT) environment.
- Describe telehealth/PCEHR integration approaches for production environments.

The Clinical Information System mentioned at step 3 in section 4.12.1 above was implemented as a web application. Figure 78 shows the user interface of that web application with a selection of SVT test patient records. Some test patients have a PCEHR and all but one have a vital signs report available for upload.

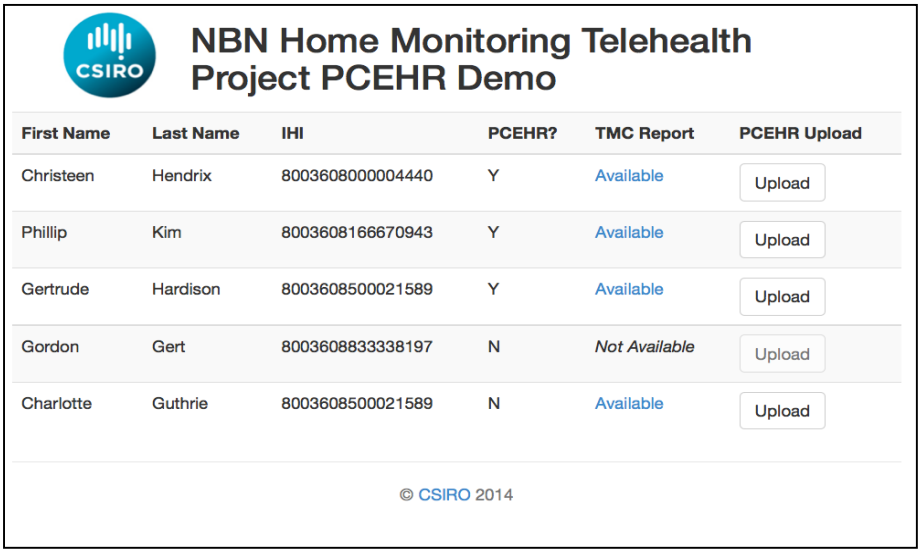


Figure 78 Vital Signs Monitoring Report PCEHR Upload Demonstration

The project team determined the most appropriate PCEHR clinical document type currently available to hold vital signs monitoring report was Event Summary. In the PCEHR an Event Summary is used to capture key health information about significant healthcare events that are relevant to the ongoing care of an individual.

8.6.1 Project PCEHR Integration

Figure 79 below shows a high level contextual view of the relationship between various project components and the PCEHR Software Vendor Test (SVT) environment.

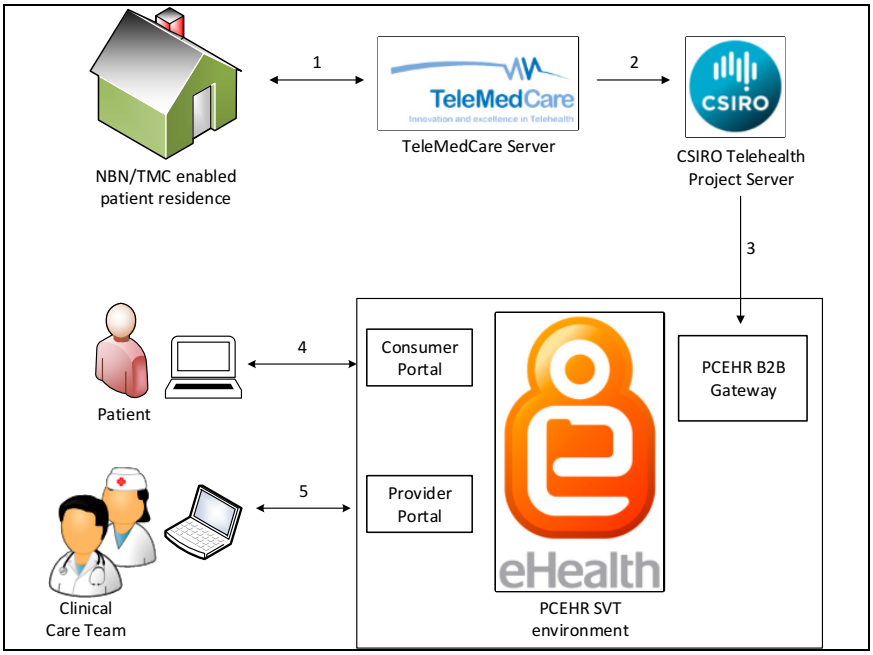


Figure 79 Overview of PCEHR integration

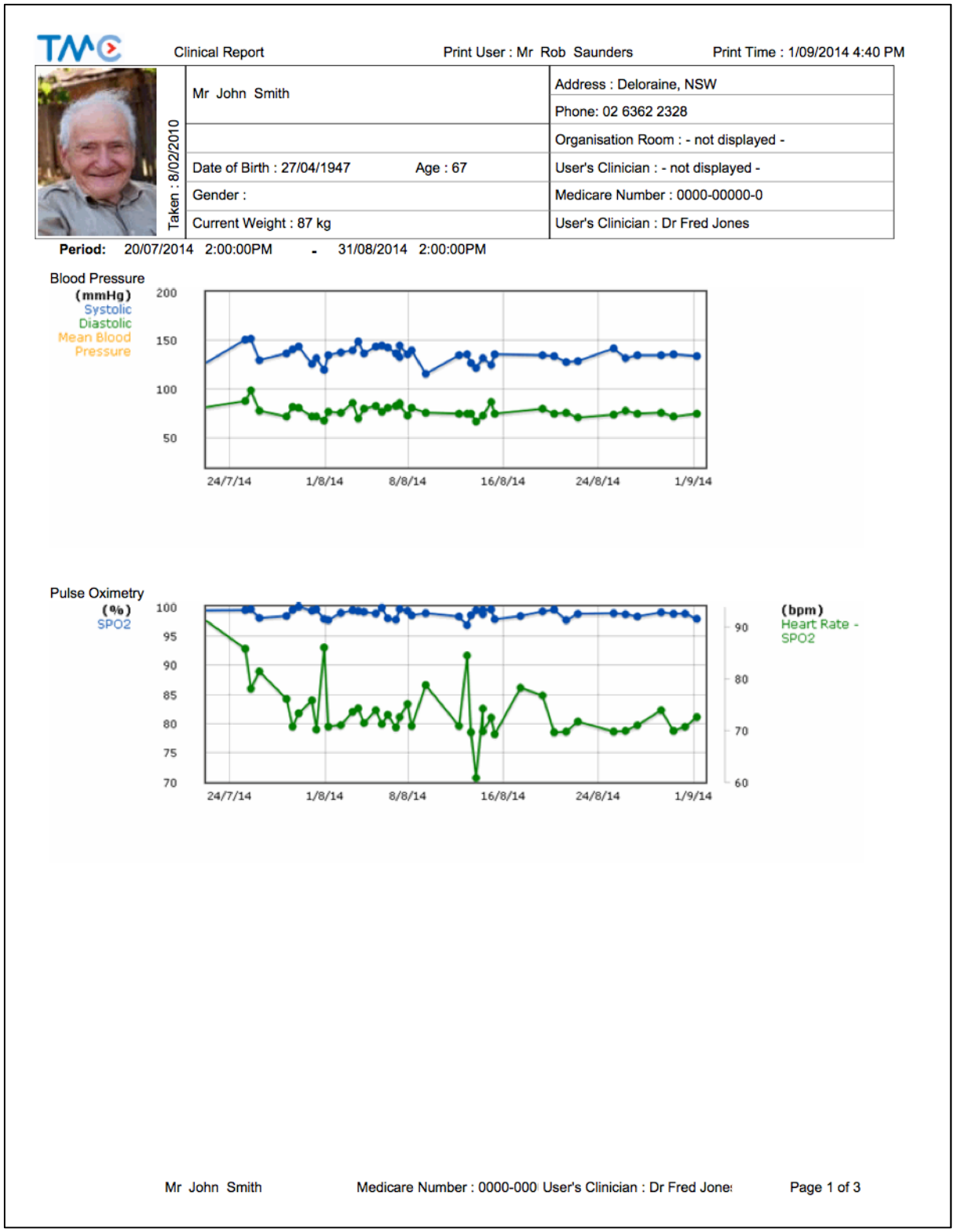
The following labelled interactions between system users and components are shown:

1. The trial participant uses the TMC device in their home. The device sends vital signs and other data to TMC's servers.
2. On a periodic basis TMC sends vital signs monitoring reports to CSIRO's project server.
3. CSIRO software, acting in the role of a PCEHR Clinical Information System within the Software Vendor Test (SVT) environment. This software packages the vital signs monitoring report into an Event Summary XML document, then uploads the XML document to the PCEHR via the Business-to-business (B2B) gateway.
4. Study team members, acting as patients, demonstrate how patients view vital signs monitoring reports as Event Summary records using the PCEHR consumer portal.
5. Study team members, acting as members of the patient's care team, demonstrate how health care providers view vital signs monitoring reports as Event Summary records using the PCEHR provider portal.

This schema was implemented as a test environment as described below.

8.6.2 Example of automatically generated telehealth Report suitable for uploading to PCEHR

The vital signs monitoring report shown below was developed in collaboration with TMC. This example consists of a three-page PDF document.



Clinical Report — Print User : Mr Rob Saunders — Print Time : 1/09/2014 4:40 PM

Taken : 8/02/2010

Mr John Smith	Address : Deloraine, NSW
	Phone: 02 6362 2328
	Organisation Room : - not displayed -
Date of Birth : 27/04/1947 Age : 67	User's Clinician : - not displayed -
Gender :	Medicare Number : 0000-00000-0
Current Weight : 87 kg	User's Clinician : Dr Fred Jones

Period: 20/07/2014 2:00:00PM - 31/08/2014 2:00:00PM

Blood Pressure (mmHg)
Systolic
Diastolic
Mean Blood Pressure

Pulse Oximetry (%)
SPO2

(bpm)
Heart Rate - SPO2

Mr John Smith Medicare Number : 0000-000 User's Clinician : Dr Fred Jones Page 1 of 3

Period: 20/07/2014 2:00:00PM - 31/08/2014 2:00:00PM

ECG

Mr John Smith Medicare Number : 0000-000 User's Clinician : Dr Fred Jones Page 2 of 3

The patient report provided by Telemedcare focuses almost entirely on the reporting of longitudinal vital signs data and Telemedcare acknowledges that a significant visual redesign and an upgrading of the content is required in order for this report to be acceptable to clinicians.

Based on its experience, and understanding of the PCEHR architecture and operational environments, suggests that PCEHR integration for telehealth vendors such as TMC is viable. Vendors will need to choose the most appropriate PCEHR system role from a number of possible alternatives (Clinical Information System or a Contract Service Provider).

An enhancement to the PCEHR identified by this study and in the PCEHR review[20] is the development of a new clinical document type for clinical measurements that would allow clinical measurements to be inserted directly to Electronic Health Records and GP management systems. The PCEHR integration work conducted for this study would have utilised a clinical measurements document type in preference to Event Summary, had it been available, as a more appropriate means of storing vital signs monitoring data.

8.7 Risk Stratification System – Prototype development

The prototype patient risk stratification reports (also called the patient well-being reports) discussed in this section were supplied to Clinical Care Coordinators (CCC) to assist them manage the well-being of patients under their care. These reports could also be used by carers and doctors. Patient well-being reports are meant to be used as an aid to CCCs (not as a final decision tool) and are meant to be used in conjunction with the nurses' clinical experience and background knowledge of the patient.

This report tries to flag statistically significant departures from the baseline measures made on the patient at the start of the study. Choosing the baseline measures as the first 30 days of the patient study period for the comparison point may not be a good idea but it is selected as the start point until we have the nurse feedback on what is appropriate.

Definition of terms

1. **Baseline:** In this report the baseline level is always taken as the first 30 days average measurement. Future measures are compared to this baseline.
2. **Local in time:** Measurements change as the well-being of the monitored patient alters over time, and if the measurement is repeated directly after it is measure it is never the same so we are interested in making a reasonable estimate of the patients well-being now given this measurement uncertainty, this is achieved by taking an average of the most recent observations (called a moving average).
3. **Level:** Level is defined as the average measurement. For example the local level is taken as the moving average value which is regard as the estimate of the local expected measurement for the patient.
4. **Scale:** Scale is used to gauge the natural variation in the patient measures, for example how much do we expect a patient measure to differ in absolute magnitude on average from day to day if their well-being did not change. In statistics this is sometimes referred to as variance or standard deviation.
5. **A change is statistically significant:** This means that the change is large enough to be considered very unusual. Measures vary naturally (they differ from time to time) and the trends from the baseline level needs to be large enough relative to this natural variation to be considered unusual.

[20] http://www.health.gov.au/internet/main/publishing.nsf/Content/PCEHR-Review

6. **A change is clinically significant:** If this measurement shifts far enough to consider that the person's well-being is in danger. For example if someone body's temperature shifts to a level of 39^{o}C then this is mathematically high enough to be of concern.
7. **In-control**: If a patient's measures are predictable within their normal range then we say that the patient's well-being is within statistical control. This is a way of describing that the patient well-being is stable and not wandering all over the place.
8. **Trend**: If a measurement remains on average unchanged, i.e., they are randomly distributed around a fixed level then we say there is no trend in the measurements. However if the level starts moving to lower/higher values in a persistent way then we say that this measure is exhibiting a trend.
9. **Change point**: The change point is the determination of the date when the patient's measurement changes significantly. Two changes are considered. The first are changes in level, for example a body temperature shift from 36.5^{o}C to 39^{o}C. The change point is the day when the measurement started to change from an average of 36.5^{o}C to an average of 39^{o}C. The second is the change in uncertainty or standard deviation which is a measure of the day-to-day variability in the measurements.
10. **Change in magnitude**: This report assumes a step change and estimates the magnitude of these changes only if they are statistically significant, i.e., it estimates what the measure changes from and where it moves to.
11. **Stationary**: Although stationary, in most circumstances, means that it does not move – in this report we refer to it as not moving beyond certain bounds. If we refer to a process measure being stationary we mean that it can wander around a little but it always wanders back to a global average value. In other words, although the measure wanders in a way that neighbouring measures are correlated, it does not wander off to-wards infinity. Most of the measures are like this when in-control. The only measure that exhibits natural wandering behaviour such that neighbouring measures are positively correlated is body weight and in theory these measures, if you survive, are expected to wander within bounds.

All the statistical tests that follow establish significant departure in well-being relative the baseline measures. The expected measure is taken as the mean and standard deviation for the first 30 days of the patient study period (and this is called the baseline).

The report consists of following graphical tools to assist Clinical Care Coordinators:

1. The **Overiew plot (**Figure 80**)** which uses "traffic" lights to flag what measures to look at for the CCC. Each CCC has 25 test patients to care for and there are eight measures patients can take daily. This in total, amounts to a potential 200 (25x8) measure-patient combinations to examine. This overview plot provides the CCC with a snap shot of what measure-patient combinations to follow-up on (i.e., only look at those with red signals should be followed up first, because they indicate significant departures from baseline measure).
2. The **Trend plot (**Figure 82**)** indicates the raw measurement, the average trend in these and flags whether this average trend has departed from the average measure during the baseline period (first 30 days of monitoring).
3. The **Change Point plot for Level (**Figure 84**)** indicates the estimated time point where the level of the measure changed and estimates the magnitude of this change. This only considers step changes and not gradual changes. What we are looking for are rapid large changes in measures. Please note that this approach will regard all changes as step changes and therefore a gradual

change will either be reflected as a level change at some stage, but initially it will be regarded as a change in uncertainty (scale). If the change point line is horizontal without a change then this indicates that there has not been a change in the level of the measure throughout the current study period. Identifying the change point and the nature of the change is a tough applied problem that has not been completely solved in the literature. We start with the simplest change point technology. The change point is important in identifying the hazard event that facilitated the change – identifying these hazards are important for managing a patient well-being risk.

4. The **Change Point plot for Scale (**Figure 84**)** indicates whether the estimated time point where the uncertainty (scale or variance or standard deviation) of the measure has changed and estimates the magnitude of this change. This only considers step changes and not gradual changes. Changes in uncertainty could have two causes. Firstly it could be caused by greater or lesser measurement error. Secondly it would be due to the patient entering into a period of unstable well-being.

Examples of plots and their interpretations are illustrated in Figures 81-88.

Note that trend plots and change point plots are only produced if the overview plot has a red traffic light.

Overview plot

The overview plot offers a view of all patient measures in a traffic light matrix form. The matrix has the number of rows equal to the number of patients and the number of columns is the full number of measures. . An example for Tasmania's patients on the 17 March is reported in Figure 81.

Note the following rules:

- The solid green circles traffic lights indicate when the local measurements do not significantly depart from the baseline average measurements, e.g., patient 53 and systolic blood pressure (SBP).
- Red indicates that the local trend has departed statistically significantly from the baseline average measurements, e.g., patient 2 and measurement body temperature.
- A positive red sign indicates a significant departure on the high-side, that is the more recent measurements are statistically significantly higher that baseline average level.
- A negative red sign indicates a significant departure on the low-side, that is the more recent measurements are statistically significantly lower that baseline average level.

Note that there is a false discovery rate of 1 in 100 days which means that a false significant change is flagged on average every one hundred days.

- If a specific measurement is not taken by a patient then a solid black circle appears for the patient-measure combination, e.g. patient 2 and measure SBP.
- If a specific measurement is never taken by a patient then the patient-measure combination space is left blank., e.g. patient 11 has only measured body weight in the past
- If a measurement is excluded as extremely unusual by the measurement quality assurance process then it appears as a solid orange circle.

This allows the nurse to quickly observe what measurements the patient is taking and what is unusual relative to the baseline average measure and how it is unusual, e.g., on the low-side or on the high-side

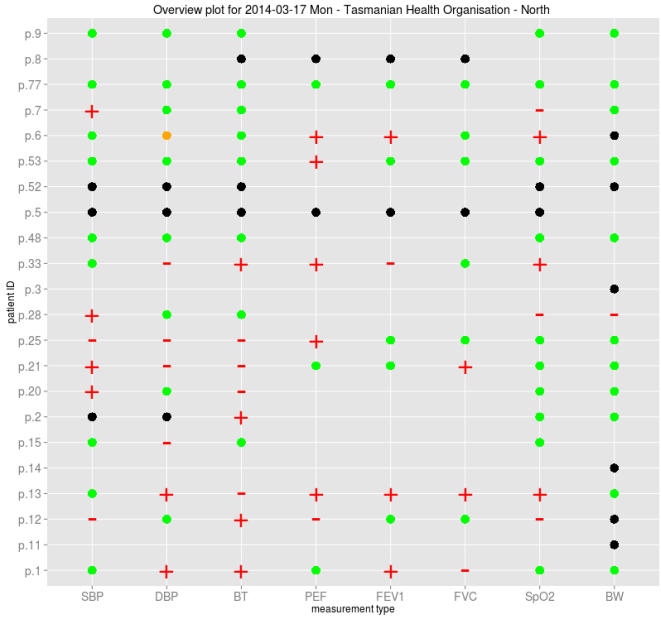


Figure 80 An example of an overview plot for Tasmanian patients

Patient 2 in Figure 80 only measured BT, SpO_2 and BW on the 17 March 2014. Of these only BT and BW flagged a statistically significant change in level from the baseline average value. This patient has never measured PEF, FEV1 and FVC hence these fields are left blank.

Ideally you would want to follow the trends in the traffic light signals from one day to the next to understand what trends are emerging in the suite of measurements.

A Within Patient Overview Plot: Interpreting a patient stability of wellbeing over the past 7 days

The "parallel coordinate plot" is used to display trend over the most recent past 7 days for all measures so that clinicians can get an overall prespective on the patient's current wellbeing relative to the baseline period. This plot attempts to display whether the patients wellness changes recently from the benchmark. The trends in all measurements are used toflag an overall health concern or to flag the need to celebrate a major improvement. This plot is only produced in the report for patients with three or more unusual flagged trends during the last day. It is designed to highlight patient that are either doing persistently better than baseline or unusually badly relative to baseline. The parallel coordinate plot is designed for the nurse to view the overall trends in wellness across all the measures – it may take time getting used to the plot but once user get the hang of it, the plot may prove useful.

An example of the parallel coorinate plot is presented below in Figure 81

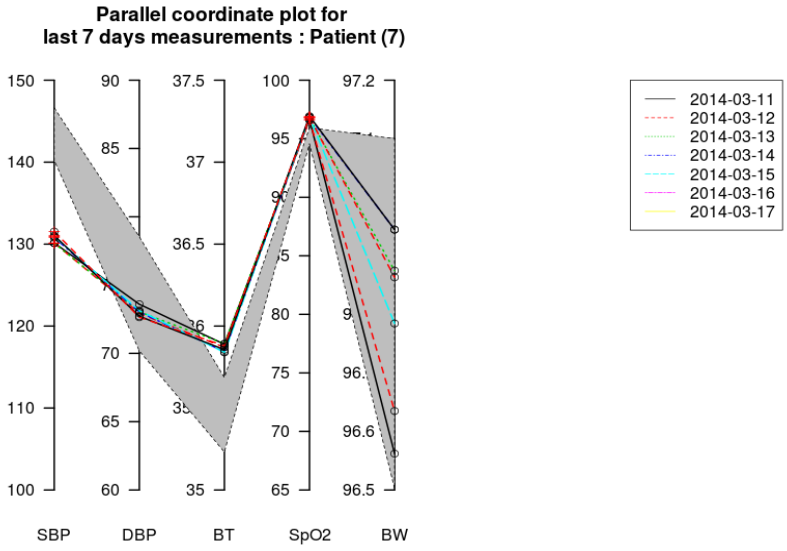


Figure 81 Parallel coordinate plots indicating multivariate trends in a patient's measurement

Figure 81 indicates that patient 7 only measures blood pressure, body temperature (BT), SpO_2 and Body weight. The grey region indicates whether the measurement would expect to be (given the current variation in values) in the level was equivalent to the baseline. Figure 81 clearly indicates that over the past seven days that:

- Systolic Blood Pressure (SBP) has been very consistently below the baseline average.
- Diastolic Blood Pressure (DBP) has not departed from the baseline level.
- Body Temperature (BT) has been consistently above the baseline value but not mathematically (clinically) high enough to be a concern.
- SpO_2 has been consistently higher than the baseline.
- Body weight (BW) in the past week has not departed from the baseline average value.

The fact that there are times when the lines cannot be separated should not be a concern as this is in fact information. It suggests that the measurements are very consistent from day to day. We only want to look at this if several measures are trending away from baseline. This plot is currently only produced for patient with 3 or more significant trends just as a way of restricting the information dump on the clinicians and nursing staff.

Trend plot

The flagged changes in level of measures for a patient in the **overview plot** are indicated by red solid circles. Whenever this occurs in the **overview plot** then the report delivers three graphs. The first graph is labelled the **trend plot**. This is designed to indicate the nature of this change in trend and how far it has departed from the baseline average measure, e.g., Patient 2 in Figure 82 whose temperature shows a significant increase but not to the level that would be a concern (e.g., above 37.5^{o} C). For technical details see Montgomery (2005).

The following information is included on the trend plot:

- The **green line** on the plot indicates the average measure during the baseline period (baseline is taken as the first month in the report).
- The region between the **red dashed lines** indicates where **trend plot** lines should remain if it is not significantly different from the baseline distribution of measures**.**
- The **trend** in the average BT values is the black line in Figure 82 which is the moving average of the measured values.
- The grey region indicates the confidence interval for the smoothed estimate of the local trend.
- If the black line trend remains within the grey shaded region then the trend is more believable.
- If the grey region lies outside the region spanned by the red dashed lines then we are almost certain the patient condition from this measure differs from the baseline.

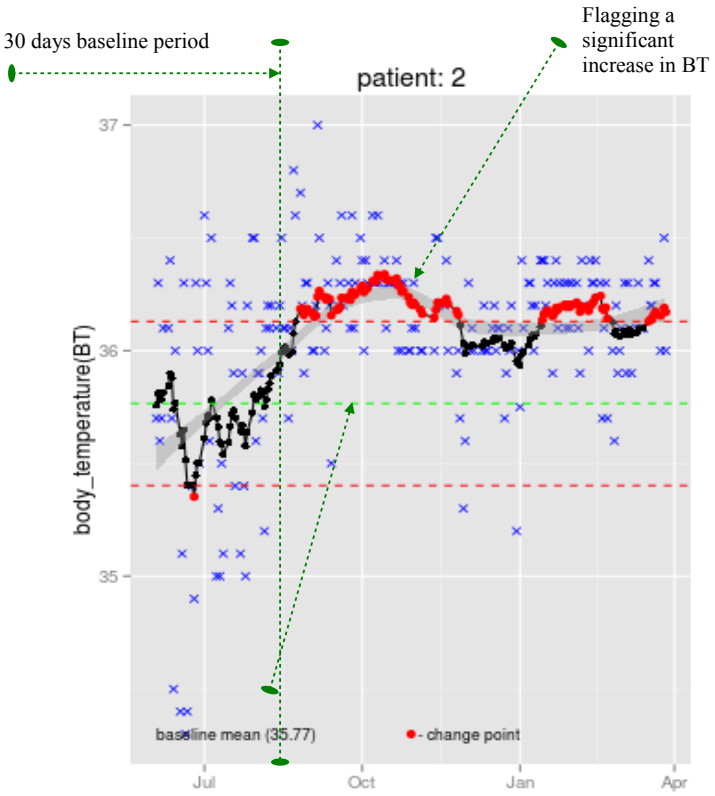


Figure 82 An example of the trend plot for patient 2 from Tasmania

Change point plots

The remaining two plots are change point identification plots (labelled change point & magnitude for level or change point & magnitude for scale plots). This change point is tested over the whole history of the patient measurement process. If a significant change point is detected then the change points are estimated together with the magnitude of the change and then the change is plotted in a graph. Two types of changes are detected (see Capizzi and Masarotto, 2010):

a) Change point & magnitude for level

The change point and magnitude for level plot flags a **step change in the trend** of the measures. The step change trend plot confirms what the trend plot indicates, but change point plot does so assuming that there is a step change rather than a continuous change in level as in the trend plot. The extra information this plot offers on the trend plot is the estimate of the date of the change and an estimate of its magnitude.

Figure 83 indicates a step change in level of Systolic Blood Pressure (SBP) to lower values that occurred in September 2013 but since then the measurement level stabilised at just below 80. The p-value in the brackets of the plot title is the level of significance of the change point, e.g., with p=0 this indicates a highly significant change point.

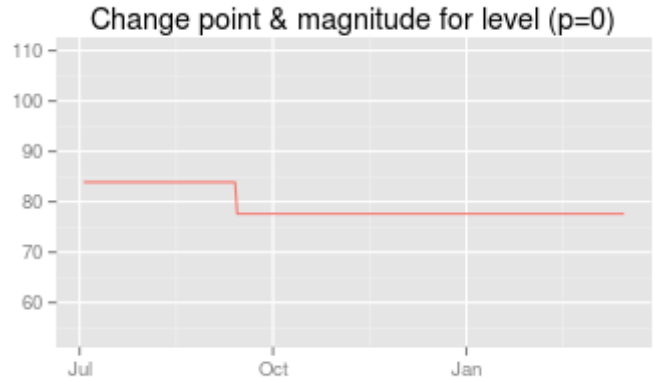


Figure 83 An example of step change in the trend

b) Change point & magnitude for scale

The **step change in the variance** of the measures is the last plot displayed. This change in variance is often referred to as a measure of the uncertainty in the level of the measurement. Uncertainty here is both the small day-to-day movements in level of a measure and the inability to reproduce the same measurement if the same entity is measured again. This tests whether the uncertainty in measures has increased/decreased significantly.

Figure 84 indicates several step changes in the scale of Systolic Blood Pressure (SBP) but these changes bounce around the 2 standard deviation mark. Recently there is greater uncertainty in the measures (e.g., nearly a standard deviation of 3). It is often difficult to interpret this plot but we are largely interested in gross changes in uncertainty not moderate changes that are recorded above. The p-value in the brackets of the plot title is the level of significance of the change point, e.g., with p=0 this indicates highly significant change points the time series plot of standard deviations.

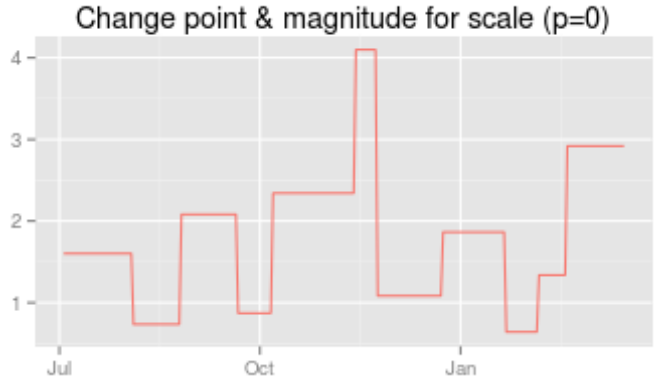


Figure 84 An example of a change point & magnitude for scale plot.

Figure 84 shows a step change in the scale (uncertainty) of the measures.

What does a trend plot look like when it fails to flag a significant trend?

Since a plot is not produced if the patient-measure combination does not flag a significant departure from the baseline, the CCC would not have the knowledge of what the plot should look like when there was no change in the measures from the baseline. The following plot illustrates an example of measures that have not changed significantly from the baseline.

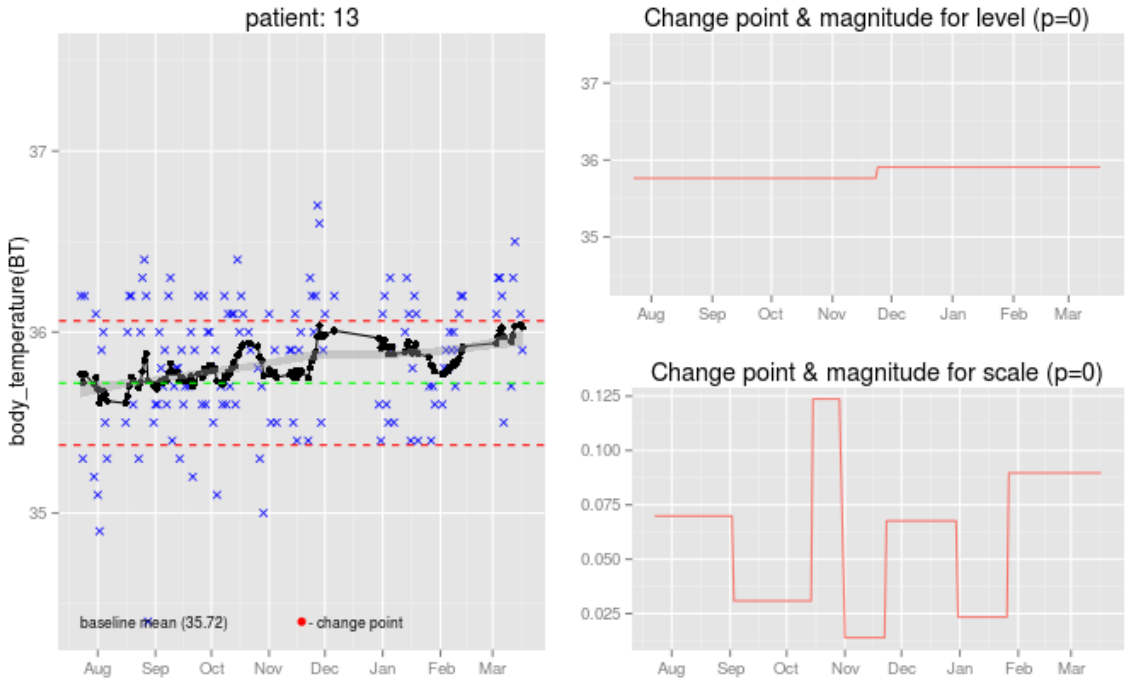


Figure 85 An example of measures that have not changed significantly from the baseline.

In Figure 85 above the trend plot indicates that the local average BT has not moved sufficiently to indicate a significant departure in the measure distribution for the first month. Although the level change indicates a significant increase in body temperature near the end of November 2013 in the level change point analysis, this change is so small in magnitude that it is of no concern and therefore unimportant. The measurement uncertainty is less than 0.1 which indicates a high degree of certainty in the measurement process. Statistically speaking we normally refer to this patient as in-control.

Appendix: Example of plots and their interpretations

Example 1

History of body temperature for patient 1 in Tasmania can be observed in Figure 86 below. This patient started with an average temperature of 36.5°C and there is evidence that the temperature increased significantly from this baseline on two occasions. Although the temperature has increased significantly; it is still well below 37.5°C and therefore is not mathematically high enough to be a concern.

The change point in body temperature is very soon after the first month but although there are other changes in level of body temperature, it always remains within the normal range for BT.

The change in scale happened later but again there are no concerns.

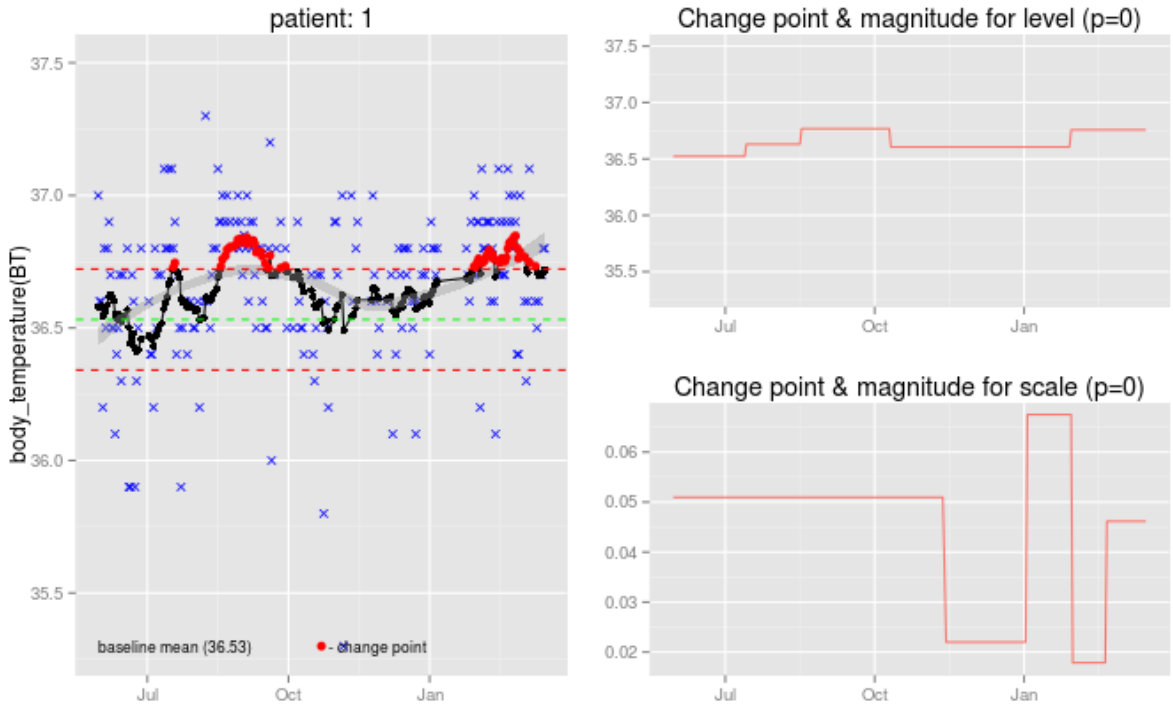


Figure 86 Body temperature values for patient 1

Example 2

SpO_2 values for patient 6 in Tasmania can be observed for the full study period in Figure 87 below. This patient started with an average blood oximetry level of 99.6% in the first month and there is evidence that this has decreased significantly from this baseline in recent months. Although the blood oximetry level has decreased significantly from the start it is still close to 99% and therefore is not mathematically low enough to be a concern.

The change point in blood oximetry level has been observed in the last few months but this change is mathematically negligible.

The change in scale happened earlier after the first month but the change in magnitude of the level is mathematically very small albeit statistically significant.

There is also an increase in the uncertainty of the measures which may need an investigation.

The advice to the nurse is to monitor this patient closely over the next month to see if this down trend persists or stabilises at a level that remains well out of the concerned region.

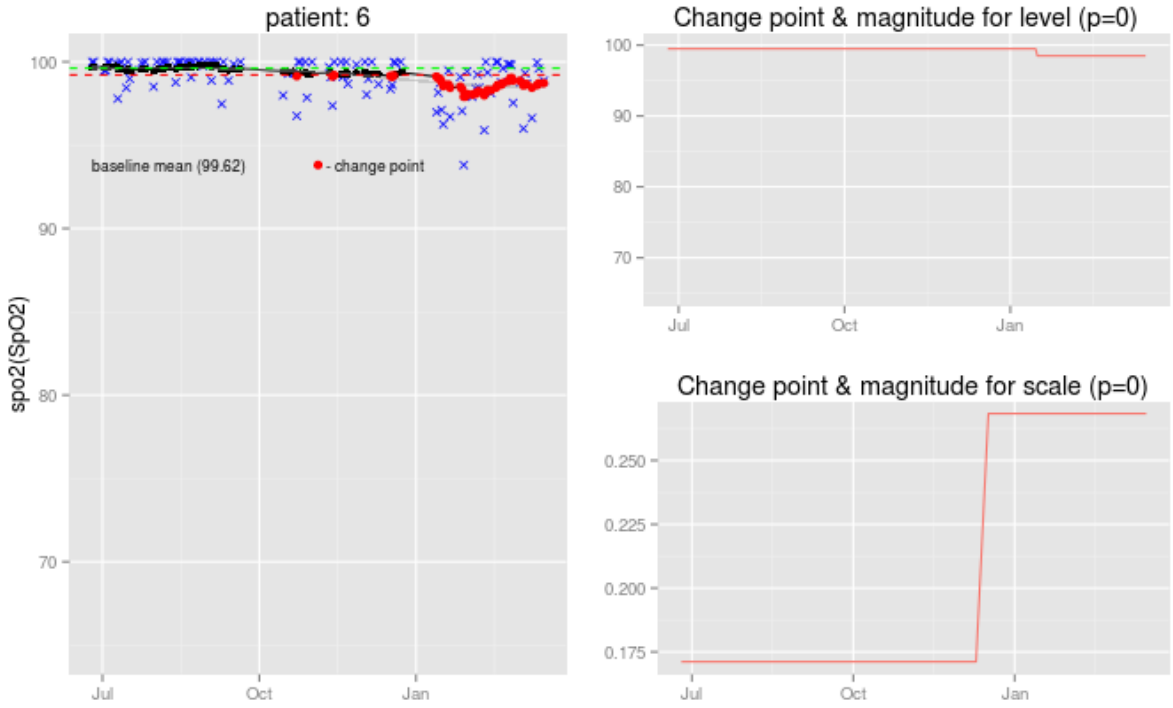


Figure 87 SpO2 values for patient 6

Example 3

We can examine the SBP for patient 7 in Tasmania in Figure 88 below. This patient started with an average SBP of about 144 in the first month and there is evidence that this has decreasing significantly after the first month of monitoring. Although the SBP level has decreased significantly from the start it seems to have stabilised close to 130 on average. This level change has been in the direction of safer levels and now the SBP is not mathematically high enough to be a concern.

The change point in SBP level has stabilised after the first few months.

The uncertainty in the SBP measure (scale) has changed several times but on the whole seems to be reducing slightly over time.

This patient should be congratulated for managing their SBP health well.

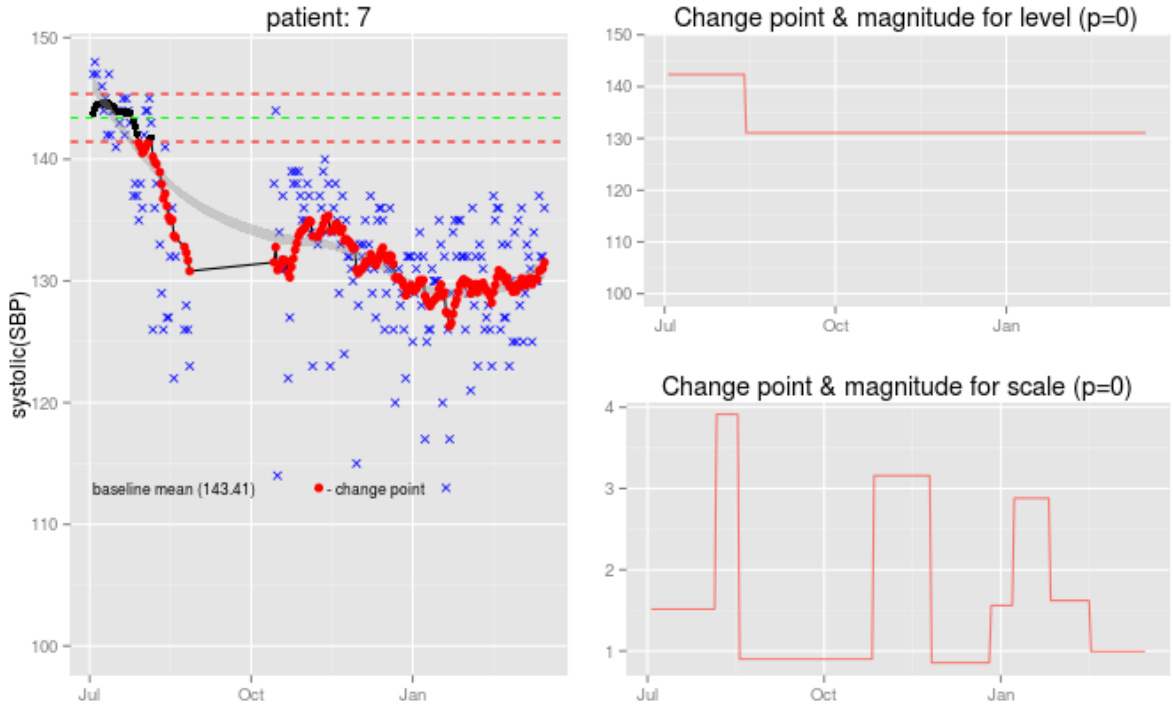


Figure 88 SBP values for patient 6

Example 4

Body weight for patient 9 in Tasmania is reported in Figure 89 below. Body weight is handled differently to all other variables because it is the one measurement that usually is correlated over time, e.g., the last measurement is highly related to previous measurement. Therefore it is assumed to wander naturally and we allow this measure to have a "stationary" trend but we try to determine if this trend is unusually high. The green line here is the one step ahead forecasted body weight which estimates the amount it is expected to wander using past data. We are looking at whether the black line decreases/increases faster than the forecast value.

This patient started with a forecast body weight of about 112.5 kg and within three months this increased at an unusual rate to nearly 125 kg. There is evidence of a rapid reduction in weight in early November and thereafter the chart flags this as an unusual decrease in January and February 2014. However, recently this weight is increasing again. There may be times where this patient was losing weight too fast and gaining weight too fast. It seems that this patient has difficulty controlling his/her weight.

The change point chart tests are based on the assumption that the data are uncorrelated, and since this is not true, the change point analysis for weight should only be viewed as a rough guide.

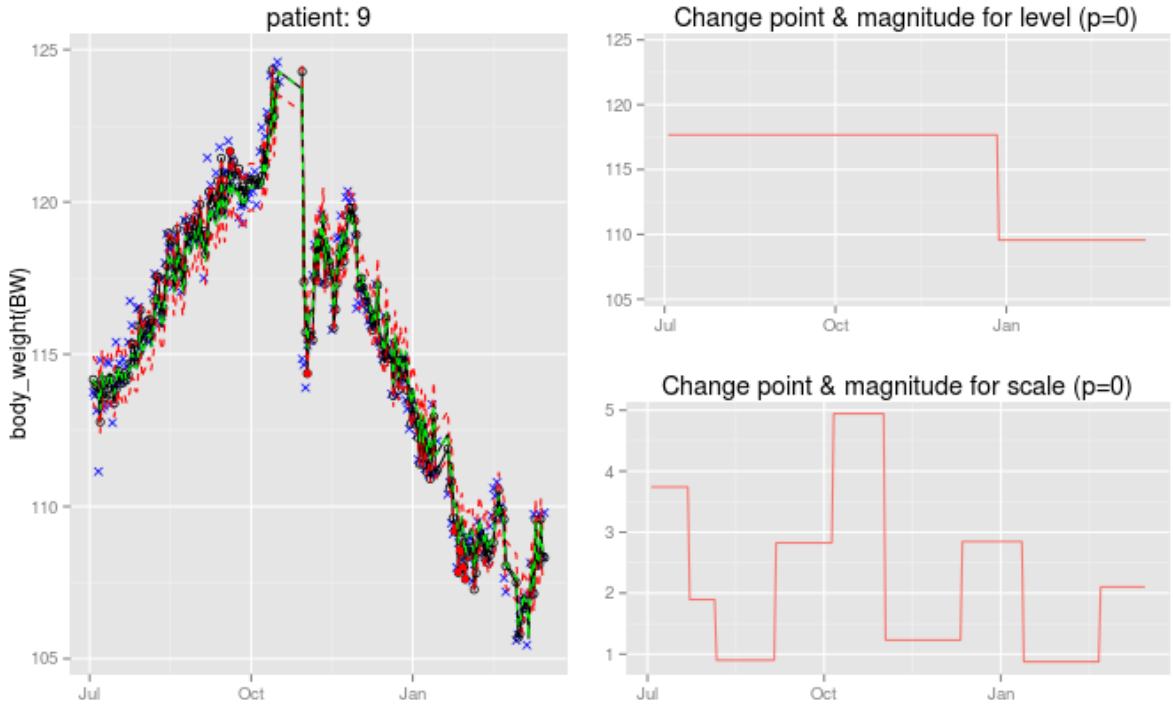


Figure 89 Body weight values for patient 9

Example 5

Body weight for patient 28 in Tasmania is reported in Figure 90 below. This patient started with a forecast body weight of about 69 kg and within three months this was very stable at this level. From mid-February this has steadily increased with several flagged increases. The change point also indicates a change by assuming that this ramping up is a step change and indicates that the change point is later than mid-February. In addition, the uncertainty in BW has also changed in mid-February. This indicates that the charts suggest a period of unstable BW prior to the upward trend.

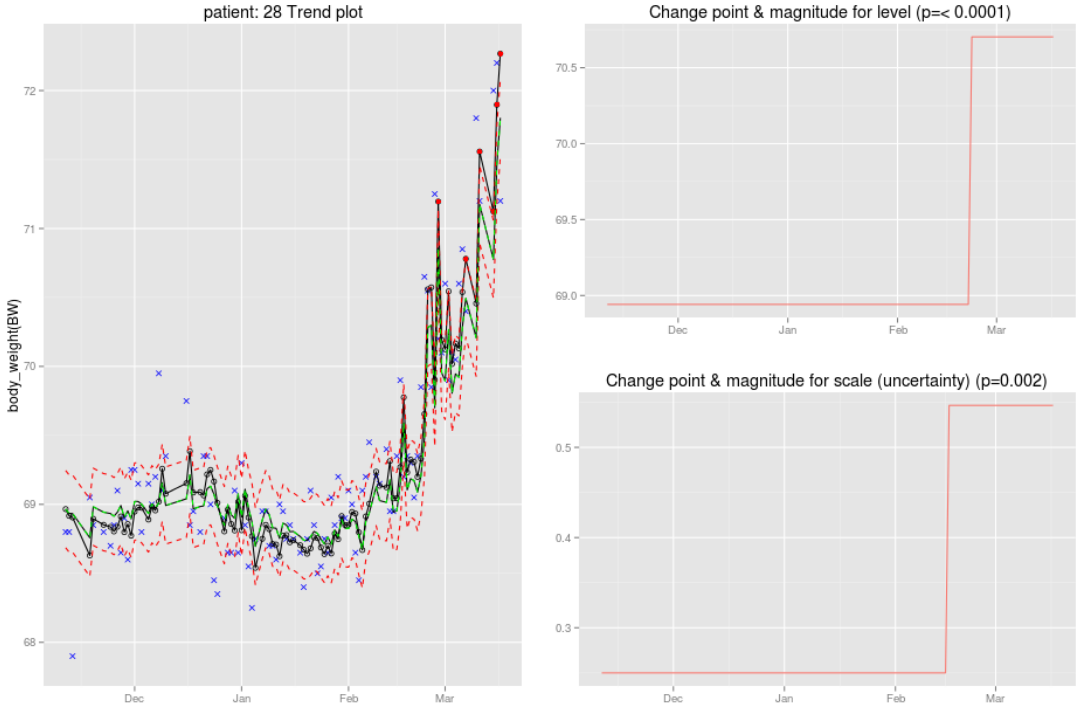


Figure 90 Body weight values for patient 28

Looking at the well-being of a single patient on one particular day

When investigating the well-being of a patient we should examine all flagged statistical significant changes and try to interpret the patient overall well-being using all the available information.

We now investigate patient 2 on a day where the following measures are flagged as having an unusual change: body temperature, body weight, heart rate and diastolic blood pressure. These plots are now explored and interpreted.

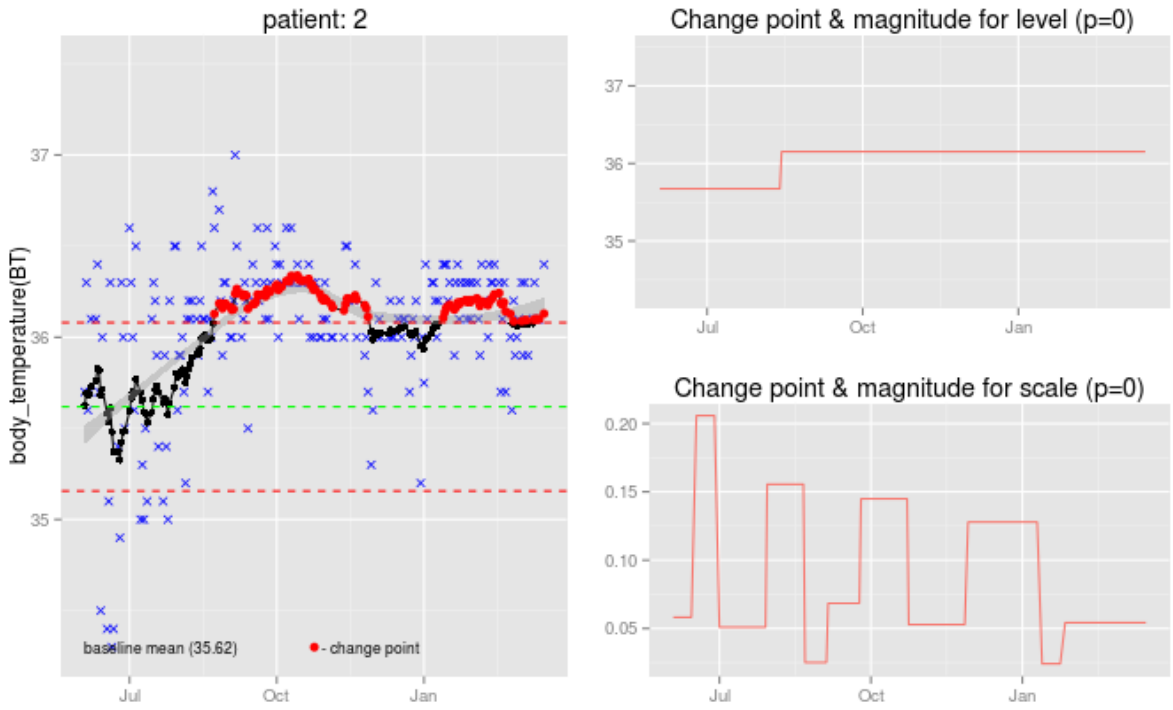


Figure 91 Body temperature of Patient 2 until the end of March 2014

The body temperature has increased (Figure 91) but not to the level where there would be a concern – the smooth estimates of the local average measurement are within the normal range, i.e., less than 37^{o} C. The uncertainty in the measures moves around but the trend is towards less uncertainty.

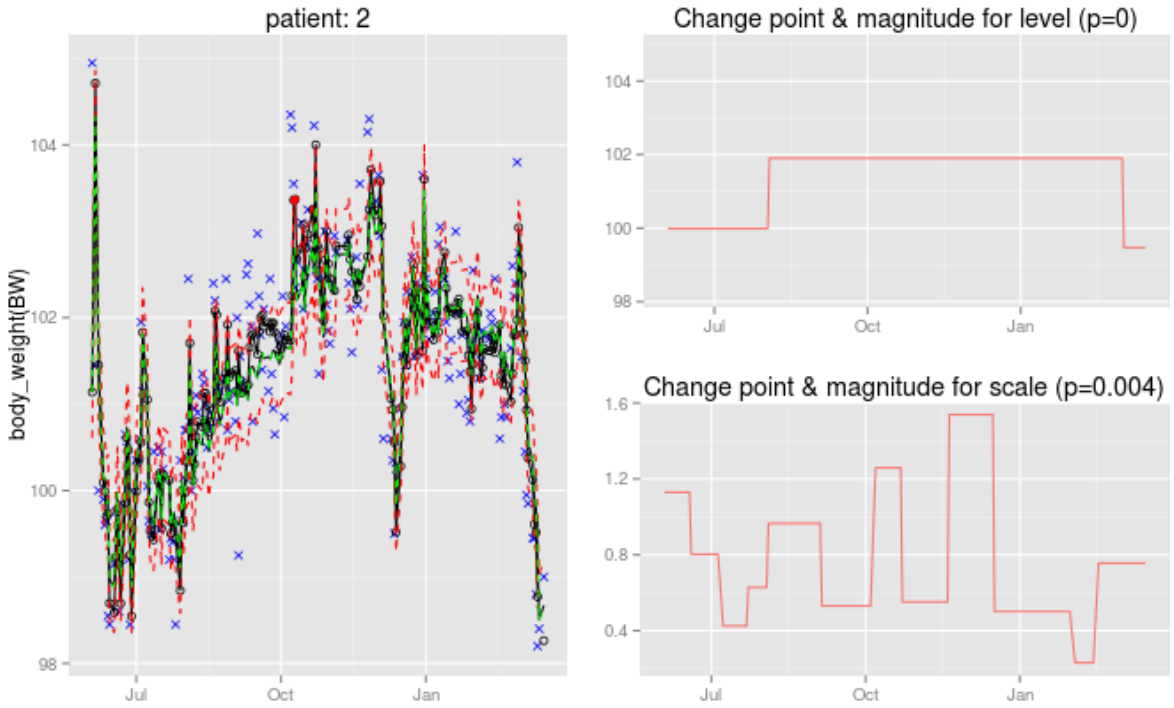


Figure 92 Body weight of Patient 2 until the end of March 2014

Although patient 2 has lost a statistically significant amount of weight recently, mathematically these changes are not high (see Figure 92), i.e., less than 3 kgs. The current average weight is within the historical range experienced in the past. The carer would want to watch whether this trend persists in the next few days or weeks and if it does, then concerns would be raised particularly if the patient is not trying to lose weight.

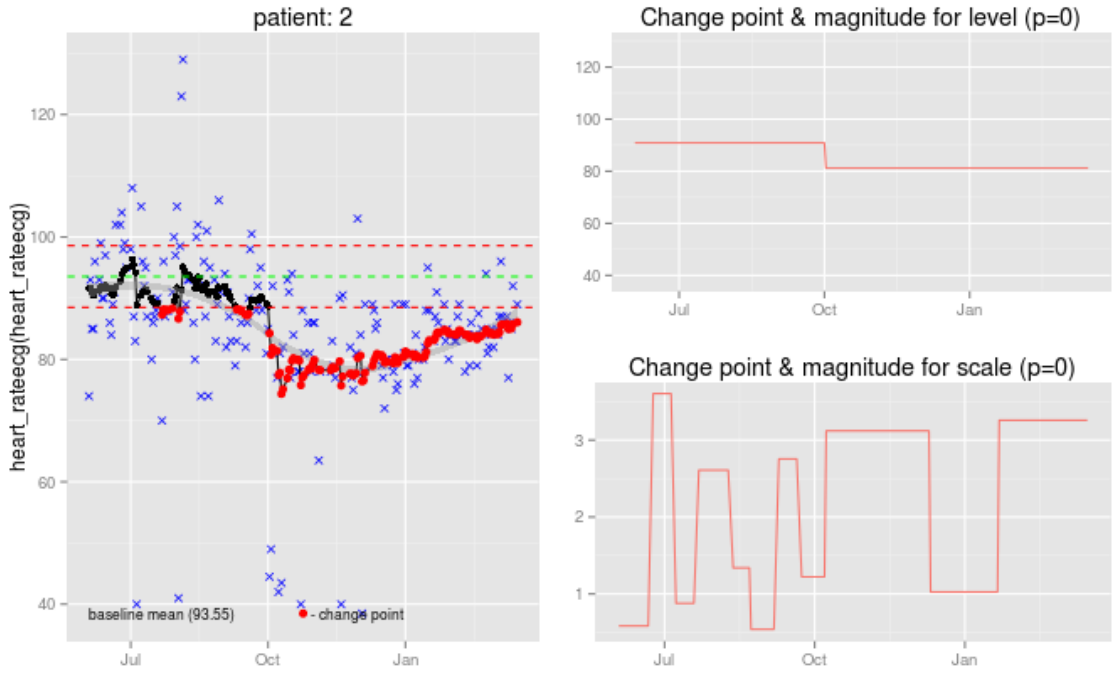


Figure 93 Heart rate of Patient 2 until the end of March 2014

The heart rate in Figure 93 has dropped significantly to a level of about 80 beats per minute but this is well within the normal range and so there are no concerns here, particularly with it progressing slowly back up to the level of the baseline.

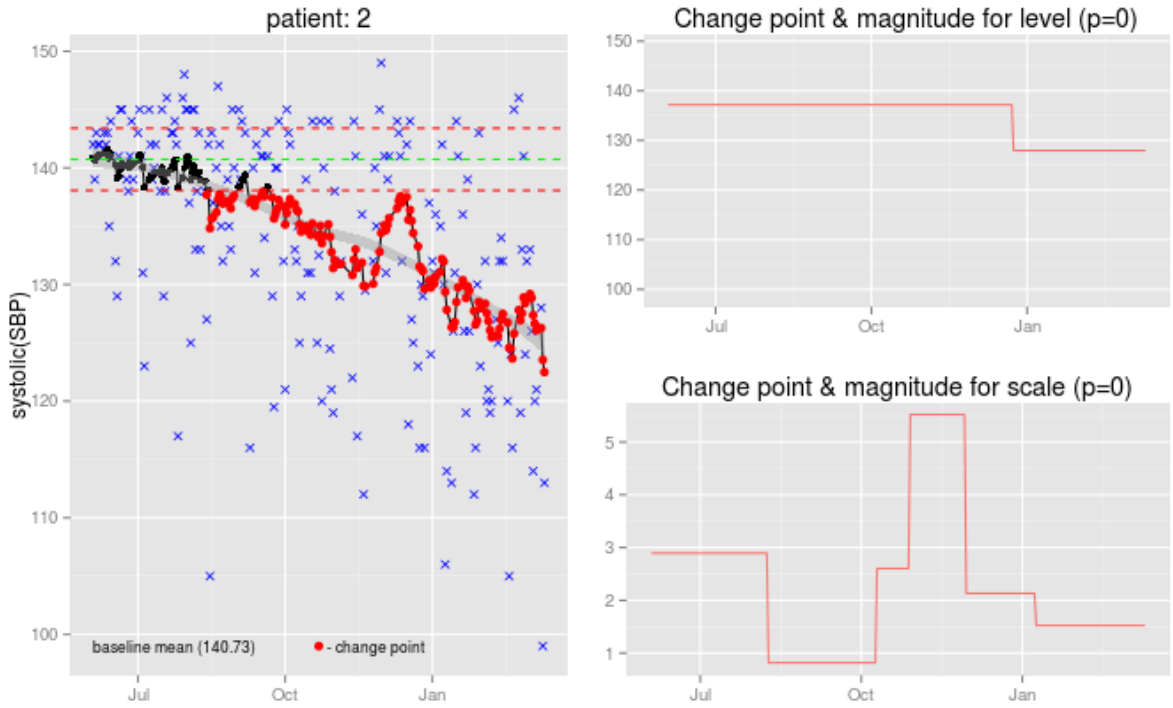


Figure 94 Systolic blood pressure (SBP) of Patient 2 until the end of March 2014

The SBP has dropped significantly from a level of about 140 to a level of about 125 and it has moved within the limits of the normal range (Figure 94). The change point plot is not good at identifying when this change occurred. It suggests the change occurred near January 2014 however the trend plot clearly suggests that the change occurred around mid-August 2013. The trend upwards in early 2014 and late 2013 confuses the change point estimation process.

In summary this patient seems to have improved his/her health outcome where most measures that flagged significant changes were tracking in the direction of better health – maybe this patient should celebrate his/her success.

Some useful rules for monitoring

1. Don't over exert yourself responding to day-to-day variation. Only respond to trends that matter in a magnitude sense (i.e., that clinically raise a concern).
2. Statistical significance is a guide to what is considered unusual. Generally we only consider responding when trends are both unusual and large enough in magnitude to be a clinical concern.
3. Level change points ideally should be match to either a critical event or an assignable cause – **monitoring is mostly about understanding variation and learning from past critical events or assignable causes**. This understanding leads to better control of the patient well-being.
4. Change points in uncertainty are generally less important than trends in level, but often are helpful in managing measurement error. It is important to distinguish between measurement uncertainty due to errors and uncertainty in patient well-being.

Technical details

Some tests are based on the measures being normally distributed and others are based on distribution free tests. The trend plot assumes that the measures are normally distributed to test whether the trend in the local average has shifted enough to flag a significant departure from the baseline average value. Since this test is on the local average it generally will not have the same power as the change point test for finding change points, however on the other hand the trend plot is not restricted to step changes and considers general changes in trend. So if the trend is not a step change the trend plot may offer better inferential judgements (e.g.,Figure 93).

In the change point plot we only check for a step change using a distribution free test, and we only estimate the change point if this change is significant. This is tested at the level of significance of 0.05. The p-value indicates the level of significance of the test – the smaller this is the more significant the change is (i.e., the more certain we are that it is a real change and not a false discovered change has occurred).

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8.8 Reflections of a Project Officer

Before commencing the project I could envisage many benefits of the telehealth home monitoring model with patients with chronic disease. These benefits included improved clinical management of patients in a primary health setting, as well as economic and efficiency benefits to the health system.

I perceived the improved clinical management benefits to include fewer acute exacerbations through early detection and fewer subsequent hospitalisations. This should lead to patients receiving the right care in the right place. It should also improve long term health outcomes for the patients.

Benefits to the health system include reducing the burden on high demand, high cost acute hospital beds. It also has the potential to reduce the burden on sections of primary health care by potentially reducing GP visits. GP visits could potentially be more productive by provision of patient trend data enabling good clinical management decision making.

At this project site, the project has been very successful in achieving all of these outcomes to varying degrees.

The project has achieved some level of integration across a number of health sectors, including acute care, primary care and general practice. The model has been very well embraced in some areas, to the point where GP's are reviewing their patients data online during consultations, and even some GP's are monitoring their patients in between consultations.

What has surprised me is a number of unforeseen or discounted benefits (on my part). The model has provided an added layer of support to patients with chronic disease. Patients have commented on their added feelings of security by knowing that their condition is continually monitored.

The most surprising outcome to me has been the level of empowerment and knowledge the home monitoring has given the patients in their self-management, as well as discussing and managing their condition(s) with their GP's and health care practitioners.

All in all the project has shown significant quality of life benefits to patients as well as benefits to the health care system overall.

Sharon Williams RN
Telehealth Home Monitoring Project Officer
Tasmanian Health Organisation – North
24th September, 2014

9. Publications

9.1 Refereed Journal Publications

1. Sparks, R., Celler, B., Okugami, C., Jayasena, R., & Varnfield, M. (2016) Telehealth Monitoring of Patients in the Community. Journal of Intelligent Systems, 25(1): 37-53. DOI 10.1515/jisys-2014-0123.
2. Jang-Jaccard, J., Nepal, S., Celler, B & Yan, BO. (2016). WebRTC-based video conferencing service for telehealth. Computing, 98(1-2):169-193.
3. Celler, B. G., & Sparks, R. S. (2015). Home Telemonitoring of Vital Signs—Technical Challenges and Future Directions. IEEE Journal of Biomedical and Health Informatics, 19(1), pp. 82-91.
4. Celler, B. G., Sparks, R., Nepal, S., Alem, L., Varnfield, M., Li, J Jang-Jaccard, J, McBride, SJ & Jayasena, R. (2014). Design of a multi-site multi-state clinical trial of home monitoring of chronic disease in the community in Australia. BMC public health, 14(1), 1270.

9.2 Conference Proceedings

5. Celler, B.G., Sparks, R., Alem, L., Nepal, S., Varnfield, M., Sparks, R., Li, J., Jang-Jaccard, J., McBride, S & Jayasena, R.G. et al., (2015). "*Optimizing Point of Care Engagement. Telehealth POC Technologies to Enable Assimilation/adoption in the Aging, Chronically Ill Community.*" Mini-Symposia: 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Milan, Italy, 2015.
6. Celler B.G., & Sparks, R. (2015), "*Model Based Methods for the Analysis of Non-stationary Effects of Telemonitoring as an Intervention for the Management of Chronic Conditions at Home*", 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Milan, Italy, August 25-29, 2015.
7. Celler B.G. Basilakis, J., Goozee, K., Ambikairajah, E. (2015), "*Non-Invasive measurement of blood pressure - Why we should look at BP traces rather than listen to Korotkoff sounds*", 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Milan, Italy, August 25-29, 2015.
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9. Jayasena R, Varnfield M, Li J, Cellar B, Sparks R, Nepal S. (2015), "*Organisational challenges and moving towards a national deployment model for chronic disease management in the home using Telehealth* ", HISA Health Informatics Conference, Brisbane, 3-5 August 2015.
10. Sparks, R., Okugami, C., Good, N., Jayasena, R., Cellar, B., Varnfield M. & Nepal, S.etal., (2015), "*Tele-monitoring of chronically sick patients.*", HISA Health Informatics Conference, Brisbane, 3-5 August 2015.
11. Varnfield, M., Li, J., Jayasena, R., Celler, B. (2015), "*A study on the quality of life and psychological outcomes in elderly patients in home telemonitoring.*" HISA Health Informatics Conference, Brisbane, 3-5 August 2015.
12. Li, J., Alem, L., Varnfield, M. & Celler, B. (2014). "*A study on the implementation of large-scale home telemonitoring service"*. In Proceedings of the companion publication of the 17th ACM conference on Computer Supported Cooperative Work & Social Computing, ACM, pp. 193-196.
13. Celler, B., Alem, L., Nepal, S., Varnfield, M., Sparks, R., Li, J., McBride, SJ, & Jayasena, R. (2014), "*Integrating care for the chronically ill using at home telehealth monitoring*." International Journal of Integrated Care. 2014;14(9).
14. Celler, B., & Sparks, R. (2014), "*Improving the clinical value of at home telehealth*." International Journal of Integrated Care. 2014;14(9).
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9.3 Conference Presentations

16. Celler, B.G., Varnfield, M., Li, J., Jayasena, R., Sparks, R., Nepal, S., & McBride. S. (2016) "*Results of the Australian CSIRO National Multi-site trial of at home telemonitoring*", The Eighth International Conference on eHealth, Telemedicine, and Social Medicine, Venice Italy IARIA eTelemed, April 24-28,2016.
17. Jayasena, R., Celler, B., Sparks, R, Varnfield, M., Li, J. & Nepal, S. (2016). "*Monitoring of Chronic Disease in the community: Australian Telehealth Study on Organisational Challenges and Economic Impact".* Digital Health and Care Congress, May 23-25th 2016, Barcelona, Spain.
18. Celler B.G. (2015), "*Telehealth Point Of Care (POC). Technologies for the monitoring of vital signs at home. Where? How? What technologies are needed?*", 10th EAI International Conference on Body Area Networks. September 28–30, 2015, Sydney, Australia
19. Celler B.G. (2015), "*The New Shape of Healthcare – the role of telehealth technologies and services – the CSIRO trial*", New Shape of Aged Care 2015, October 1-2, 2015, Toowoomba
20. Celler B.G. (2015) "*Vital signs monitoring for the management of chronic conditions at home and in the community.*" AAS and HBPRCA Workshop, University of Sydney, Perkins Centre, 12th September, 2015.
21. Jayasena R. (2015) "*Chronic Disease Management in the Community using Telehealth*", Successes and Failures in Telehealth, 6th Annual Meeting of the Australasian Telehealth Society, Brisbane, 12-13th November 2015.
22. Celler B.G. (2014) "*Telehealth – is this the best that we can do? Predictive Analytics, better monitoring and more!*", Integrated Care – how can technology help. Royal Society of Medicine, London, 24-25 Nov 2014
23. Celler B.G. (2014) "*Lessons from NBN Pilot Projects – Preliminary results of the CSIRO multi-site national trial of telehealth for the management of chronic disease in the home*", Integrated Care – how can technology help. Royal Society of Medicine, London, 24-25 Nov 2014.
24. Celler B.G. (2014) "*Deploying Telehealth nationally – Design and preliminary results from a multi-state, multi-site trial of home telemonitoring in Australia*.", Integrated Care – how can technology help. Royal Society of Medicine, London, 24-25 Nov 2014.
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