Waitemata District Health Board
Best Care for Everyone

THE NATIONAL INSTITUTE FOR HEALTH INNOVATION
THE UNIVERSITY OF AUCKLAND

REMOTE HOME MONITORING FOR CHRONIC CONDITIONS

Introduction

Chronic conditions account for 60 to 70% of all deaths worldwide and are the leading cause of inequality in health outcomes across social groups. As the prevalence of chronic illness continues to increase with our aging population, remote home telehealth monitoring is emerging as a possible means of delivering care in a more cost effective and patient-centred way, overcoming problems of inaccessibility. It has become the biggest driver of the global telemedicine market – a market whose revenue is expected to increase from $440.6 million in 2013 to $4.5 billion in 2018, as the number of patients using telehealth services is estimated to rise from fewer than 350,000 to around 7 million in that time.[1]

How it works: Patients measure relevant biometric data from home daily eg, weight, BP, blood glucose, and monitor their symptoms by answering a series of pre-programmed questions. This information is entered into a telehealth device and sent electronically to the care team for review. If recordings fall outside an individual's target parameters, or no data is received, the care team will contact the patient (by electronic messaging, telephone call or videoconference), to advise appropriate course of action and provide self-management education.

The idea is that self-monitoring, and educative feedback from the care team will teach patients and their families to self-manage their long-term conditions, enhancing quality of life, reducing the burden on health care professionals, and enabling frail elderly patients to manage independently in their homes for longer. Through continual patient monitoring, rather than episodic doctor's

IN A NUTSHELL

Daily remote home monitoring of clinical parameters provides psychological benefit to patients with chronic illness, can improve their ability to self-manage their health, and raises health awareness and literacy levels throughout the family/whanau.

There has been little compelling evidence however, that current home telehealth programs reduce doctors' office visits, hospital admissions or mortality rates.

It is likely that telehealth benefits are restricted to specific, still poorly defined, subsets of patients with chronic conditions, and that more sensitive, measureable, physiological markers of early decompensation will need to be found before telehealth programs will show improved outcomes.

Further refinement is therefore needed, but telemonitoring remains a promising model of future care for NZ as our population ages and the costs of technology go down.

office check-ups, home telehealth importantly also aims to reduce hospital admissions for acute exacerbations of chronic illness by detecting and treating signs of clinical deterioration at an early stage, before a downward spiral necessitates a visit to ED or hospital admission.

In pursuit of this latter goal, the USA has become the world leader in home telehealth care – primarily because US hospitals now face financial penalties for high heart failure readmission rates under the Patient Protection and Affordable Care Act (PPACA). The majority of telemonitoring programs have focused on heart failure, but COPD, diabetes and hypertension have also been included.

Following the trend set by the US, the UK has also targeted home telehealth for the future of English healthcare in its "3million lives NHS England Delivery Plan" – which aims to have 3 million people with long-term medical conditions on home telehealth monitoring by 2017.

Does it work?

With the vast sums of money and service redesign being poured into implementing home telehealth in the US and UK, the implication is that remote monitoring must be a good idea – and intuitively it does seem to make sense – empower people to self-manage their chronic conditions with electronic tools (which are becoming cheaper and more user-friendly everyday)and the burden on health services should go down. Unfortunately however, the evidence that home monitoring actually results in better patient outcomes is far from clear.

Benefits

The good news is that the literature consistently reports that patients seem to love this model of care. Within our local NZ context, the positive qualtitative results from a 2010-2012 trial of home telemonitoring[2], involving both urban and rural populations, were striking:

- **Patients feel looked after and safe** – this was the strongest message received from study participants. Telemonitoring gives patients the peace of mind that a health professional is looking out for them daily. As one 86yr old woman living alone with CHF stated,

  "The psychological benefit is hard to explain … It's magic … it gives me total safety"

- **Patients become more knowledgeable about their condition and learn to self-manage** – as they see first hand the effect of behavioural change on their clinical parameters, and receive feedback from the care team

  "…. It also made me realize that if I had one more prune that night, [nurse] was ringing me up in the next day to say 'why was my blood sugar so high' …So there was definitely education for me. In terms of what I could eat and what foods I definitely couldn't eat"
  – Focus group patient

Staff also found that telecare acted as a catalyst for rapidly increasing patients' health literacy.

- **Patients are motivated to pay increased attention to their health and engage in self-care –** from the knowledge they are being monitored by the care team, and by themselves, on a routine basis. Focus group study participants noted:

  "Telecare pulls you up because you're not the only one that's seen the results"

  "It helps keep me focused on my well-being"

  "I need to rely on that machine as a monitor because I can't see inside me … those machines that you've given us have given us a better appreciation of where we are at in life"

  "It's given me a routine – so now I check my blood sugars more frequently".

- **Increased and more convenient access to health care -** Telecare can help engage people in their healthcare when they were unable to do so previously due to distance/employment context. For example, one diabetic study participant had always had difficulties attending clinic appointments due to his work as a long distance truck driver. With telecare, he established a routine of testing his blood sugar during work breaks and entering them into the hub device when he got home late at night. The nurses would then ring him the following day if needed.

- **Shift in clinical roles from doctor to nurse-led care –** Telemonitoring programs are mostly nurse-led. In New Zealand, this involves a 'cultural' shift for patients who are generally used to seeing the doctor for all consultations and medication changes, as well as an expansion to the scope of nursing roles, particularly in primary care. The NZ trial patients were accepting of this change; they reported enjoying the convenience of not having to go to the doctor for routine check-ups, and valued not 'being a nuisance to the doctor' as the nurse-led telemonitoring program 'took the weight off the doctors'.

  A primary care nurse felt that telecare increased her profile with patients such that they were confident to approach her rather than a doctor:

  "I find it's been good. A lot of the people who would normally come th=ot the doctor two or three times a week… they'll ring me and they'll say 'I need to see the nurse because my blood pressure is up a bit' …

- **Positive effects of family involvement** – home telemonitoring often increased family/whanau attention to, and support for the patient, which acted as an encouraging/motivating factor in self-management. In some cases, the telecare process triggered family collaborations that enabled patients to engage in self- care, when previously they would have not have considered doing so. For example, one woman with many years of poorly controlled diabetes, trained up her husband to use the telecare hub device, so that she could take her recordings while at work, then ring her husband with the information and he would enter it into the hub for her. Her husband valued being able to keep an eye on her health and the knowledge that he was playing a crucial part in improving her quality of life.

"It's good for the whole family because it helps us watch our blood pressure"
– Male, Maori,48yrs

"My grandchildren think it's a buzz – they like to get involved" – Female, Maori, 57yrs

Staff saw family involvement as a promising advantage of telecare and one primary care manager thought this was the strongest reason to provide the service.

"... the clinicians were saying [telecare equipment] would actually assist in not just the individual's awareness but a whole whanau in terms of just increasing their awareness about health issues and how they might overcome those issues"

"... a generation of tomorrow will benefit from the experiences and input that we are going through."

- **Staff are generally positive about the telecare model** – All staff in the NZ trial could see the potential benefits of telecare and , after some initial technical problems, many felt that telecare enabled them to effectively monitor more patients.

Inconclusive evidence of improved outcome

Despite the positive patient and provider experiences with remote telehealth, whether telehealth actually improves patient outcomes remains unclear. While some US health providers such as the VA and Duluth Heart failure programmes (see case study) report impressive reductions in hospital readmission rates and cost savings, others have not. The Cleveland Clinic recently stopped its post-discharge home monitoring for heart failure because it was not producing the results (of lowered readmission rates) hoped for.[3] Several recently published large scale randomized controlled trials measuring the effects of telehealth have produced mixed results.

The UK's 3 million lives program grew out of the UK's Whole System Demonstrator (WSD), the largest randomized telehealth trial to date, involving 3230 patients across 179 general practices in three areas of England, which began in May 2008. The WSD found that home telehealth did not make any significant difference to the number of general practitioner or practice nurse contacts or in the total numbers of clinical recordings on the general practice systems.[4] There was no increase in quality of life or psychological status.[5] Compared with controls, telehealth was associated with a staggering 45% lower mortality and 20% reduction in emergency admission rates[6] – although this was largely contributed to by an unexplained large increase in ED admissions in the control group at the beginning of the trial (possibly due to the trial recruitment process). Length of hospital stay was reduced in the telemonitored group by 0.64 days. It is evident however, that the study contained multiple variables making it difficult to draw meaningful conclusions. There was no attempt to standardize technologies or monitoring systems across the participating study sites. The study examined a range of differing medical conditions (COPD, CHF and diabetes) with no differentiation of clinical severity - without analyzing the effect of telehealth on each condition separately. Possible bias from cluster randomisation (GP practices either assigned

to the telehealth or the control group) included different skills levels of nurses and carers, the degree of cooperation by individual practices, and differences in practice populations eg age ranges, ethnicity.

A 2011 Cochrane Review meta-analysis[7] concluded that telemonitoring appeared to be effective for CHF management. Eleven RCTs of telemonitoring were reviewed, involving 2710 patients. Telemonitoring reduced all-cause mortality (number of deaths fell from 150 per 1000 in control group, to 100 per 1000) and CHF-related admissions (falling from 285 per 1000, to 225 per 1000). Patients reported improved quality of life, some studies reported reduced costs, and the intervention was acceptable to patients. Improvements in prescribing, patient-knowledge and self-care, and functional class were also observed.

However, other recent large studies published such as the TIM-HF[8], Tele-HF[9], HIM-HF[10] trials, and the largest single RCT of telehealth for COPD (Scotland, 2013)[11] have shown no benefit from telemonitoring programs for CHF, COPD or multiple comorbidity, in terms of hospital admission rates or mortality. The Scottish study concluded that the positive effect of telemonitoring seen in previous trials could be due to enhancement of the underpinning clinical service rather than the telemonitoring communication.

Although the lack of positive outcomes from these studies may seem to cast a dim picture of home telehealth, the results must be interpreted with caution. The trials conducted have been heterogenous in their intensity and duration of telemonitoring, the type of technology used, disease management interventions offered, patient populations targeted, and the 'usual care' offered to the control groups. Furthermore, the speed at which technology is advancing (both in terms of affordability and user-friendliness), makes many of these results irrelevant in the context of today's latest home telehealth devices. The value of these studies is the insight they provide into what *doesn't work,* or what to avoid in future telehealth design and implementation. For example, the large scale Tele-HF study, which required heart failure patients to firstly measure their vital signs, and then telephone an interactive voice–response system and respond to questions using the telephone keypad, had very low patient engagement - with 14% never using the system and only 55% still making at least 3 calls per week to it after 6months. Taking this into account, the study's lack of positive outcome in terms of mortality or hospital readmission rate is not surprising; but of greater interest, is the implied user-unfriendliness of the specific technology utilized in this model.

What emerges is a picture of home telehealth that is likely to be effective for a specific subset of patients with long-term conditions, when integrated into a co-ordinated health system and social care system, particularly as more sensitive and specific biometric markers become measurable with minimal patient involvement. Further study is required to more clearly define the characteristics of this target patient population, the type of clinical data

to be collected, and local cost-effectiveness. However, the following conclusions can be drawn from analysis of the literature and trials conducted to date.

Conclusions

The success of a home telehealth program hinges on the following factors:

1. **Patient selection**:
    - Only choose patients (or patients with carers) who perceive at the outset that home telehealth is useful to them and that the technology is easy to use. These are significant predictors of compliance with frail elderly and their carers.[12] [13] Patients who prove unable to comply with the program should be returned to standard care, to allow others to utilize the telehealth equipment.
    - Currently, the model seems most suited for patients at high risk of readmission – the so-called "frequent fliers". Once the patient is stable, and education/self-management confidence achieved, then they can be taken off the home telehealth program. Generally, this would be expected around 12months, subject to individual variation. Compliance by these 'expert patients may likely drop off anyway, as compliance is related to patients' perceived usefulness of the telehealth intervention to manage their health.
    - Home telemonitoring is unlikely to produce improved quantitative health outcomes in stable patients who have alternative high quality care available to them – such as an easily accessible multidisciplinary specialty outpatient follow-up programs (TIM-HF study). Correspondingly, in NZ, the most striking stories of personal and family engagement came from the rural community, which has traditionally been underserved. Telemonitoring may therefore be better suited to primary care management, or patients who do not have access to specialist level heart failure programs (due to location or lack of resources at secondary care clinic).

2. **Monitoring Device selection:** Patient compliance with a remote monitoring program is highly dependent on the usability or userfriendliness of the electronic devices involved. Tablets and smartphones are paving the way of future home monitoring. Important factors include:
    - Aesthetics and consumer experience; sensor technology is continually improving to produce more smaller, discreet, and often continuously wearable, wireless devices that can link to a mobile phone apps to capture data such as activity levels, heart rate variability, blood glucose, blood pressure, and weight.
    - Portability / Wirelessness; allowing patients to continue with the program while travelling, at work, or on holiday. The pervading growth of smartphones and into everyday life dictates that mHealth platforms for chronic disease monitoring are

the way of the future. 60% of New Zealanders now own a smartphone – and the number continues to rise. Global mobile data volumes are expected to increase 11-fold in the next 4 years. Steve Jobs' famous prediction that we are moving into a Post-PC era has become a reality - Americans now use smartphones more than computers, according to a Nielsen Digital Consumer Report (spending on average 34 hours per month using mobile apps and mobile web browsers, vs 27 hours a month online with their PCs). Most recently, Apple has just launched a new health app called "Health" and a cloud-based health information platform, "Healthkit". The Health app will constantly monitor key health metrics (eg, blood sugar or blood pressure), and if any of them begin to move outside the healthy range, the app will automatically send a notification to the user's doctor. The app will share all its information with "HealthKit" – which is designed to act as a global repository for all the user's health information. Healthkit will also accept data from various third-party devices and apps eg, Nike's health and fitness apps are now being integrated to work with HealthKit. Apple consulted Mayo Clinic doctors to incorporate ways for healthcare providers to access and add to patient information in HealthKit. The company has also been working with Epic (electronic patient records company), along with a large group of hospitals, to devise ways for HealthKit data to be made available to hospital information systems.

- Ease of use: With regard to measurement of vital signs at home, systems that automatically download the biometric data to the remote monitoring station as soon as the patient steps on the scales for example, rather than requiring the patients to enter their recordings manually, are more convenient, less prone to error and likely to achieve higher compliance. Basically, the less patients have to do the better. In the only trial to find significant benefit from heart failure telemonitoring, data was transmitted automatically from cardiac implants to the remote monitoring unit. The lead researcher, Dr Gerhard Hendricks speculated that the success of the trial may be largely due to the absence of patient involvement.

The home telehealth model also involves symptom tracking, patient education modules, and provider messaging/feedback. Devices that are easy to read, easy to hear, and easy to type on are particularly important in the frail elderly group of patients, for whom utilisation of new technologies has traditionally posed challenges. Tablets, with their portability and connectivity, and large, userfriendly, colourful touch screens, are proving to be among the most promising devices for remote data monitoring. A recent Mayo Clinic iPad trial[14] for cardiac surgery patients showed an unprecedented level of 98% patient engagement among 149 patients aged 52 to 85years – who were repeatedly

described by study leader, Dr David Cook, as "70-year-olds on morphine", utilising iPads to complete educational modules and to record their pain scores and activity levels, using a specially created app called My Care. Built in algorithms alerted providers to deviations from expected recovery, for both pain and mobility – allowing for example, a physical therapist to be sent in without a physician ever having been notified. While the pilot study involved post-operative inpatients only, Dr Cook saw the model as applicable to chronic disease in the home setting, conditional upon improved security and EHR integration being achieved.

3. **Data selection –** measurable indices of disease that can accurately detect decompensation early enough to allow effective intervention. The ability of home monitoring to reduce ED/hospital admissions and mortality, relies on the fundamental assumption that the physiological data monitored is capable of facilitating early detection of clinical deterioration, allowing corrective intervention to avert adverse clinical outcomes. The patient data collected must help to accurately anticipate decompensation with sufficient lead time to permit intervention. The equivocal outcome results of the numerous telehealth trials suggest that the physiological data currently being collected in telehealth programs may not be sensitive enough to allow effective early intervention – explaining the counter-intuitive observation that increased physiological surveillance added little or no benefit over usual care. Lending support to this conclusion, are the promising results of the 2013 European 'IN-TIME' trial[15] – the first trial to show that home monitoring can significantly benefit outcomes for heart failure. In contrast to the usual parameters of weight, pulse, brachial BP, and symptoms, that are routinely monitored in heart failure programs, the IN-TIME study monitored patients' electrophysiological data, captured by their implanted cardiac devices eg, arrhythmias, heart rate variability, activity, percentage of ventricular pacing. From this, clinicians were able to detect distinct trends in clinical parameters that precede clinical events, sparking early medical intervention that reduced hospitalizations, reduced all-cause mortality, reduced cardiac mortality, and improved clinical condition compared to usual care at 12 months. There were two other important variables that set this trial apart from previous studies – including a clearly delineated target population comprising the subset of heart failure patients with an indication for implantable cardiac defibrillators (ICD) or cardiac resynchronization devices (CRT-D); and the absence of any patient involvement in transmission of data (cardiac implants were programmed to transmit data automatically). It seems likely that all 3 factors contributed to the beneficial trial results.

4. **Disease selection** –following on from above, only those long-term conditions that are easily tracked through measurable physiological data; and in which early intervention *will actually* prevent acute decompensation, are suitable for remote health programs.
   Heart failure is seen as a chronic condition suited to remote monitoring because hospital admissions are often preceded by several weeks of small, apparent increases in filling pressures – providing a window of opportunity for remote surveillance to detect impending decompensation and intervene early, largely by adjusting diuretic doses. In any home monitoring program for heart failure, an accurate estimation of volume status is therefore critical. However, remote providers do not have physical examination findings (eg, JVP, pulmonary crepitations, peripheral oedema, S3 gallop), or serum electrolyte and renal function measurements available to them, which collectively, can give a reasonable estimation of cardiac filling pressures. Instead, telemonitoring data is typically limited to the patient's vital signs, weight, and symptoms – and the predictive utility of these to improve clinical outcome is questionable. Studies have shown that while rapid weight gain is a relatively specific predictor of heart failure decompensation, it is not a very sensitive marker (fewer than 50% of patients gain > 0.9kg prior to hospitalisation for decompensation) and may be inadequate to recognise impending decompensation in sufficient time to intervene to prevent hospitalization.

5. **Cost-effectiveness and affordability of implementation** –there is much interest in the potential for telehealth to reduce the costs of chronic disease care, while maintaining or improving patient outcomes. However, evidence on the effect of telehealth on service use and cost effectiveness remains scarce and mostly conducted overseas, which may be of limited relevance to NZ. A cost effectiveness study (2013)[16], of the WSD trial in the UK concluded that "Telehealth does not seem to be a cost effective addition to standard support and treatment". This was not surprising given that patient outcomes with telehealth were not significantly different to outcomes with standard care – the evidence suggesting that to be cost effective, telehealth would need to be implemented at a large scale.
   In New Zealand, cost was the prohibitive factor in continuation of a telemonitoring pilot for chronic disease in Auckland in 2012. The communication costs paid to Docobo (the UK healthcare solutions company that supplied the "healthcare hub" telemonitoring devices, collected the data and relayed it to the local monitoring stations) were almost half the total ongoing costs during the trial - a rate that was not sustainable for the DHBs longterm. The study team concluded that there would be major benefit in exploring whether the telecommunications and infrastructure could be either developed internally within Waitemata DHB, or purchased to be provided internally.

[1] http://www.clinical-innovation.com/topics/mobile-telehealth/successful-telehealth-driving-market-growth
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[3] http://www.beckershospitalreview.com/quality/when-readmission-programs-fail-what-s-next.html; and Cleveland Clinic Journal of Medicine January 2013 vol. 80 e-Suppl 1 e-S20-e-S26 http://ccjm.org/content/80/e-Suppl_1/e-S20.full)
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