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Results from Telehealth

Malcolm Clarke

Abstract

Telemedicine and telehealth have a wide range of definitions and understanding. Telehealth has been described as taking many forms and having many terms to describe its activities such as; home health care, telecare, tele-dermatology, tele-psychiatry, tele-radiology, telemonitoring, and remote patient monitoring. In general, the purpose of telehealth is to acquire information on a patient in one location, make that information available in a separate location, usually for the convenience of the clinician, and then use that information to provide management to a patient, who may be in a further location, through the mediation of a remote clinician, or directly to the patient. Typically this has taken the form of the patient being in their own home or at a clinical establishment remote from the hospital such as the district hospital, remote clinic, and primary care, with clinical information being collected and transferred using technology between locations. This chapter focuses on results from telehealth in the form of remote patient monitoring (RPM), in which data is collected from the patient whilst they are in their own home, or other non-clinical setting such as residential care.

Keywords: telehealth results, telehealth outcomes, remote patient monitoring, RPM, cost-effectiveness, patient benefits, telehealth technology

1. Introduction

The earliest form of telehealth was via telephone, which has included patient-doctor consultation, doctor-doctor (specialist) for advice and referral, and clinician (nurse) led structured telephone support, with the first reports of management of chronic disease appearing in 1995 [1]. This review [1] shows a steady increase in the number of reports from telehealth from 1995 to 2011 (**Figure 1**), with the greater number of reports being on management of diabetes, followed by congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD), with smaller numbers for asthma and hypertension. There has been continued growth and the Covid pandemic of 2020 has caused significant increase in its use.

Telehealth has mainly been favoured in locations where significant distance between parties is involved, such as between primary and secondary/tertiary care, with most of the results being reported from countries such as USA and Australia, where significant distance between sites is involved. In a review [2], more than 50% of reported results were from USA.

Telehealth has been applied in many applications. **Figure 2** shows the range identified in a review of reported successes and failures [3], together with the perceived advantages that were provided in the studies in **Figure 3**.

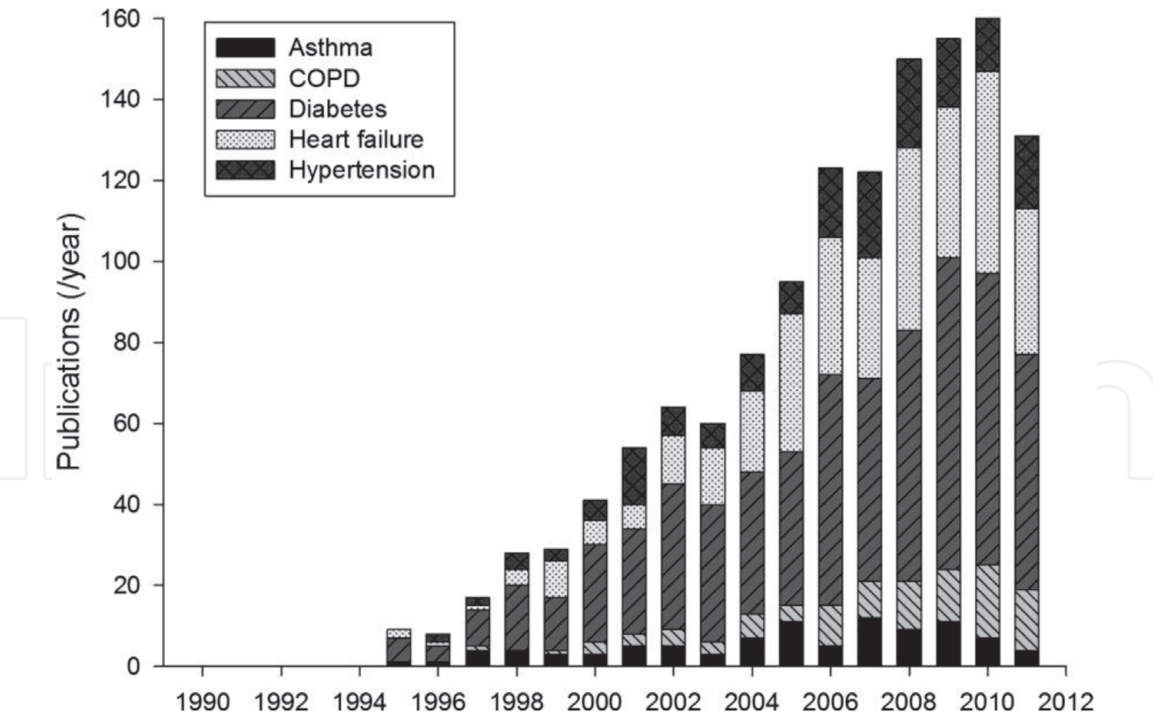


Figure 1.
Telehealth publications by year [1].

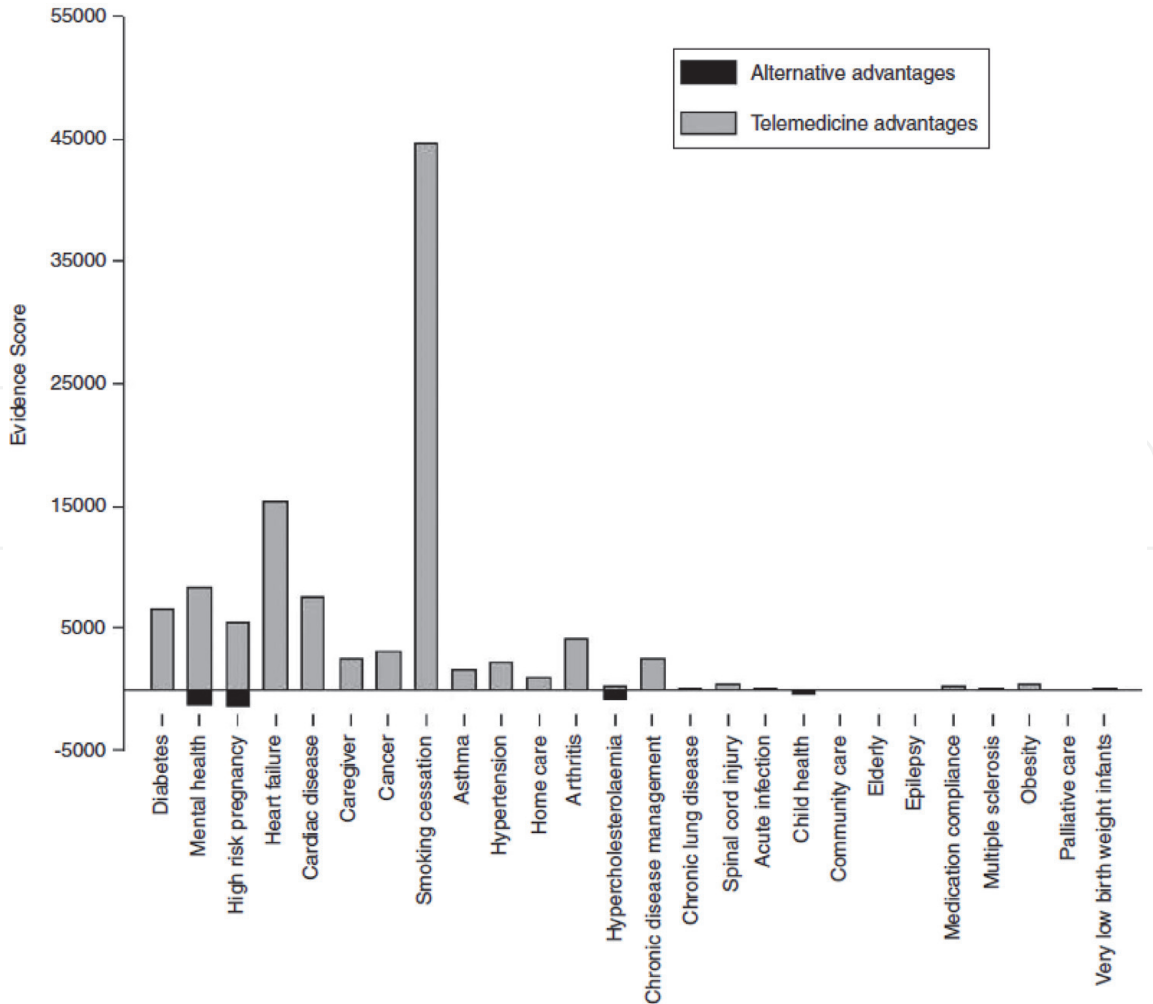


Figure 2.
Advantages of telehealth by application [3].

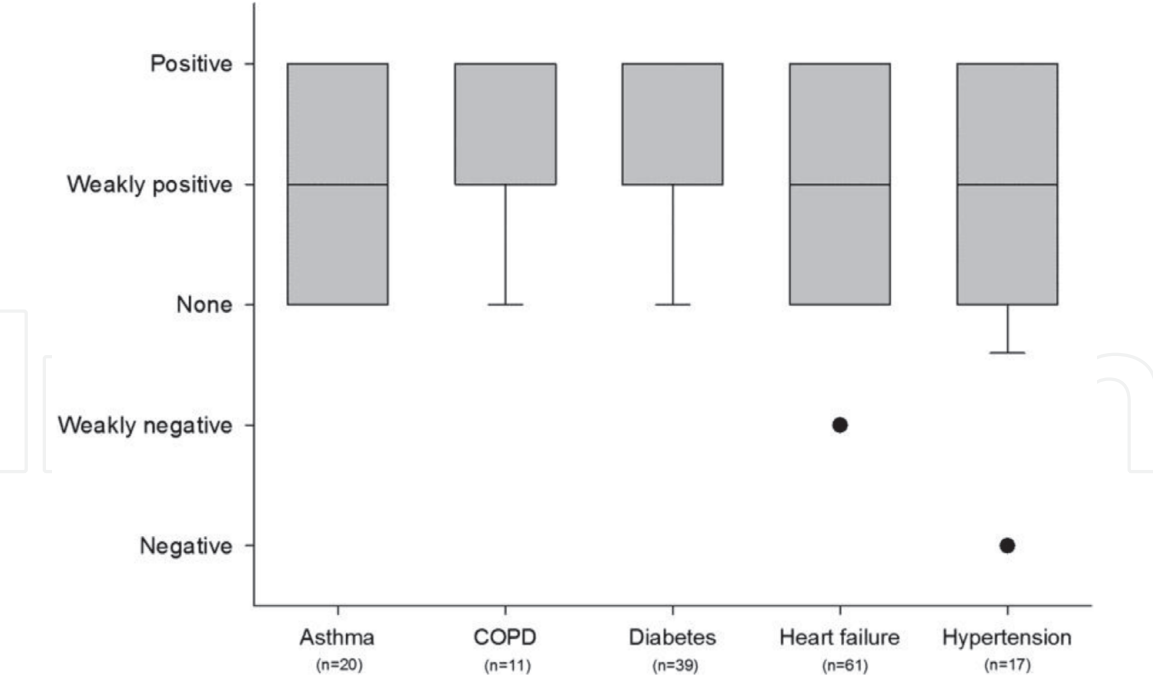


Figure 3.
Advantages of Telehealth by application [3].

However the application of telehealth remains intermittent and patchy and its use has been determined primarily where economic advantage can be demonstrated. This is most frequently demonstrated where the economic benefits of introduction can be gained elsewhere within the same organisation through savings in travel or impact on the provision of services across the organisation. This is most clearly seen in the introduction of telehealth in the indigenous health programs in the USA, such as in Indian Health Service (IHS) providing services to reservations and the Alaska Federal Health Care Access Network (AFHCAN) providing services to remote Inuit communities [4]. These have exploited store-and-forward telehealth to support services such as diabetic retinopathy (IHS), and a wide range of services including ENT, dermatology, and ECG examinations (AFHCAN), for which a purpose cart was designed.

The Veterans Administration (VA) is a US Federal programme that provides health care to those who have served in any of the US armed forces and their families, whilst in the forces and upon discharge anywhere within the US. Many of retired return or settle in small communities throughout the US, which may be far from VA clinical facilities. In order to serve these patients, the VA instigated a programme of telehealth that included many approaches that included video clinic telehealth and store-and-forward being used for home monitoring and capturing retinal images to manage diabetic retinopathy. The use of the programme between 1994 and 2014 is reported in [5] and the increasing number of encounters using the store-and-forward is shown in **Figure 4**.

The growth in use of telehealth within the VA continues, with the latest release of a request for procurement in 2021 for over \$1 billion, accelerated in response to the Covid pandemic, with most patients preferring to consult with their doctor from home [6].

There are similar experiences of an increase in the use of telehealth during the Covid pandemic. For example the NHS in the UK turned to online and telephone consultations with GPs (family doctor). It is to be seen how delivery of health will evolve post Covid.

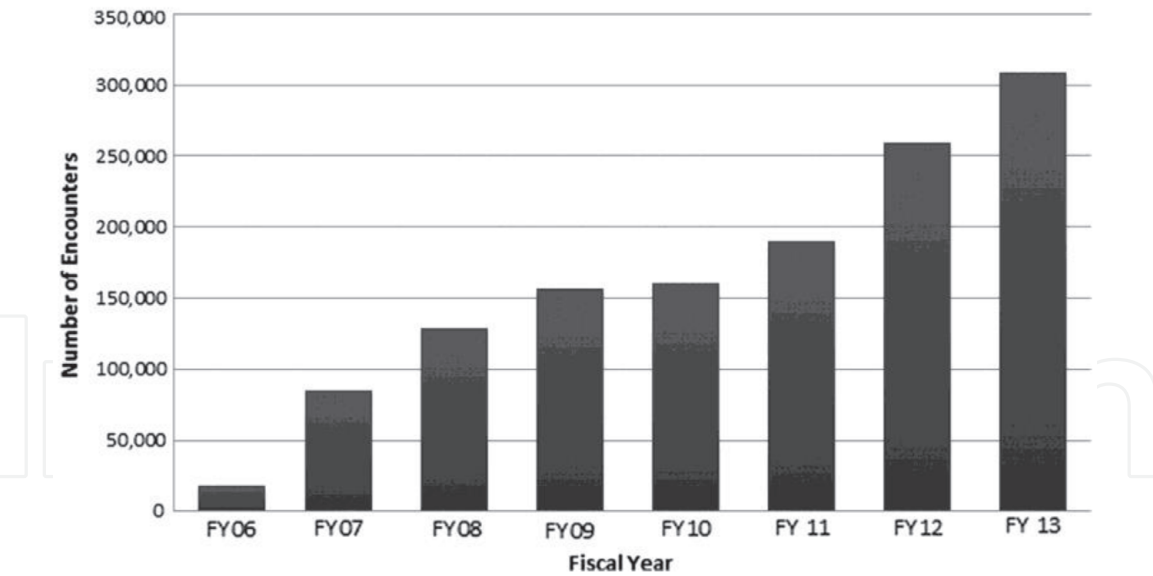


Figure 4.
Veterans Health Affairs store-and-forward telehealth encounters, fiscal years 2006–2013 [5].

2. Acceptance and feasibility

The majority of the projects undertaken to evaluate telehealth have been small scale pilots that include only small numbers of patients and run for relatively short periods, reporting short-term outcomes. This presents difficulty in determining the effect of telehealth on clinical outcomes and obtaining evidence on other benefits such as economic outcome. For this reason such projects generally report on measurable outcomes that include feasibility and acceptance of the technology by the users; patient and/or clinician, with the majority of studies on the clinicians. Despite the limited outcome of such studies, they can provide valuable information on understanding how technology should be introduced to promote successful adoption, and data to direct larger studies.

Most studies on acceptance are based on one of the models of user acceptance, with the Technology Acceptance Model (TAM) [7, 8] being particularly popular, which considers perceived usefulness and ease of use to be its primary constructs. However this approach has limitations when applied to evaluation of telehealth.

2.1 Acceptance by the clinician

A systematic review [9] on factors affecting front-line staff acceptance of telehealth technologies identified the factors that can act as facilitators (**Table 1**) or barriers (**Table 2**), and their importance.

A further systematic review of the experiences of nursing professionals [10] reinforced the findings of [9] and expanded detail on some of the topics to include aspects such as prior experience with technology. It also focussed on the post-experience of telehealth rather than prospective perspectives of participants and recognised that, although the nature and practice of delivering care may have changed during the project, this brought advantages, such as the ability to monitor more parameters and provided a continuous flow of information.

Longitudinal studies such as [11] are therefore invaluable in identifying the pre-conceptions of the users and understanding how these might change during the course of usage of the technology. Such studies also show how certain personality types will remain resistant and seek to influence the group dynamic to thwart the

Facilitators to staff acceptance	Occurrence
Easy-to-use, reliable equipment	7
Collaboration	6
Training and support	5
Flexible and responsive working practices	4
Risk and safety assessment	4
Integration into routine practice	3
Personalization and patient feedback	3
Strong leadership and local champions	3
Trust in technology and service design	3
Maintaining quality of staff–patient interactions	2

Table 1.
Facilitators to staff acceptance [9].

Barriers to staff acceptance	Occurrence
Negative impact of service change/implementation	7
Negative impact on staff–patient relationship	7
Low expectations of outcomes/need	6
Negative impact on staff autonomy/credibility	6
Interoperability, information sharing and data security	5
Technical/usage issues	5
Concerns about user-friendliness	4
Reliability/accuracy concerns	4
Technophobia/lack of confidence in technology	4
Installation issues	3
No reduction in workload/improvements in efficiency	3
Patient safety concerns	3
Poor change management	3
Communication issues	2
Lack of training	2

Table 2.
Barriers to staff acceptance [9].

introduction of new technology and approaches. Such insight is essential to understand effective techniques for change management.

The standard approach in information systems research is to understand the dynamics of interaction between the key stakeholders, the wider context of the organisation, external factors, and the technology innovation, through models and frameworks. The usual technique is based on grounded theory, where information is gathered through interviews, communications and documentation, and analysed to determine the themes (often by frequency analysis) that are then connected together.

A general view of this approach may be seen in the Triality Framework [12], which relates all possible interactions between the key stakeholders (the technology, the organisation, and the user), highlighting how the interactions may include a two-way effect, which extends significantly the concepts which should be considered compared to TAM (**Figure 5**).

Therefore a broader consideration of interaction will bring in the concepts of the Triality Framework [12], and that are highlighted within the factors of **Table 1** and **Table 2**, such as acceptability (does it provide for the role of users), demand (are changes required), efficacy (does it fulfill the role), expertise (are users able to use the technology), trust (is it reliable and safe), legitimacy (does it meet legal requirements), optimality (does it perform the task), and equity (does it provide equal service to all patients).

2.2 Acceptance by the patient

Patient acceptance is less well studied and understood as it is influenced by very many more factors than acceptance by the clinician. However the majority of the studies using TAM have been conducted in the work place on cohorts largely familiar with technology. Patients present very different characteristics and circumstances and therefore have different motivations and responses.

For example, one study [13] used assessment of the perceived usefulness of telehealth services to act as a predictor of acceptance, but had to extend the concepts to include effort expectancy, social influence, and facilitating conditions as its root constructs when applied to patients.

Moreover it is essential not to consider patients as a homogeneous group; patients differ greatly by age, education, social status, economic status, belief, coping strategy, stage of disease, prior experience, familiarity with technology,

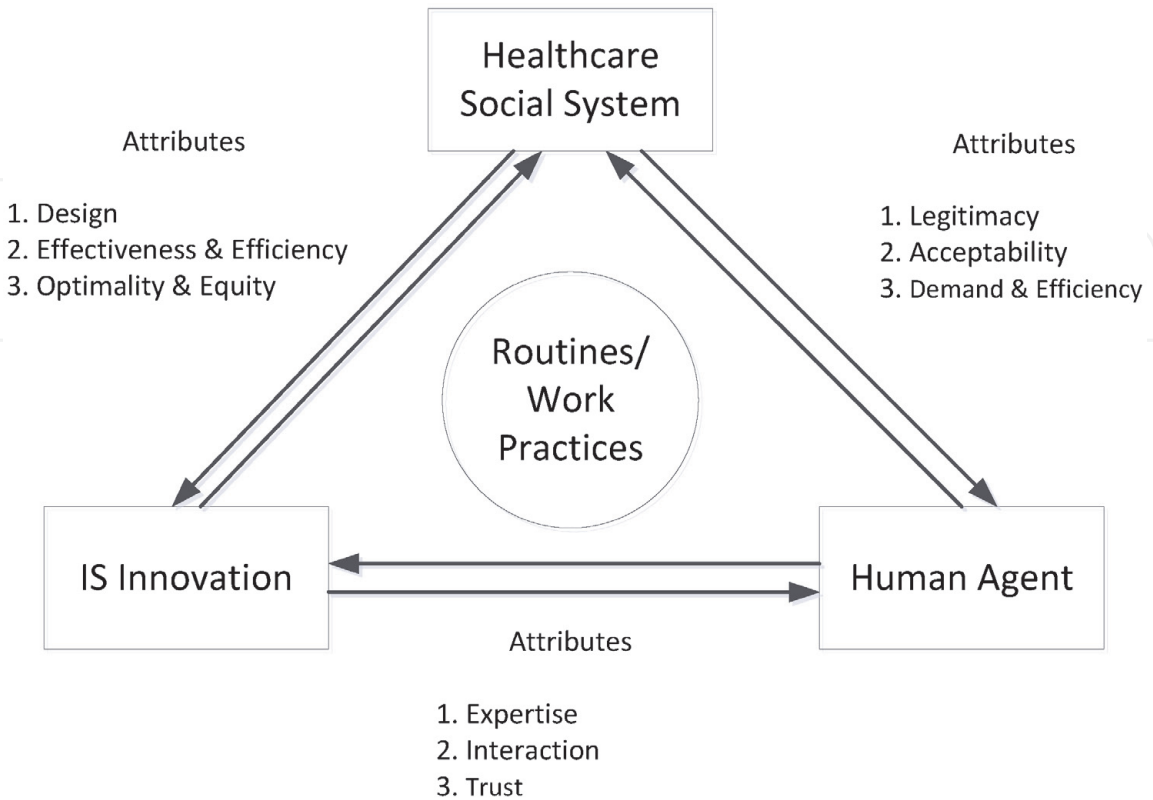


Figure 5.
Triality framework [12].

surrounding support, relationship with their physician, and location. A much richer model to describe factors affecting patient technology acceptance is required.

In one model [14], age and stage of illness are considered as primary influences, and further recognises that age impacts illness and that the severity of illness can impact on the age perceived by the patient. The patient then brings a further multiplicity of factors that affects their willingness to accept telehealth and continue its use.

In addition, the approach and support of the physician can influence the understanding of the need and purpose for telehealth, and thus the acceptance and use (Figure 6).

The effect of the stage of illness is considered in the transtheoretical model (TTM) [15] which identifies individuals moving through six stages as their condition changes:

- Pre-contemplation stage - not thinking about their health condition, or ready to change their behaviour related to the problem.
- Contemplation stage - begin to recognize their health problem and consider the pros and cons of seeking treatment.
- Preparation stage - intention to take action and may make small behaviour changes.
- Action stage - take overt steps to treat their health condition.
- Maintenance stage - able to sustain the health changes they have made.
- Termination – added by some to complete the stages.

It is observed that people in the later stages of the TTM are more likely to pursue intervention and are more likely to have successful outcomes than people in earlier stages, and therefore adhere to a programme of telehealth.

Age has a major influence on acceptance of a technological approach. For example, a survey of usage of smartphones [14] reveals the majority of people over 60 are

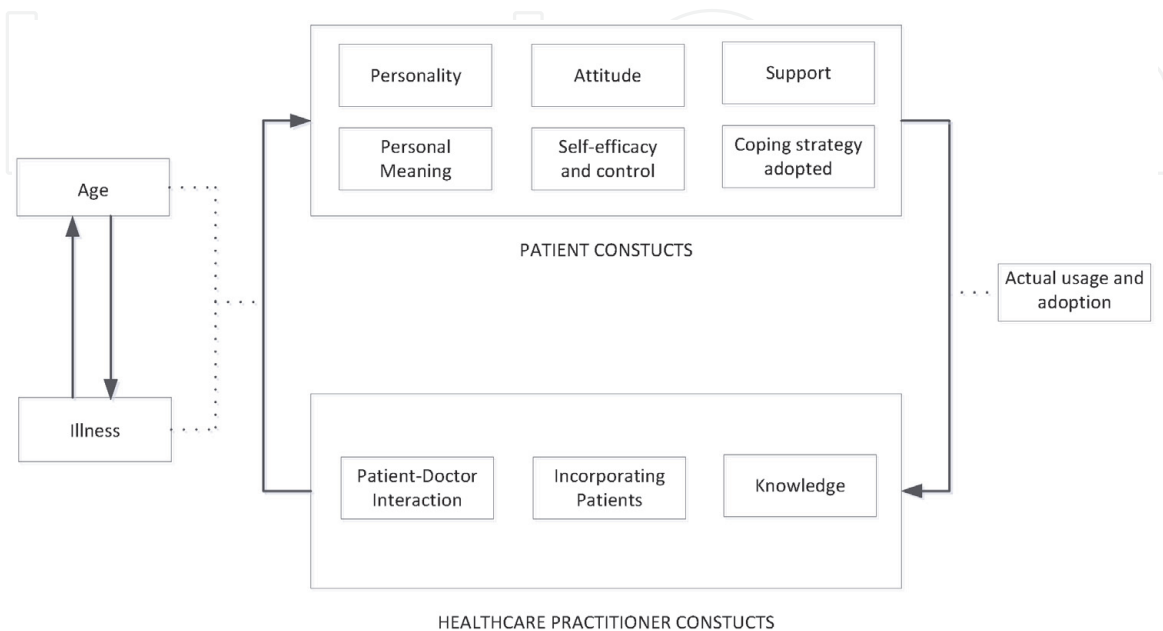


Figure 6.
Patient Technology Acceptance Model (PTAM) [14].

non-users (with many others having only trivial use), with a significant proportion of people in the 46-59 age group also being non-users. A similar proportion will not have access to broadband, and many will have little or no experience of use of technology. It is therefore important to understand how to deploy telehealth in a non-threatening and unobtrusive way. It is therefore appropriate to develop specific models to describe the behaviour of the elderly, such as the Senior Patient Technology Model [16], that must address the specific concerns of this group, such as stigmatisation, simplicity, unobtrusive, independent (no reliance on broadband or telephone), non-threatening, and privacy in use (hidden from general view). It should complement their relationship with the clinician, and not threaten to remove (Figure 7).

2.3 Factors for readiness and adoption

In addition to consideration of the acceptance by the patient and the clinician, there is also a need to understand the readiness of an organisation to host telehealth. This can include understanding the readiness of the technology and the key stakeholders.

Readiness of technology will include understanding the availability and capability of the communication technology (networks) that will span between the parties involved in the telehealth activity, and the availability of suitable end equipment. Understanding the availability and capability of the technology can be complex, as this must be assessed for its ability to support specific applications; the bandwidth and delay required for video and store-and-forward are quite different and will be affected in different ways. Likewise the bandwidth required to transfer images and a vital sign will be quite different. Network capability can easily be assessed by consideration of the technology being used, undertaking performance measurements on the network using one of the many tools such as iPerf [17], and assessing the performance of typical applications. For example, in the implementation of the AFHCAN network, the large delays experienced using a satellite based network caused problems in many applications that were based on the TCP protocol (such as web), and had to be modified to use the UDP protocol.

Assessing readiness of the key stakeholders takes the form administering questionnaires (quantitative research) and conducting interviews through focus groups

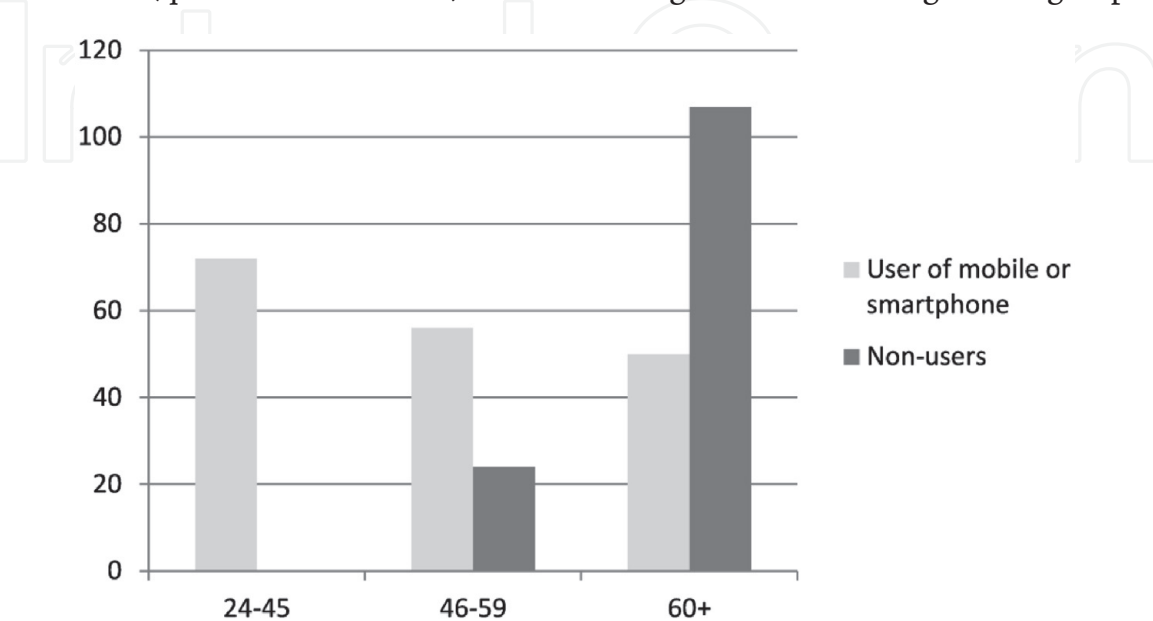


Figure 7. Smartphone Usage [14].

and with individuals to gain deeper understanding (qualitative research) (see [18] for details on design of research studies).

Issues that are raised can be complex depending on the country, politics and situation, and may not relate only to professional issues. For example [19] considers the effects of culture on the acceptance of telehealth in Middle Eastern countries. Standardized methodology has been developed in order to undertake assessment of readiness in studies such [20].

2.4 Feasibility and acceptance

Most projects that develop or investigate use of technology will report on its feasibility and acceptance. Such projects tend to include small numbers of patients, are short duration, and study a single group. There is also a tendency for projects to be repetitive of earlier work. Outcomes are therefore limited in scope. However they can provide anecdotal evidence to guide design and small scale results that can be used in the design of larger trials. These projects have a tendency to be over-zealous in their approach to evaluation. For example [21] references 10 similar pilot studies and administered a questionnaire with 37 questions to patients. The project also found that 84% of the participants preferred the telehealth to having to visit the hospital and 87% were very or extremely satisfied. This is a common outcome in such short term projects.

However the reasons for the acceptance may need to be fully understood in order to interpret outcome appropriately. In [21] patients with postpartum hypertension were monitored at home, in place of having to travel to hospital with a new-born, waiting in an out-patient clinic with a fractious baby, and interfering with feeding and sleep. However this small study also reported that 16% of participants developed severe hypertension, 45% had some change of medication and 11% had to be referred to the emergency department for evaluation of symptomatic severe hypertension. None were referred for readmission. Such data can inform likely group size in larger studies and determine prevalence in outcomes if deployed at scale.

3. Types of technology

3.1 Vital signs sensors

Many devices have been developed and employed for telehealth:

- Blood pressure meter – CHF, diabetes, hypertension, pre-eclampsia
- Weigh scale - CHF
- Pulse oximeter - COPD
- Glucose meter – diabetes
- Peak flow meter – asthma
- ECG – coronary artery disease, arrhythmia, atrial fibrillation
- Body composition analyser – CHF
- Thermometer - infection

- Insulin pump – managing diabetes
- Urine analysis – self-testing urine infection and presence of other conditions
- Sleep apnoea breathing therapy equipment (SABTE) – home management of sleep apnoea
- Continuous glucose monitor - diabetes
- Spirometer - COPD
- INR – anti-coagulation therapy

Each of these devices has an IEEE 11073 standard to define communication of its data. Several of these devices are available based on Blue Tooth Low Energy as wireless connection, although the data format is generally proprietary. Some devices follow the respective Blue Tooth device profile.

3.2 Assisted living

Telehealth for assisted living can be used to support people in their own home (referred as telecare) and can complement monitoring vital signs. Many forms of sensor are possible, from simple emergency buttons and pull-cords activated by the occupant (personal emergency response sensor - PERS), fall sensors, and sensors that monitor the environment of the occupant. Simple environmental sensors can

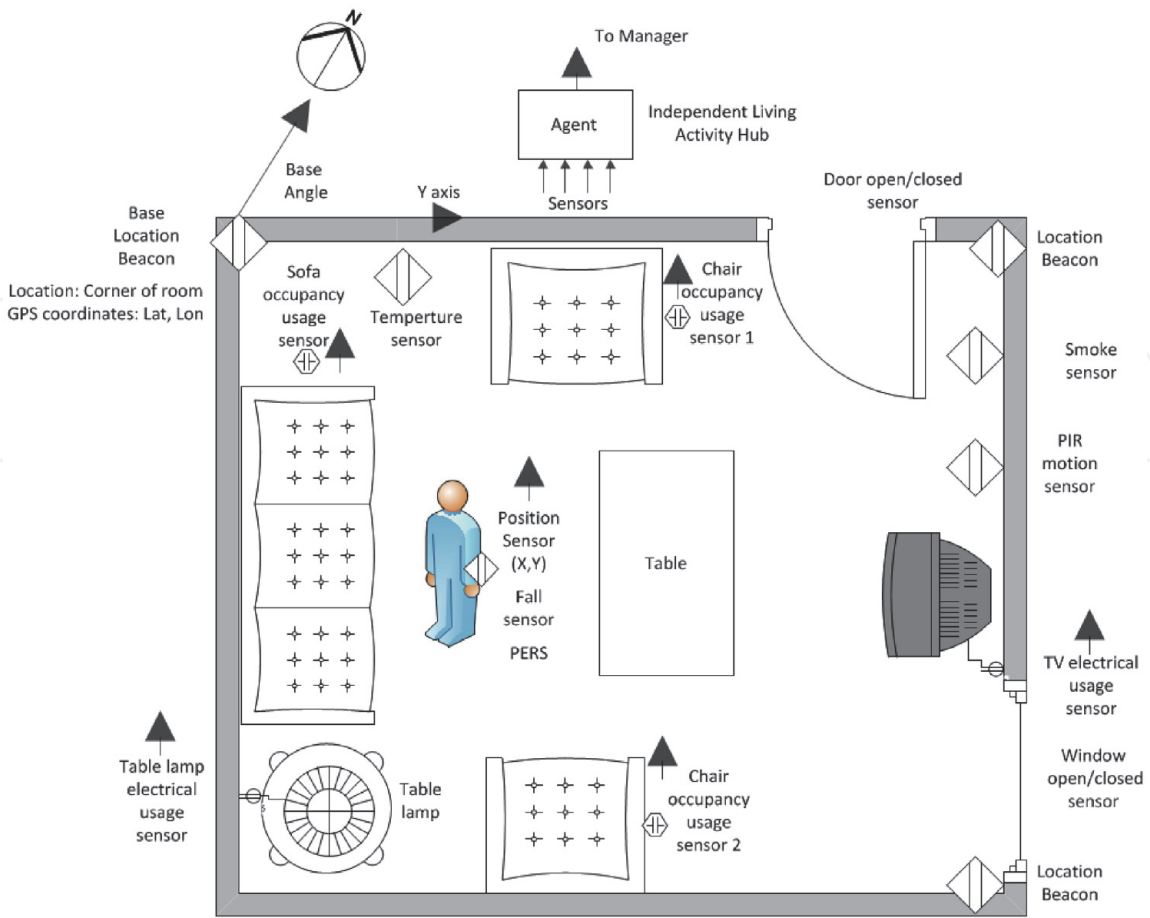


Figure 8.
Assisted Living Sensors (IEEE 11073-10471).

generate alerts such as for high or low temperature. Others sensors can monitor activity, such as use of appliances, room occupancy, or occupancy of bed/chair, from which behaviour might be inferred and alerts generated when there is departure.

Figure 8 shows the range of devices that could be deployed in an assisted living setting (taken from draft of IEEE 11073-10471) that provides a standard for transmission of data that is interoperable with the IEEE 11073-20601 [22] standard for vital signs sensors.

4. Patient benefits

4.1 Determining clinical benefits

The recognised approach to determine the effectiveness of any intervention is the randomised controlled trial (RCT), in which patients are randomly placed into groups that are designed to have equal statistics other than the intervention under study. This typically involves ensuring that each group has equal statistics for factors such as age, sex, and stage of disease. The best approach is to ensure that the type of intervention being administered is hidden from both the patient and the doctor, in the “double-blind RCT”, with the patients receiving either the intervention or placebo in order to ensure they are unaware of the intervention and exclude other factors that might influence the outcome. This approach is often referred as the “gold standard” to determine outcome (see [18]) for details on design of research studies).

However evaluating technology presents difficulties as it is not easy to “hide” the use of technology from patients to implement a double-blind RCT. Alternative approaches are adopted. This usually takes one of two forms: comparing the results from large groups with and without the technology; or comparing the results of each patient with their own data before and after the introduction of the technology, sometimes referred as a “crossover” study. In the first approach, care must be taken to ensure sufficiently large groups for comparison so that they have otherwise matched statistics. The second approach requires care that results are not affected by the deterioration in the condition of the patient over the period of the research, and that seasonal effects on a disease such as flu in the autumn and any other influences of time on a disease are avoided.

The choice of which clinical benefits are assessed also presents difficulties as telehealth is not a treatment, therefore there is no direct outcome that can be measured; rather telehealth impacts diagnosis, decision, and management, and therefore impacts secondary outcomes. In addition, the design of the services that respond to the information collected from telehealth are as important as the design of the telehealth technology; and the intervention must be designed as a complete service, with consideration of the clinical services involved and the communication and relationship between the separate key stakeholders. This important aspect of design of a study is rarely discussed in reports, which not only prevents full comparison of method to be made, but does not allow full advantage of the experience to be gained.

The ultimate analysis of the outcome of assessment of clinical benefit is the systematic review and meta-analysis of outcomes, as these permit rigorous statistical evaluation of benefits of using telehealth over usual care from aggregation of the results from multiple studies. The systematic review has a specific methodology that defines how terms are used to identify trials and how the trials are selected for inclusion and exclusion based on factors such as the number in the trial, duration of the trial, and whether RCT [23]. A systematic review will normally use at least two

reviewers to undertake the selection of papers, with an arbiter to make a final decision on selection. Outcomes from the selected trials may then be summarized and are frequently presented as a funnel plot (also referred as Forest plot) that shows the risk ratio of each study included in the analysis and overall outcome.

4.2 Assessing clinical outcome

The most common approach that is used to assess clinical outcome is through the use of a validated disease specific questionnaire. This assesses the perceived state of health of a patient and the perceived level of symptoms and their impact on everyday activities. Many such questionnaires exist for diseases such as CHF [24], COPD [25], and asthma [26].

The second approach is to use a questionnaire such as the EQ5D [27] or SF36 [28] to assess the perceived general state of health of a patient. Whilst use of these questionnaires does not assess clinical outcome directly, it can determine the perceived benefits the patient may feel from being monitored.

Direct assessment of clinical outcome is determined through disease specific measures such as ejection fraction in CHF, lung function in COPD, and glucose and HbA1c in diabetes. Secondary measures may be considered such as blood pressure in diabetes. Some projects assess secondary outcomes that include death rate, and extension of life.

4.3 Clinical benefits in patients with CHF

CHF is a common chronic condition with a prevalence of about 13% amongst those aged 85 years or above in countries such as the UK [29]. Telehealth in CHF has been found to improve health outcome for patients and reduce the number of hospitalisations [30, 31]. Many studies have considered nurse telephone support and remote patient monitoring as equivalent and either report combined outcomes or present results synonymously [32]. Telephone support typically comprises patient follow up, education and counselling delivered via a telephone call made by a specialist nurse. However, patients receiving this form of intervention usually have only mild to moderate CHF symptoms (NYHA class I-II). Remote patient monitoring involves home care of patients using specialist telecare devices to send vital signs directly to the clinician and is often done for patients with severe symptoms of heart failure (NYHA class III-IV) [33].

In reviews that differentiate these approaches and determine the effectiveness of each separately, a technology based approach to patient home monitoring (telemonitoring) is shown to be more effective [34]. In other systematic reviews, telehealth has been compared to a number of alternative approaches, including patient education, specialist (clinician or cardiologist) follow up, nurse home visiting, and telephone support [35–38]. The general conclusion is that telemonitoring alone is insufficient to reduce readmission rates and improve quality of life, and must be integrated with nurse visits and specialist management and follow up, with redesign of the service to support the intervention.

4.3.1 Mortality

Mortality has been the most reported clinical outcome in the study of impact of telehealth to manage CHF. In [39] ten studies reported mortality as a primary outcome, with five studies reporting outcomes with significant significance. However, although the pooled estimate results showed an overall reduction in all-cause mortality, this was not statistically significant (0.77, 0.61 to 0.98, $P = 0.02$). Funnel

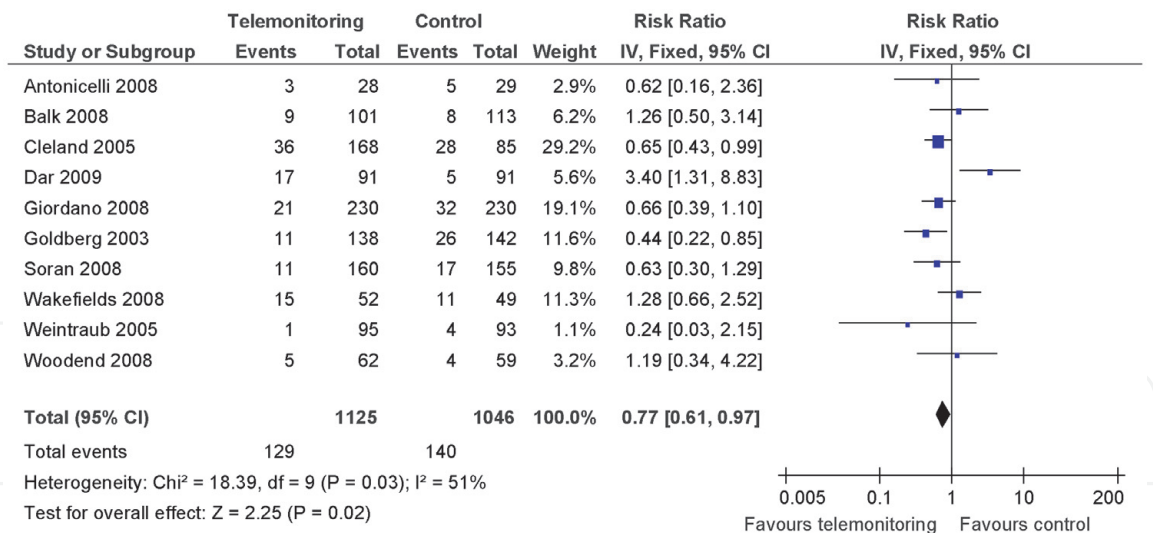


Figure 9.
Effect of telemonitoring on all-cause mortality [39].

plots did not indicate bias, however, heterogeneity was possible ($P = 0.03$, $I^2 = 51\%$) (Figure 9).

4.3.2 Medication adherence

Only 3 studies out of the 11 evaluated the effectiveness of telemonitoring on compliance by patients with their treatment and adherence to medication. The study in [40] reported no significant difference, whereas [41] reported improved compliance with treatment in the telemonitoring group.

4.3.3 Quality of life

The eight studies evaluating quality of life of patients reported no statistically significant general improvement for patients from the intervention. However some studies did report certain aspects of awareness were improved. For example, [42], using SF-36 and MLHF, reported that knowledge about CHF was significantly higher among patients in the intervention group ($P < .001$). The study in [43] reported significant difference on the vitality subscale of SF-36 at 1 month ($P = 0.022$), 3 months ($P = 0.017$) and a year ($P = 0.009$). Similarly, [44] noted that improvement was achieved over time by using MLHF. [41] reported significant difference in health perception score of SF-36 ($P = 0.046$). Only two studies assessed anxiety and depression scores. The Minnesota Living with Heart Failure (MLHF) and Short Form (SF-36) Questionnaire were used in all studies to measure Quality of Life.

4.3.4 Managing blood pressure

Blood pressure must be carefully managed in patients with CHF. Figure 10 shows how telehealth was used to manage reduction of the blood pressure in a patient to an appropriate level [45]. However the blood pressure and pulse rate became erratic. Further investigation determined the patient had atrial fibrillation. Recent blood pressure devices now provide an indication if they determine erratic pulse rate.

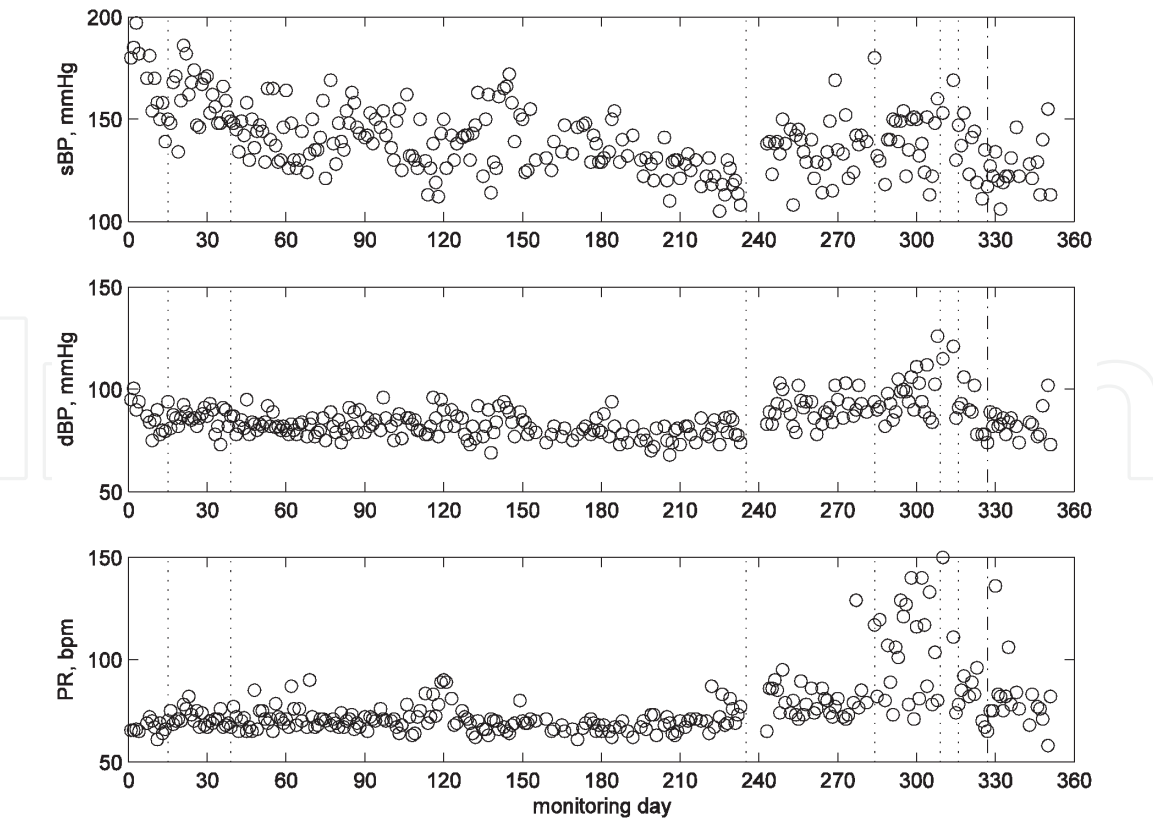


Figure 10.
Daily blood pressure and pulse rate [45].

4.3.5 Monitoring weight

Weight is often monitored in patients with CHF. During exacerbation patients will develop oedema with a corresponding gain in weight. The gain in weight is relatively rapid, over the period of a few days, and the change may be easily detected to generate an alert.

4.4 Clinical benefits in patients with COPD

Chronic obstructive pulmonary disease (COPD), which is characterized by a chronic irreversible airflow limitation, is a leading cause of mortality and morbidity globally and results in substantial costs and healthcare utilisation. Several diseases are categorised as COPD, including asthma, lung disease, and pulmonary fibrosis; each has its own characteristics, progression, and approaches to telehealth have differed accordingly.

4.4.1 Physical activity

Early telehealth approaches concentrated on rehabilitation and used education and intervention via telephone and messaging to encourage patients to perform exercises to improve pulmonary function and increase tolerance to physical activity. Meta-analysis of studies using intervention [46] showed positive outcome for telehealth to increase the duration of physical activity (**Figure 11**), tolerance to 6 minute walk (**Figure 12**), and reduce episodes of dyspnoea (**Figure 13**).

4.4.2 Progression of disease

While effective, such approaches could be considered labour-intensive, especially when continuing to contact patients who are responding. Recent efforts in

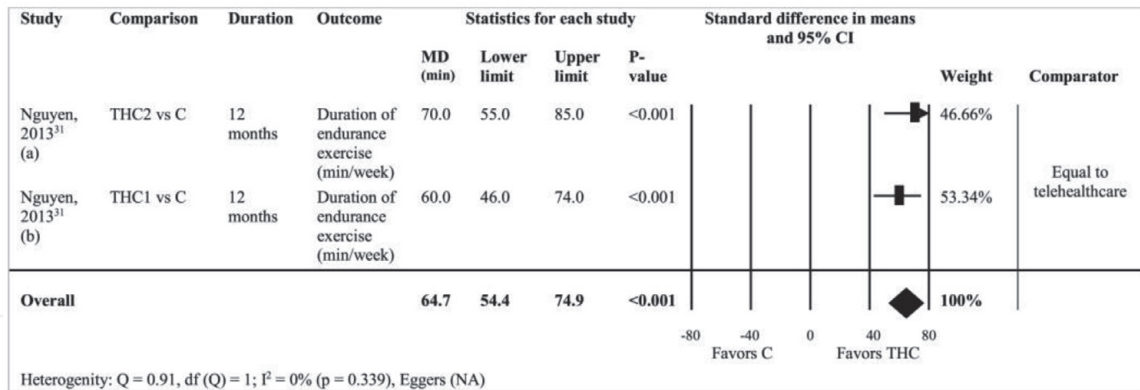


Figure 11.
Forest plot of the effect of telehealth on duration of physical activity [46].

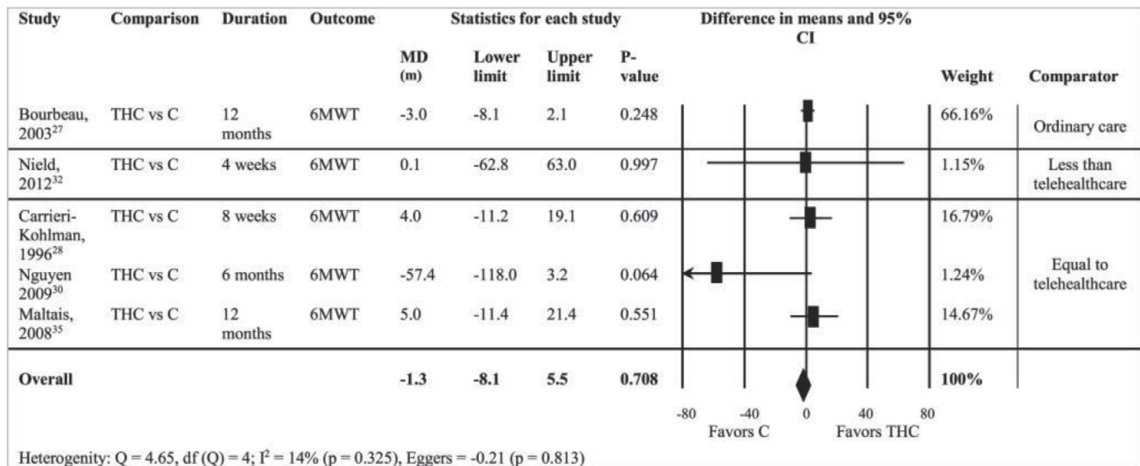


Figure 12.
Forest plot of the effect of telehealth on 6 minute walk [46].

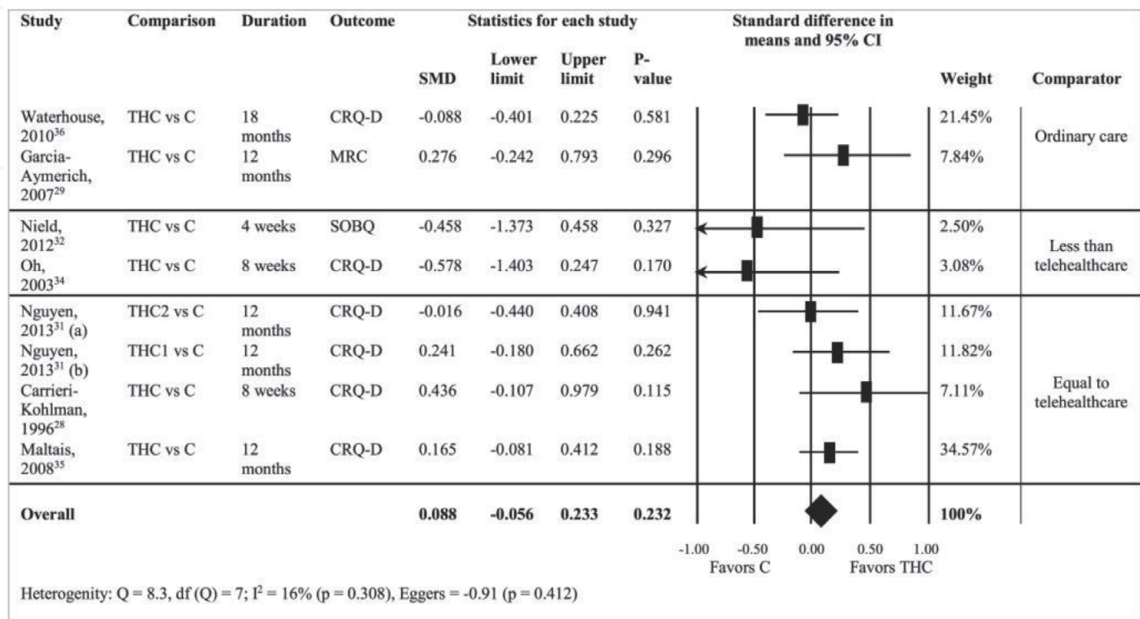


Figure 13.
Forest plot of the effect of telehealth on dyspnoea [46].

telehealth have concentrated on monitoring vital signs to predict exacerbation, primarily measuring daily SpO₂, and concentrate efforts on those in greatest need.

A meta-analysis of studies using vital signs to manage patients with severe COPD [47] shows that there is little change to FEV1; a primary measure of the severity of COPD. As telehealth is not a treatment, and COPD is progressive, then this might be expected. However, every exacerbation can reduce lung function, thus the earlier treatment for the exacerbation is started - the less might be the impact on lung function.

4.4.3 Hospital admission

The same meta-analysis [47] shows that use of telehealth to monitor for exacerbation in COPD can reduce the number of emergency room (ER) visits (**Figure 14**), however the number of hospitalisations was not significantly reduced (**Figure 15**)

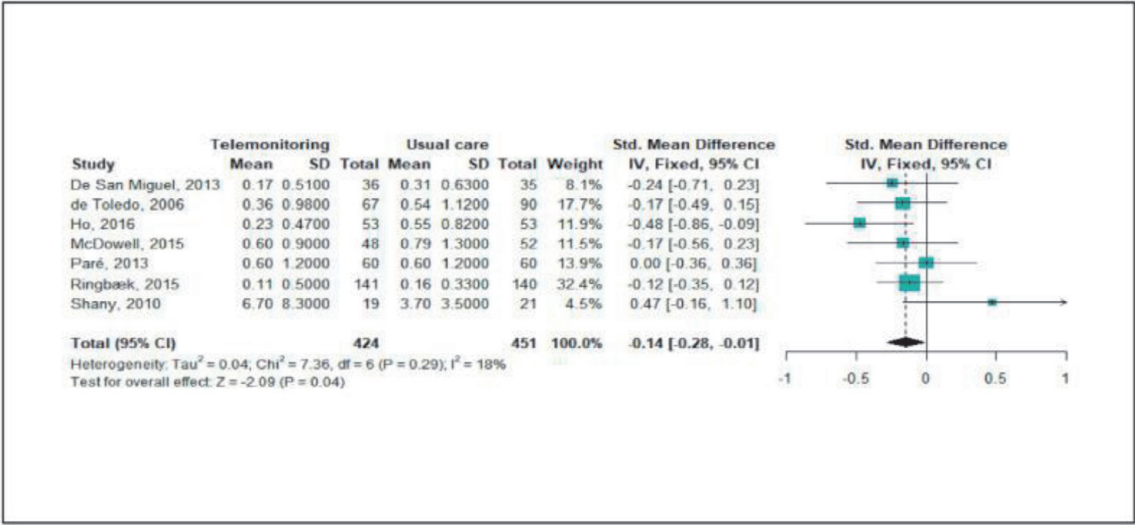


Figure 14. Forest plot for the effectiveness of telemonitoring for decreasing the number of ER visits due to severe COPD exacerbations [47].

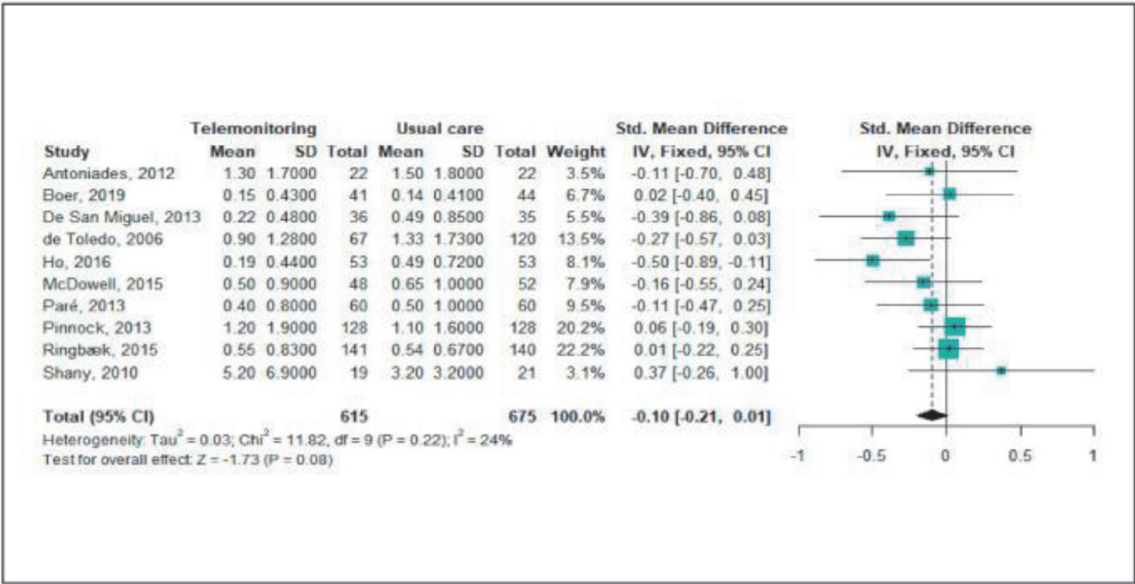


Figure 15. Forest plot of the effectiveness of telemonitoring for decreasing the number of hospitalisations due to severe COPD exacerbations. [47].

and thus there was no effect on the number of exacerbations. Similar results were reported in a study on cost-effectiveness [48], however the length of stay was reduced and thus there may be benefit from the earlier intervention permitted by telehealth.

4.4.4 Monitoring pulse oximetry

Blood oxygen (SpO_2) is the most often monitored parameter in patients with COPD. In general, COPD patients have a blood oxygen level that is lower than normal, but is maintained and the patient becomes accustomed. During exacerbation the level will fall, and a threshold may be set to generate an alert. **Figure 16** [45] shows SpO_2 measurements for a typical COPD patient, the vertical dotted lines indicate clinical events. SpO_2 is seen to fall at these times. However SpO_2 also falls at other times, which would generate false alerts. Improved algorithms are required to improve accuracy.

4.5 Clinical benefits in patients with diabetes

Diabetes is a disease in which a patient is unable to produce sufficient insulin to control the level of glucose in their blood. In Type I and insulin-dependent Type II, patients produce little or no insulin, and so must inject insulin to meet their need to maintain their blood glucose level with limits. The amount of insulin to be injected to maintain the level of blood glucose is determined by the patient by taking a measurement of their current blood glucose and calculating the amount of carbohydrate they about to ingest.

Type II patients may be able to manage their level of blood glucose by diet and exercise alone, or require an increasing level of oral therapy as their condition deteriorates until they will be required to inject insulin.

Telehealth has been applied to the management of patients with diabetes in many projects, including Type I, Type II and both forms. In addition, many approaches to telehealth have been used to facilitate early detection and diagnosis, monitor disease progression, and provide management. Methods include telemonitoring, teleconsultation, interventions delivered by computer, and combinations.

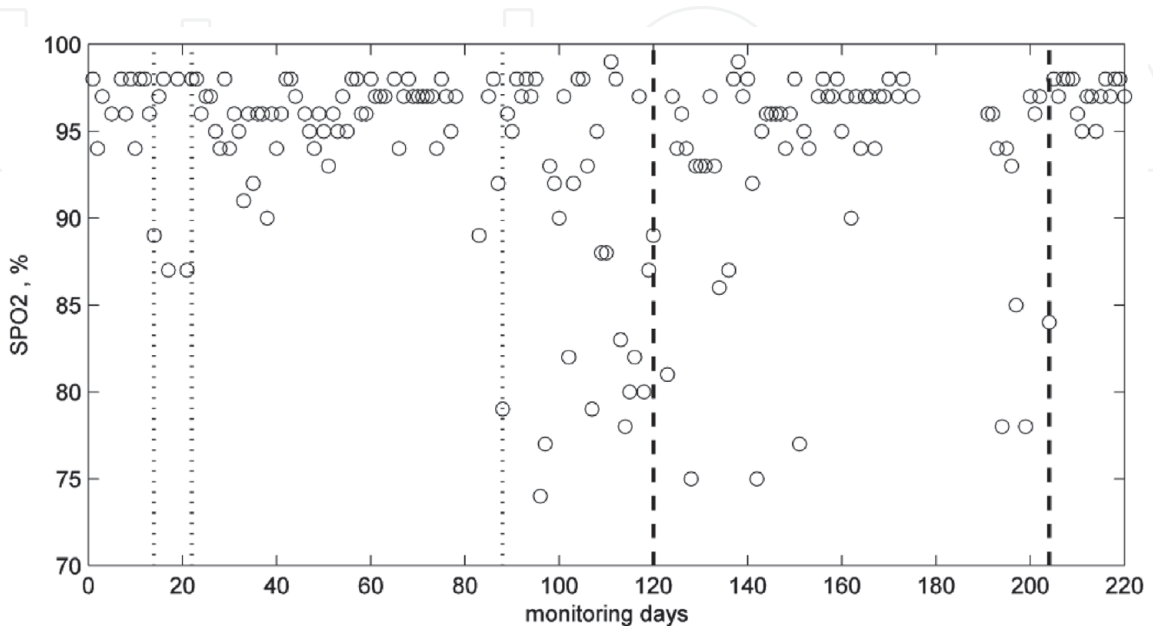


Figure 16.
Pulse oximetry in COPD patients [45].

4.5.1 Type II diabetes

The primary outcome of studies is the level of Hb1Ac, which provides a measure of the long-term level of blood glucose. It is the primary means of routine management of patients with diabetes, with the aim to bring within a target range. Daily fasting glucose may also be measured as an outcome, with the aim to maintain within a target range. A secondary outcome is blood pressure, as it is important that this is well maintained in order to prevent complications of the disease, and this may be controlled in studies. Further secondary outcomes include lipid levels, which would include cholesterol and low density lipoprotein and high density lipoprotein also to prevent complications of the disease, and may also be controlled in a study.

One meta-analysis [49] analyses the outcome from each approach separately. The analysis (**Figure 17**) shows that each approach, other than telecase-management and telemonitoring that were marginal, achieved similar outcome that was a positive outcome for telehealth, although telecase-management with teleconsultation achieved a higher average outcome but with large variation. In part, this outcome can be explained because patients have the goal to reach a target within a specified range and once attained no further change is expected or required. This will limit the mean difference, which will also be influenced by the baseline.

The meta-analysis [49] also analyses each of the secondary outcomes by approach. Secondary outcomes were generally similar between telehealth and standard care; however this will be dependent on the protocol for intervention.

Other systematic reviews and meta-analysis agree with these outcomes: [50] reports a mean reduction of 0.17% in HbA1c in telehealth compared to usual care, especially for patients with mean baseline greater than 8.0%. However, there was no clinically significant reduction in LDL-cholesterol (LDL-c), body mass index (BMI), systolic (SBP) or diastolic blood pressure (DBP); [51] reports mean reduction between 0.2% and 0.64%, with a pooled mean of 0.39% in HbA1c; [52] reports mean reduction of 0.486% in HbA1c and some improvements in secondary outcomes such as diastolic blood pressure and body mass index (**Figure 18**).

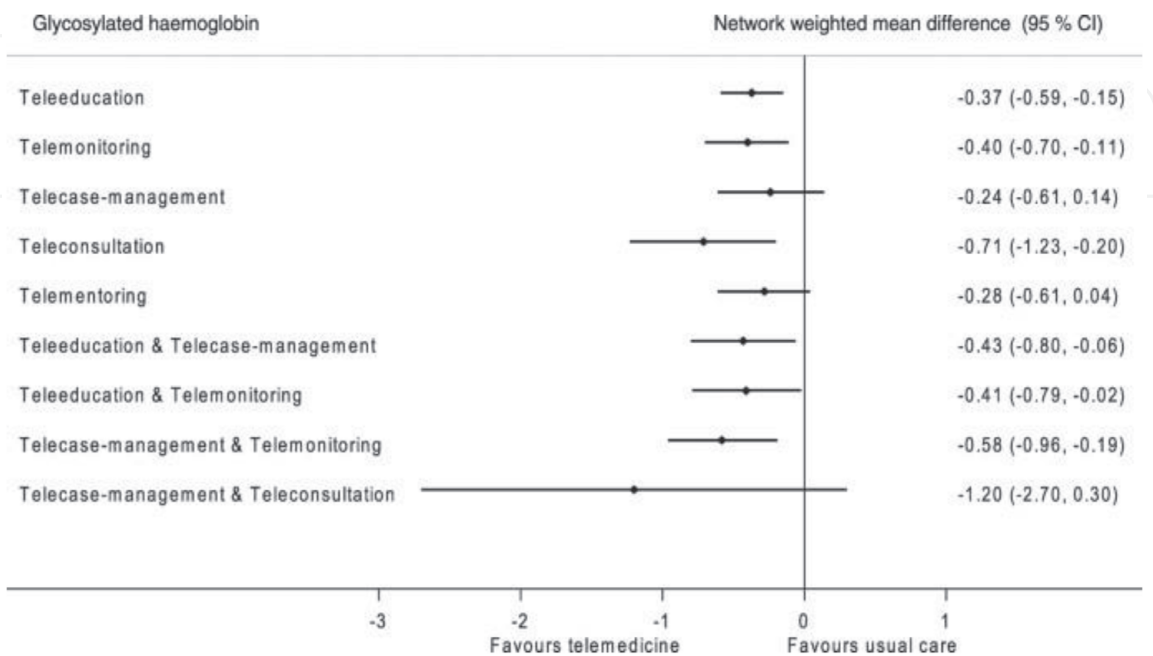


Figure 17.
Change in glycated haemoglobin in adults with Type II diabetes by telehealth approach [49].

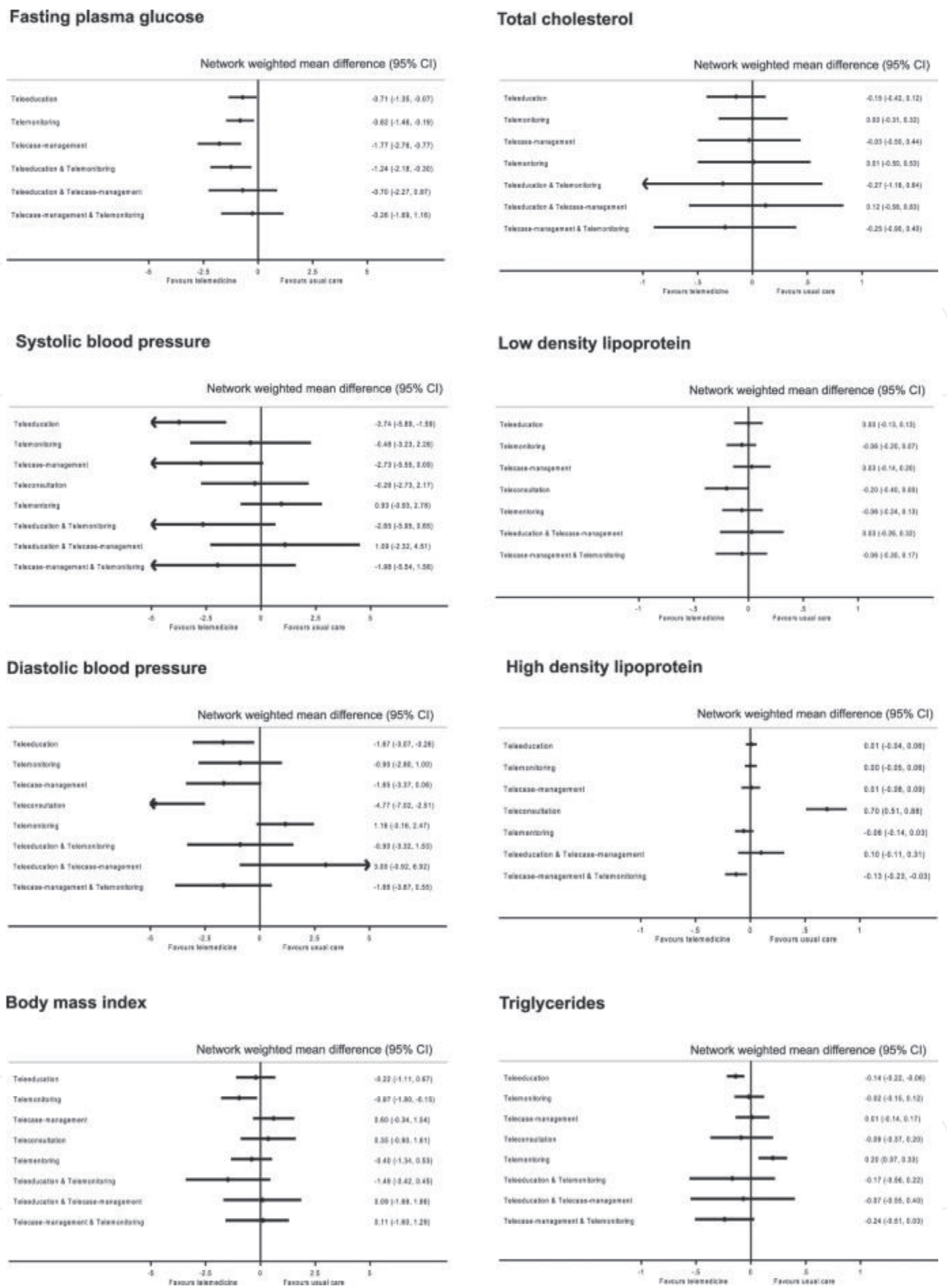


Figure 18.
Change in secondary cardiovascular outcomes of different telehealth strategies compared to usual care in adults with Type II diabetes by telehealth approach [49].

4.5.2 Intervention strategies

Most studies on telehealth are conducted on a selected group of patients that is considered homogeneous and outcomes are considered through statistical measures. One study investigated management of all patients with diabetes in a primary care setting [53], performing two weeks of monitoring daily blood glucose and blood pressure, repeated every 6 months following the UK national framework. Data from each patient was reviewed to assess whether their condition was well controlled,

and if not, intervention was used to manage the condition and establish correct control. The study identified three distinct patient groups: the well-controlled who required no intervention; patients requiring intervention to re-establish control; and patients in denial.

The well-controlled patients were aware of their condition, and managed their lifestyle and medication accordingly. They required no intervention. The daily measurements provided by the telemonitoring gave insight into the habits of the patients who required intervention and allowed directed and personalised intervention strategies, for example by identifying patients who did not follow diet at the weekend as part of a social activity, seen as a spike in daily glucose. The daily measurements also clearly identified patients who were in denial, frequently not taking any medication, and the data could be used to confront the patient in order to encourage change. Monitoring would continue until correct management was established. 37% of the patients were identified as needing intervention, resulting in a mean reduction in HbA1c of 3 mmol/mol and mean reduction in systolic blood pressure of 5 mmHg.

The short period of intervention was considered more effective than continuous monitoring of patients who were well managed. It was expected that patients would comply initially but then lapse after a period, when the monitoring would be repeated.

4.5.3 Type I diabetes

In Type I and insulin dependent Type II diabetes the goals for control of blood glucose are somewhat different. In addition to achieving a long term average, as indicated by HbA1c, within the target range, a patient with Type I diabetes must maintain their blood glucose within a target range at all times through injection of an appropriate amount of insulin to match their current blood glucose level, activity and ingestion of food. This requires frequent measurement of their blood glucose. Traditionally this has been through regular use of a finger prick and a glucose meter, usually measured before a meal to determine the required amount of insulin. Post-prandial measurements may be taken to monitor correct management. Glucose meters typically store many measurements that may be uploaded to a monitoring service for review by the clinician and telehealth service.

One meta-analysis study [54] compares separately the outcome from studies that included Type I and Type II patients. The outcomes show improvement in mean change to HbA1c in each of the three categories that were studied, Type I and Type II, Type I, and Type II (**Figure 19**); the Type II group achieving the greatest change.

4.5.4 Continuous glucose monitoring

A recent development in telehealth is the introduction of devices that can be placed on the body to monitor blood glucose on a continuous basis. Improvements in biomaterials have extended the time that the sensor remains on the body to 10 days [55]. These devices can communicate their data to a monitoring application that may be used by the patient directly to monitor their blood glucose to determine insulin dose, and detect and provide an alert when the blood glucose level goes outside thresholds. Data may also be forwarded to others monitoring the patient that includes the parents of juvenile diabetes patients and the clinician.

Studies [56, 57] have shown that continuous glucose monitoring (CGM) can reduce HbA1c in Type II patients (**Figure 20**); although it is not clear if CGM produces improved reduction in HbA1c compared to other telehealth approaches.

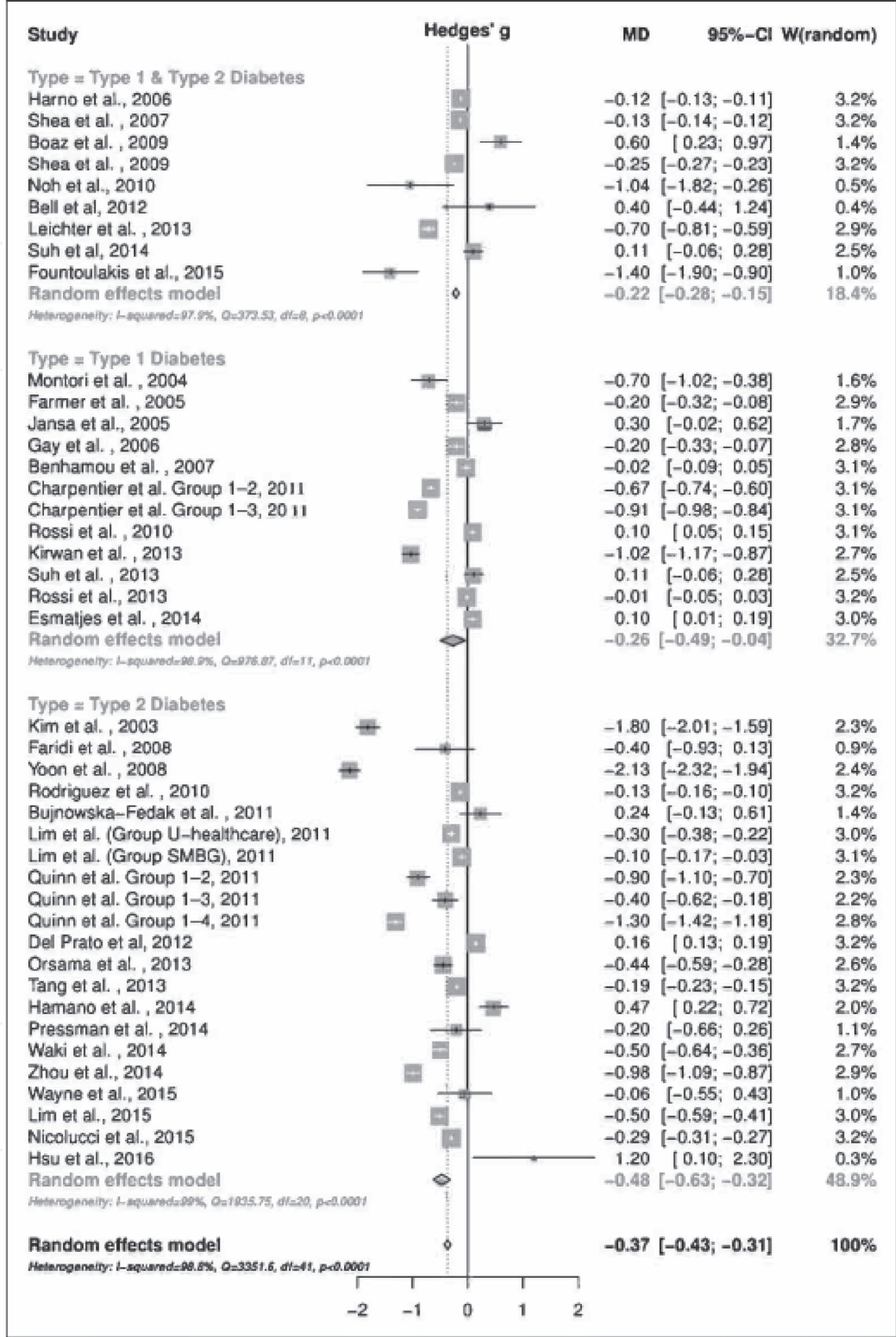


Figure 19.
Mean difference in the changes in HbA1c levels for telehealth and usual care [54].

The most valuable use of CGM is in the management of Type I and insulin dependent Type II patients as it improves short-term control, provides alerts of high and low values (hyperglycaemia and hypoglycaemia). This reduces the number of times a finger prick is required, reducing scarring and the incorrect results from taking blood from over-used sites.

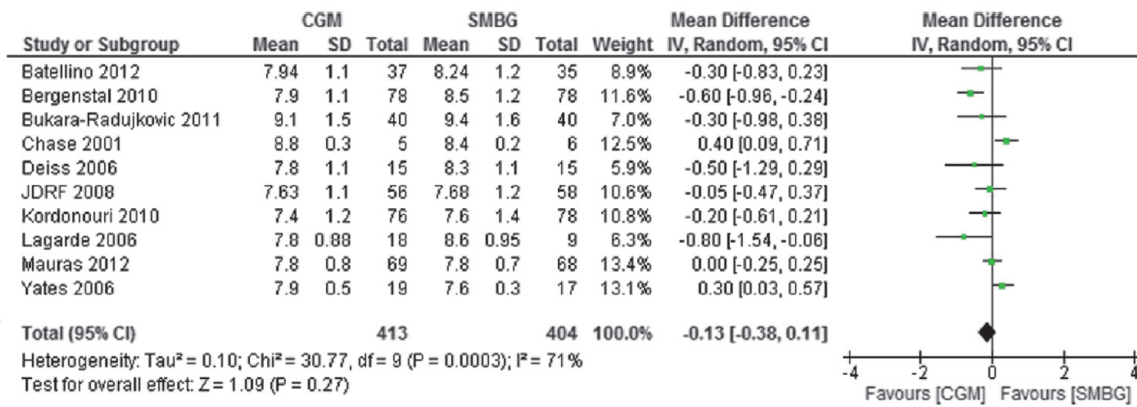


Figure 20.
Mean difference in the changes in HbA1c levels for telehealth using CGM [56].

4.6 Clinical benefits in patients with hypertension

Hypertension is a disease in which a patient has an elevated level of blood pressure. It is normally managed using drug therapy. Telehealth has often been proposed as a method to manage patients with hypertension.

A meta-analysis [58] of the use of telehealth versus usual office management of hypertension shows a statistically significant reduction of both systolic (3.4 mmHg) (Figure 21) and diastolic (1.6 mmHg) (Figure 22) blood pressure in patients managed by telehealth, however the reduction is not of clinical significance.

Again this outcome may be explained by the target being to bring patients within a threshold. Given the range of patients between those well-managed, in need of intervention, and in denial, overall outcome may be small, but impact on a small number of patients may significant. Telehealth allows resource to be targeted to those in most need.

Telehealth in management of hypertension probably has greatest effect when used with the newly diagnosed, and allows rapid titration of medication to bring them below threshold, without need for frequent visits to the clinician, especially

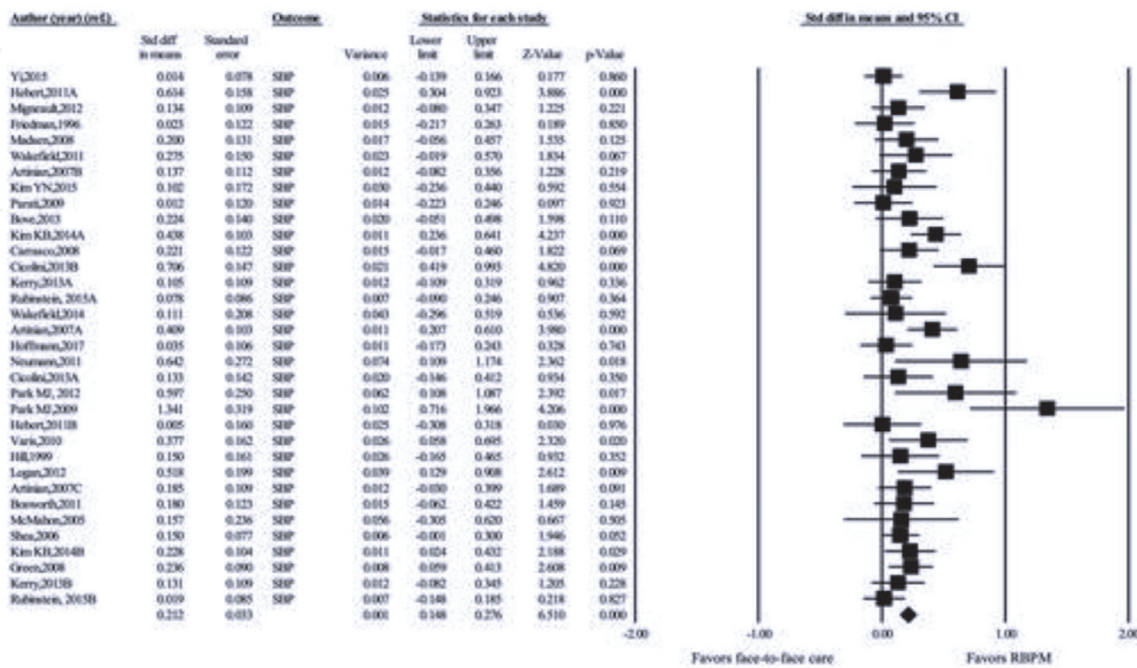


Figure 21.
Mean difference in the changes in Systolic Blood Pressure [58].

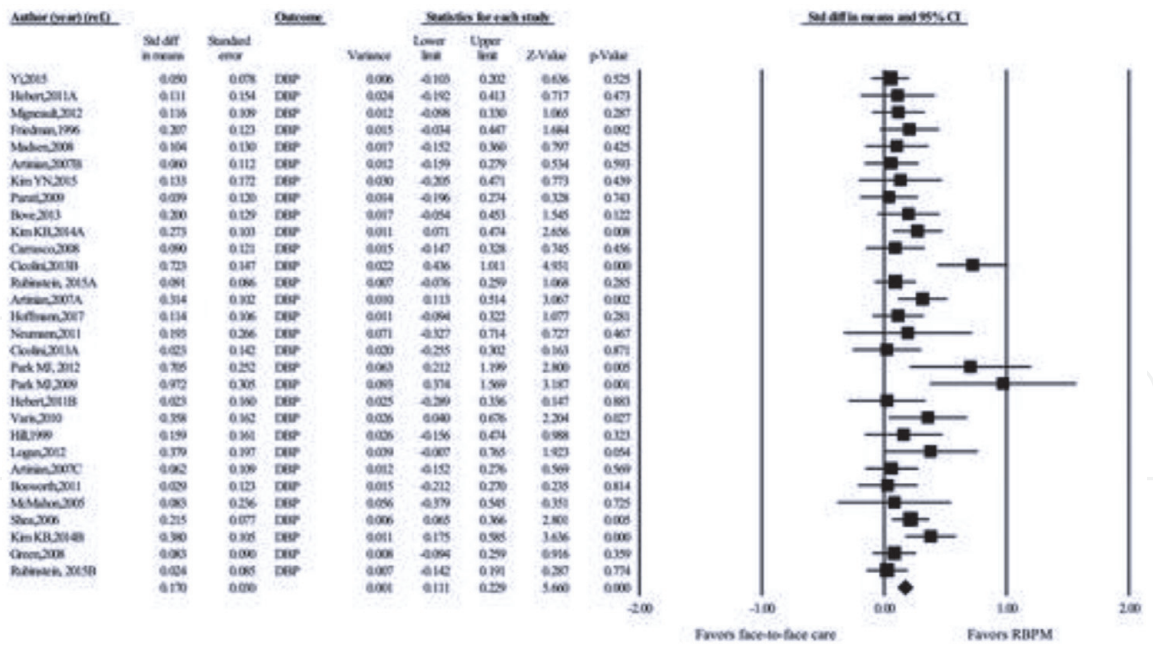


Figure 22.
Mean difference in the changes in Diastolic Blood Pressure [58].

valuable where the patient must travel a large distance. Once the patient becomes well-managed, the need for telehealth is significantly reduced and could be removed.

Telehealth has also found a place in diagnosing hypertension. The elevated blood pressure measured in the clinician office is a well-known phenomenon and can mask the presence of hypertension. Ambulatory blood pressure has been used in the past to confirm the diagnosis. Telehealth, monitoring daily blood pressure at home for a short period, has become accepted as an alternative method for diagnosis.

4.7 Clinical benefits in pregnancy

Several conditions can develop during pregnancy, including gestational diabetes and pre-eclampsia. In general, these conditions resolve postpartum, however it is important that they are monitored carefully until fully resolved. Usual care is frequent monitoring at the out-patient clinic of the maternity hospital, requiring travel with a new-born baby, and possibly other young children. Telehealth offers the means to undertake the monitoring at home.

4.7.1 Gestational diabetes

Gestational diabetes is a short term condition which may develop during pregnancy and will generally resolve postpartum. Good control of blood glucose is essential for correct development of the foetus, as high blood glucose severely impacts birth weight. Monitoring and management strategy is the same as Type II diabetes.

Conclusions from meta-analysis of the outcomes of studies of telehealth to manage gestational diabetes are mixed. One study [59] concludes glycaemic control (HbA1c, pre and postprandial blood glucose) to be similar between the telehealth and usual care groups, although face-to-face and unscheduled consultations were reduced. However, another study [60] determined significant improvement in glycaemic control in HbA1c (Figure 23A), pre-prandial blood glucose (Figure 23B) and 2 hour postprandial blood glucose (Figure 23C).

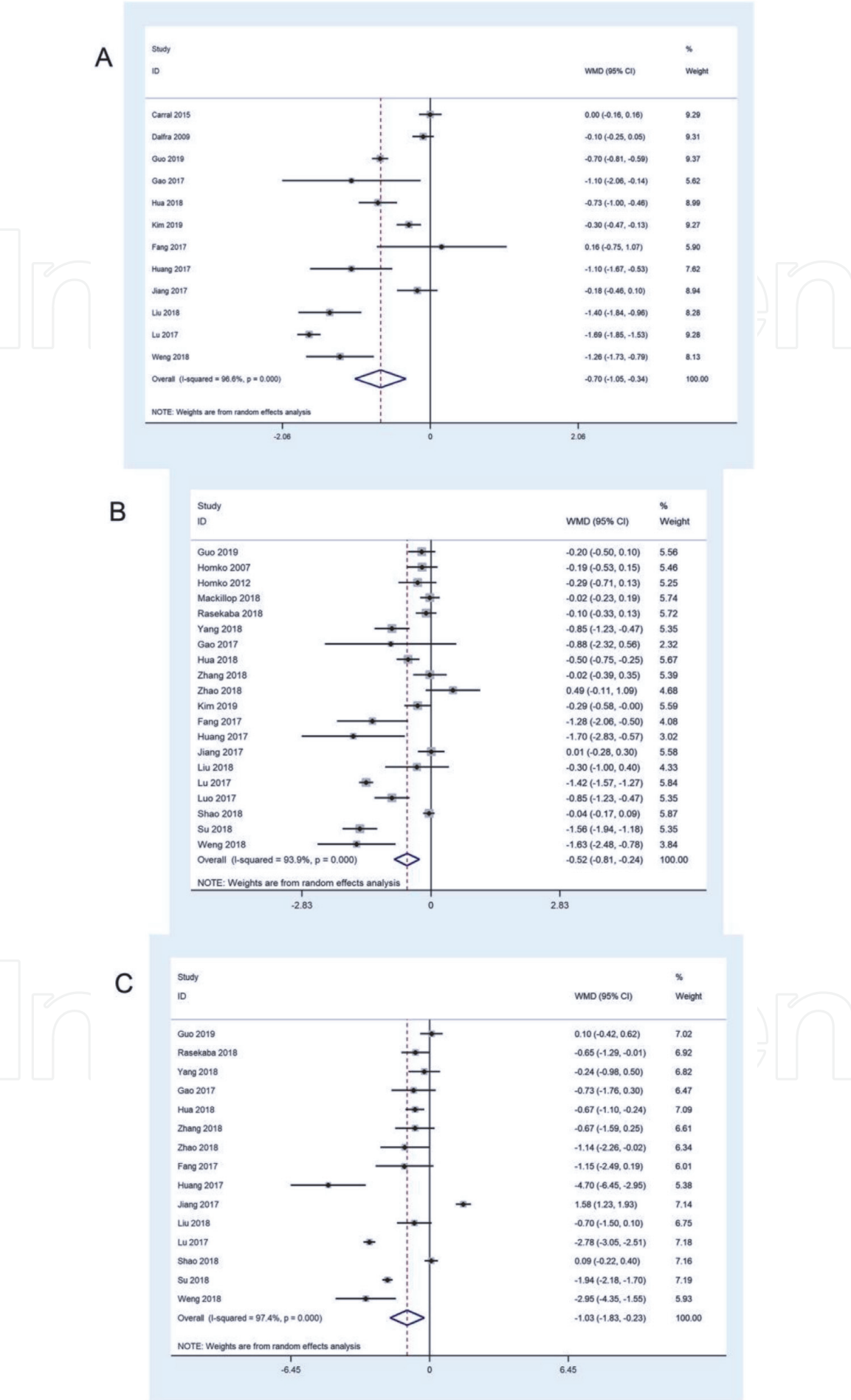


Figure 23. Mean difference in the changes in (A) HbA1c, (B) FBG (C) 2hBG [60].

4.7.2 Pre-eclampsia

Pre-eclampsia is a serious condition that usually develops late in pregnancy and will necessitate early delivery. It is associated with high blood pressure. The condition normally resolves quickly postpartum, and management is to check the blood pressure periodically until it returns to normal value. Telehealth has been used to monitor blood pressure in pre-eclampsia. Blood pressure may also be monitored during pregnancy in those at high risk of developing pre-eclampsia [61].

There are fewer reported outcomes for studies in pre-eclampsia than other uses of telehealth. The one systematic review [62] reports that telehealth is liked by participants, but there is little difference in mean blood pressure between telehealth and usual care. This is to be expected as telehealth is being used to replace visits to the clinic and provide convenience for the patient.

4.8 Clinical benefits in patients with other diseases

Use of telehealth has been reported for the management of other diseases, such as monitoring patients during the acute phase of a disease (sometimes called hospital at home), recovery and release from hospital, rehabilitation, and in high acuity settings such as specialist residential homes. For example, in [63] ECG recordings taken from residents feeling unwell in residential homes were used to recognise cardiac tamponade in one instance and myocardial infarction in a second, which allowed prompt intervention and management.

4.9 Health and wellness

Health and wellness is an often considered area for telehealth. This would be typified by the wearing of a “smart” watch that includes capability to perform measurements of pulse oximetry at the wrist, which may be used to determine the level of blood oxygen and heart rate. Devices may also include sensors to count steps, GPS to determine distance covered, and timers to monitor periods of exercise. Whilst such monitoring may be of interest to the individual and may influence adoption of improved lifestyle and impact on health, there is little evidence that this type of monitoring provides data with clinical value, as often the data is unreliable and of poor quality.

There are efforts to integrate similar sensors within clothing, but there are practical problems in where the sensors can be placed conveniently and provide meaningful and reliable clinical measurements.

Most frequently sensors are integrated in a chest belt of some form, which can then monitor ECG and respiration. This has been implemented as a vest, but most patients do not like the constricted feel. For women, it can be integrated into items such as the bra.

5. Service benefits

5.1 Service redesign

For telehealth to be most effective, great care must be given to the way in which the service is established; this includes consideration of the patient care pathway, workflow, information flow and professional relationships. For cost-effective

reasons, management and care of patients is often transferred to services in the community and primary care.

Therefore the design of the telehealth service must include assigning responsibilities for regular checking of data, making decisions on management and therapy, referral, and release from hospital. There must also be education and training for staff in community and primary care to prepare them for new responsibilities and managing complex conditions. The telehealth service must be provided with strong management that establishes good relationships between all clinicians, and has clear plans for change management.

Business Process Modelling (BPM) can be an effective methodology to capture patient care pathway, workflow and information flow, in order to understand the existing service model, and to provide understanding of the optimum structure to integrate telehealth.

Figure 24 [64] demonstrates how the components and information flows of a telehealth system may be captured and elements of the workflow depicted. This model may then be used to determine how the services are established to enact the requirements identified by the model.

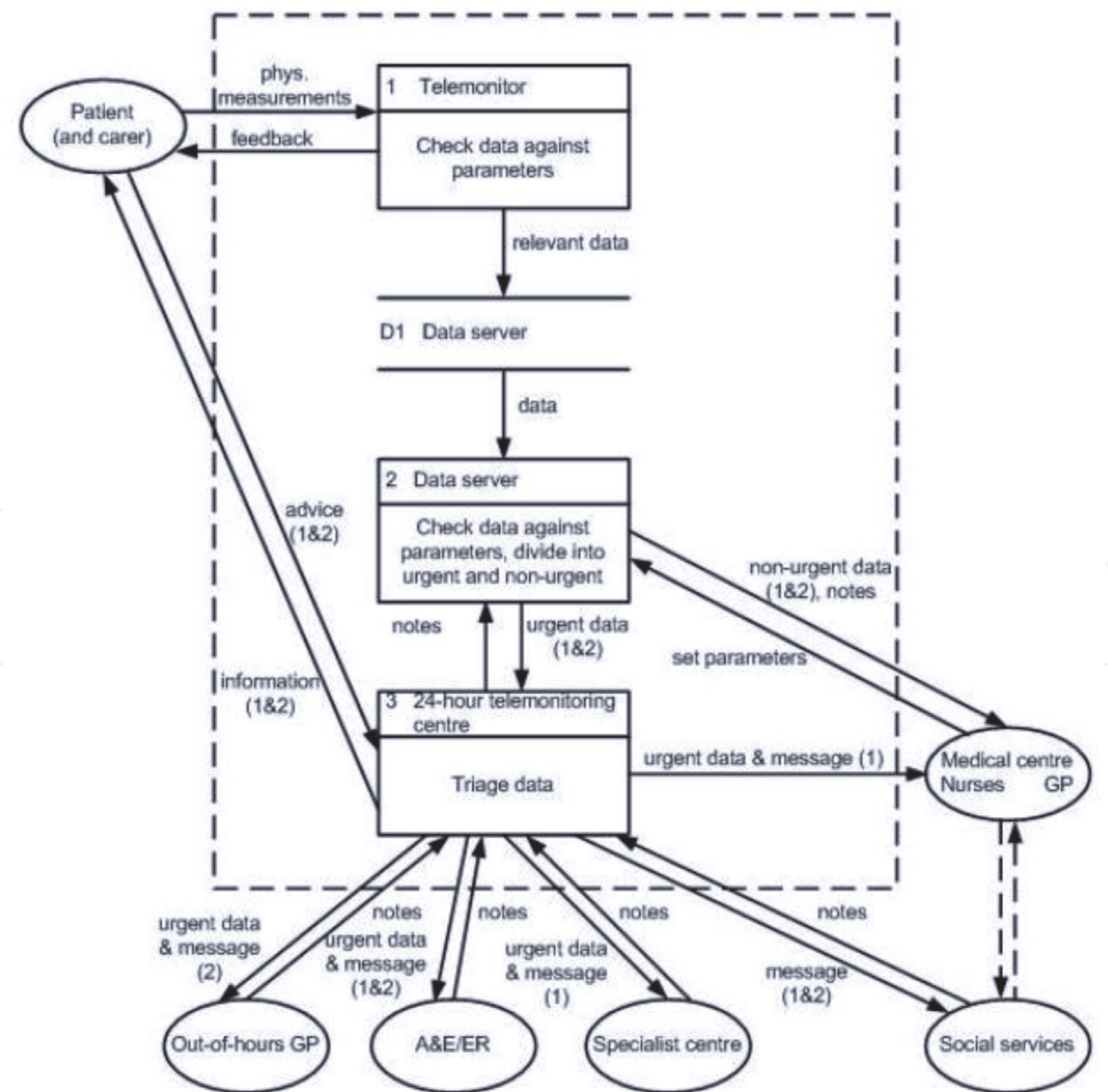


Figure 24. Optimum design of a telehealth system in the UK (1) During office hours; (2) Out of hours [64].

5.2 Cost benefit analysis

Cost benefit analysis in health is complex as it has to consider not only financial aspects (incremental cost), but also the benefits in quality life that society would expect to be given to the patient (incremental benefit). **Figure 25** shows how the analysis of economic aspects is based on the two axes of increased cost and increased benefit. This gives rise to the four quadrants with their respective consideration for a decision. Decisions in the upper left quadrant and lower right quadrant are straight-forward as they can be made on a financial basis. Decisions in the other two quadrants must include a consideration of a combination of financial and patient benefit. As these carry a societal aspect that may be difficult to quantify, patient benefit is assessed in financial terms in health economics.

The approach adopted is to determine the impact to the quality of life of the patient (e.g. hip replacement gives mobility) and how it is maintained over time. This methodology is termed the Quality Adjusted Life Year, and the aggregate of the benefit over the baseline over time is determined (**Figure 26**). A notional cost is assigned to achieve a QALY (e.g. £30,000 per QALY). This allows the cost–benefit analysis to be made on an economic basis and a decision made.

However, studies do not show telehealth provides significant impact on quality of life, thus there is little change in incremental benefit and analysis concentrates on incremental cost, or cost-effectiveness.

5.3 Cost-effectiveness

Analysis of cost-effectiveness of telehealth requires study of the impact on use of all the health services by patients. This normally focusses on hospital services, such

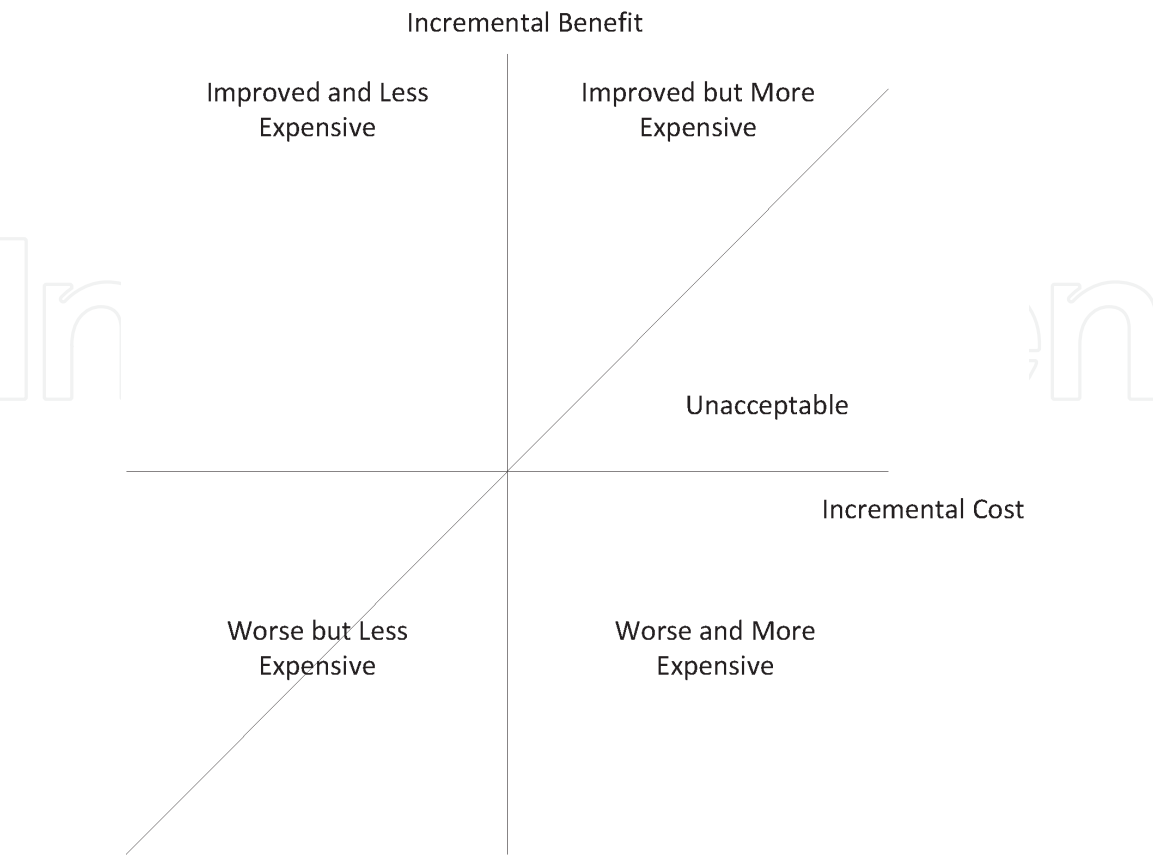


Figure 25.
Cost–benefit analysis.

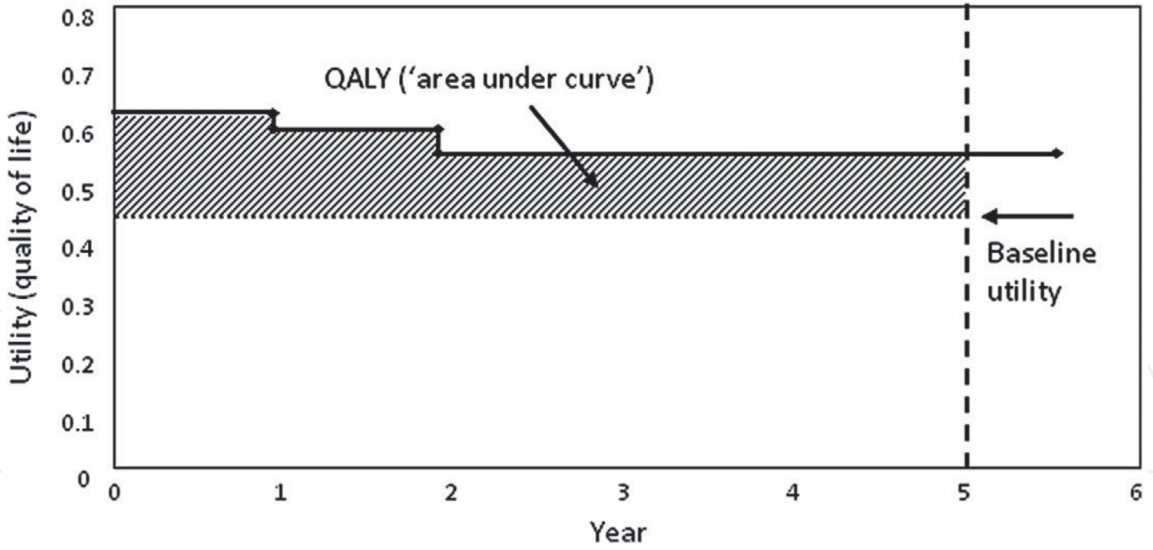


Figure 26.
Use of the QALY to assess cost benefit.

as admission, emergency room visits, and length of stay, as these contribute most. This is balanced by the incremental cost of the technology and staffing costs to provide the service. A cost model may then be created to evaluate. However few well defined studies exist. The review in [39] provides a meta-analysis of the impact on hospital services for patients with CHF; however none of the studies provided outcomes for cost-effectiveness.

5.3.1 All cause and CHF hospital admission

The same review [39] found six studies that reported all cause hospital admissions as primary outcome (**Figure 27**). None reported significant reduction and the pooled estimates support this (0.99, 0.88 to 1.11, $P = 0.84$).

In contrast, some reduction in CHF hospital admission was reported by the same set of studies (**Figure 28**). Pooled estimates of the given data indicate that there is a small reduction that is significantly relevant (0.73, 0.62 to 0.87, $P = 0.0004$). Bias was unlikely but possibility of heterogeneity could not be ruled out in all cause hospital admission ($P = 0.03$, $I^2 = 59\%$). There was little evidence of heterogeneity for CHF ($P = 0.44$, $I^2 = 0\%$).

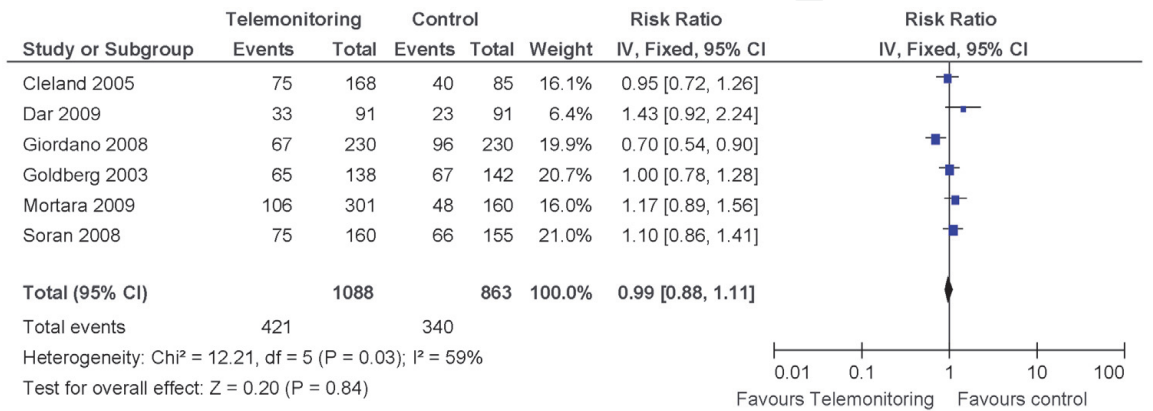


Figure 27.
Effect of telemonitoring on all-cause hospital admission [39].

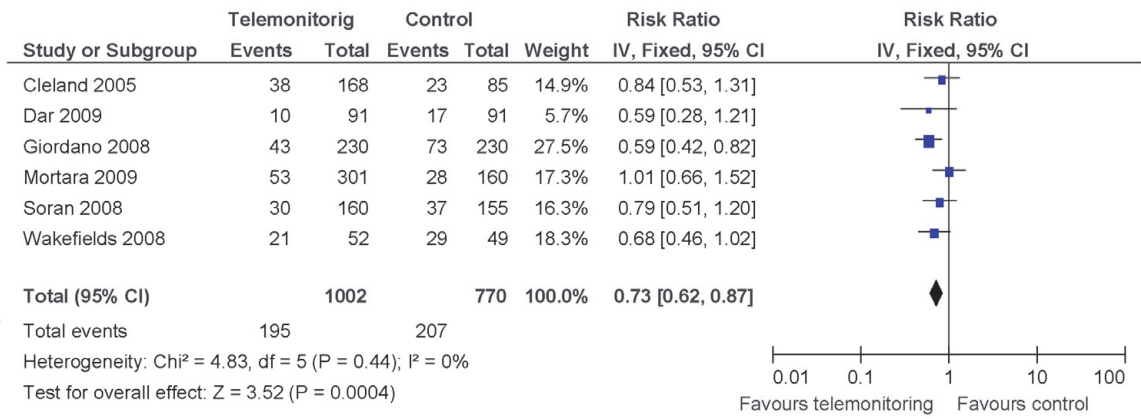


Figure 28.
Effect of telemonitoring on CHF hospital admission [39].

5.3.2 Emergency room visits

The review [39] found seven studies that provided the number of emergency visits as secondary outcome (**Figure 29**); but with mixed outcome. Some studies observed no significant difference in emergency visits among the patients in treatment and control arm ($P = 0.43$); some reported lower emergency contacts were observed; yet others reported an increase in emergency room visits. Pooled results of data extracted from 4 studies showed no significant reduction in risk of emergency admission between the groups (1.04, 0.86 to 1.26). Heterogeneity existed as $P = 0.001$, $I^2 = 82\%$.

5.3.3 Length of stay

The review [39] found nine studies that evaluated the effect of intervention on length of stay in hospital. Among these, seven studies showed no difference in length of stay at hospital due to any cause or CHF among the patients across both groups. Two studies reported reduction in length of stay among patients in home monitoring group due to CHF.

However a more detailed analysis on length of stay [48] reveals that patients with CHF who are admitted to hospital often present a complex set of issues. Patients sometimes develop complications and so remain in hospital for an extended period; likewise, earlier admissions may have been protracted, but stays during the trial are significantly shortened; this results in a significant spread in length of stay (**Figure 30**). Overall a reduction in length of stay is observed. This is often attributed to early discharge being possible as the patient feels safe to return

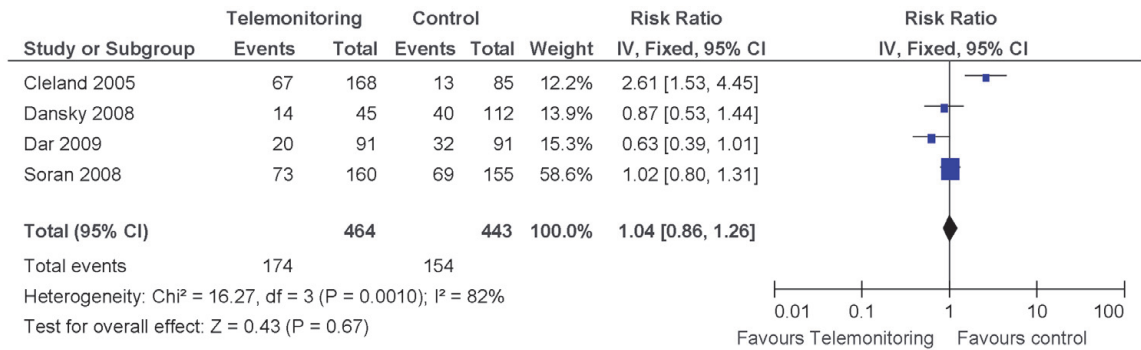


Figure 29.
Effect of telemonitoring on all-cause emergency room visit [39].

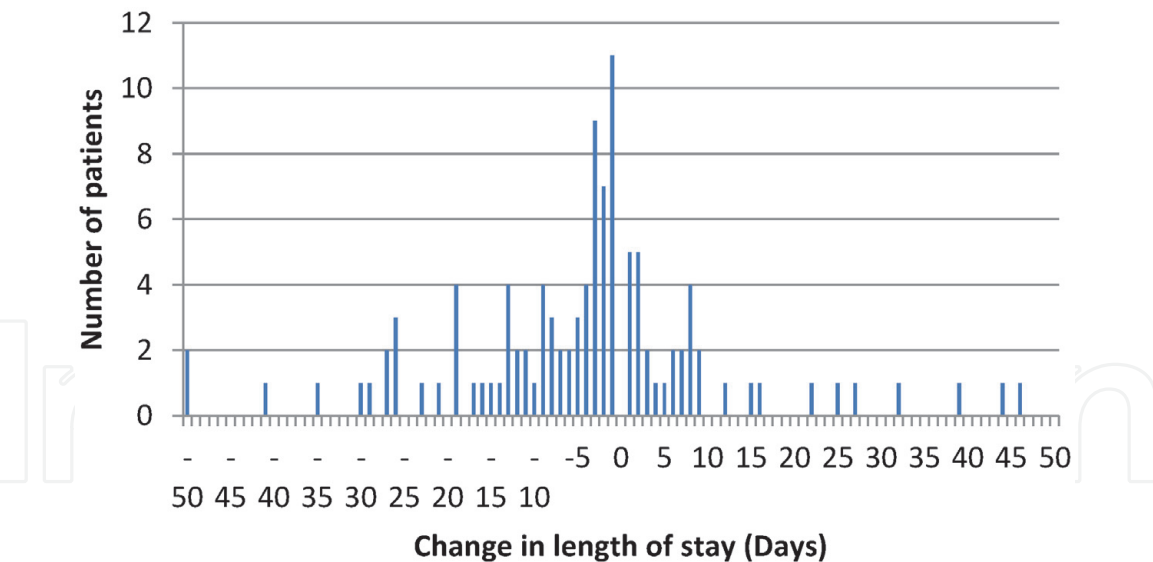


Figure 30.
Change in length of stay for each patient compared to length of stay in the period immediately before monitoring [48].

home because they are being monitored. There may be an affect due to the earlier planned admission and the prompt intervention results in reduced recovery time.

5.3.4 Cost

Two of the studies in the meta-analysis [39] evaluated the cost effectiveness of a telemonitoring based intervention against the usual care but neither determined that there was a reduction. One study on cost-effectiveness [48] undertook evaluation on two separate organisations (Primary Care Trusts) and found wide discrepancy in outcomes, indicating why the literature is inconclusive. The study determined an average annual saving of £1023 per patient, but this was highly influenced by factors pertaining to the way in which the service was established and patients were managed.

6. Future developments

6.1 Monitoring activities of daily living

An area of development for telehealth is in monitoring the activities of daily living (ADL), especially of the frail elderly. Changes in behaviour may be used to detect early deterioration in health and before it may be evident in other symptoms, which may also be being monitored by telehealth. This remains a little researched area, with almost all reported work being on development of sensors [65]. However, one of the few studies that reports ADL and correlates with clinical events [45] presents evidence that shows that deviation from an established, characteristic behaviour pattern can indicate deterioration in a health condition and impending clinical event. Anecdotal evidence suggests patients may tire easily and thus rest more in a chair; have altered sleeping patterns; become restless at night; sleep in the day; visit the toilet more frequently; and take longer to complete everyday activities. Simple sensors such as motion and bed/chair occupancy and analysis of their data can be used to monitor these events, patterns of normal behaviour can be established, and deviation can be recognised.

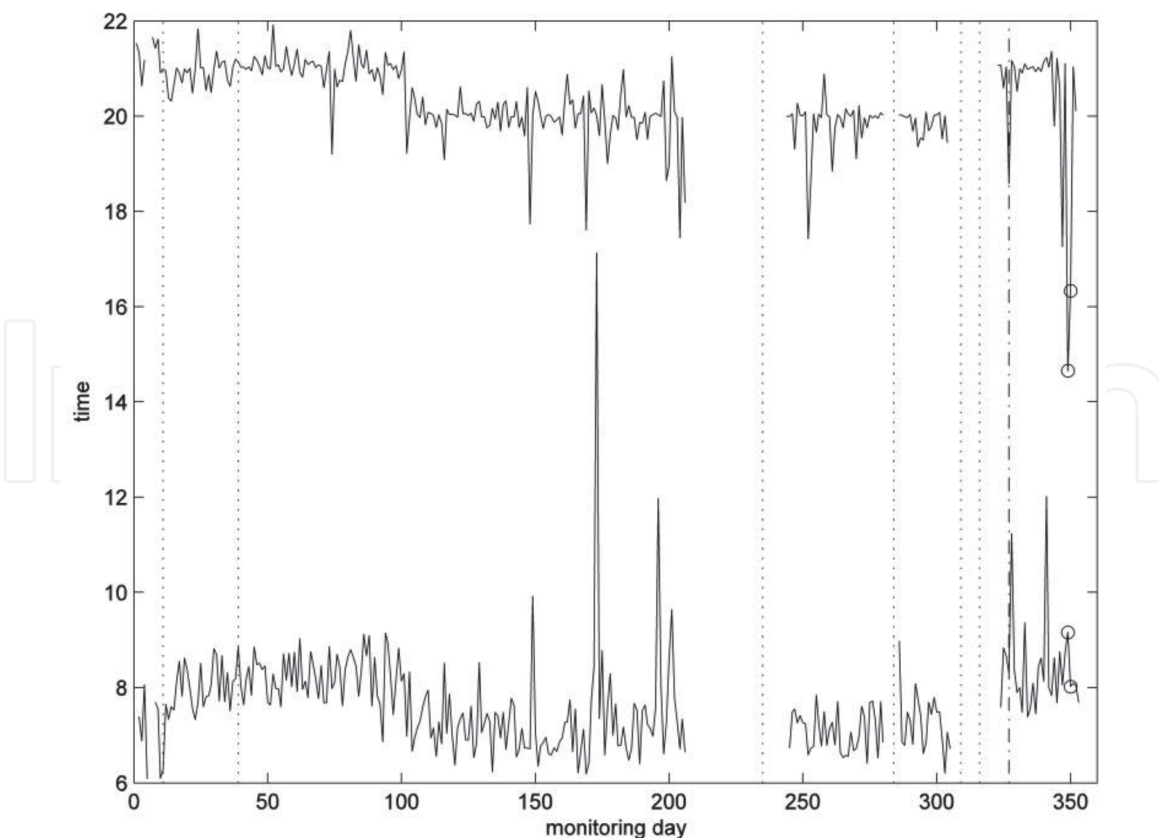


Figure 31.
 Time of first and last detected motion in living room [45].

In one example (**Figure 31**), the time of first and last motion in the living room is determined, from which the regular bed and waking time can be inferred. On some days, there is a much later time of waking and earlier bed-time. Naturally caution is required in interpretation of such events, as differences may be easily explained by events such as a trip away from home.

Figure 32 shows the bed occupancy of a patient with pulmonary fibrosis. The black bar shows the time in bed each day. In this example, the patient continued to go to bed around 23:00 each day, but during times of deterioration the patient started to wake earlier, and as severity of the condition worsened they had less sleep.

A similar pattern of disturbed sleep was observed in COPD patients during periods of low blood oxygen as indicated in **Figure 33**.

6.2 Technology developments

Technology for telehealth continues to evolve, improve and be developed. This would include sensors becoming lighter, smaller and the emergence of new types of sensor. Technology continues to improve with microcontrollers becoming more powerful, faster, and use less power, at the same time batteries give greater periods of use. This has made possible an explosion in the availability of wearable devices, particular wrist-worn, that can monitor heart rate, blood oxygen and capture ECG.

Chemistry and biomaterials continue to improve, allowing longer periods of use and providing sensors with greater accuracy in applications such as continuous glucose monitoring.

Wireless technology continues to evolve, with improvements to the range and reductions in power. This allows devices based on technologies such as Bluetooth to operate for longer or use smaller batteries. Likewise improvements in mobile

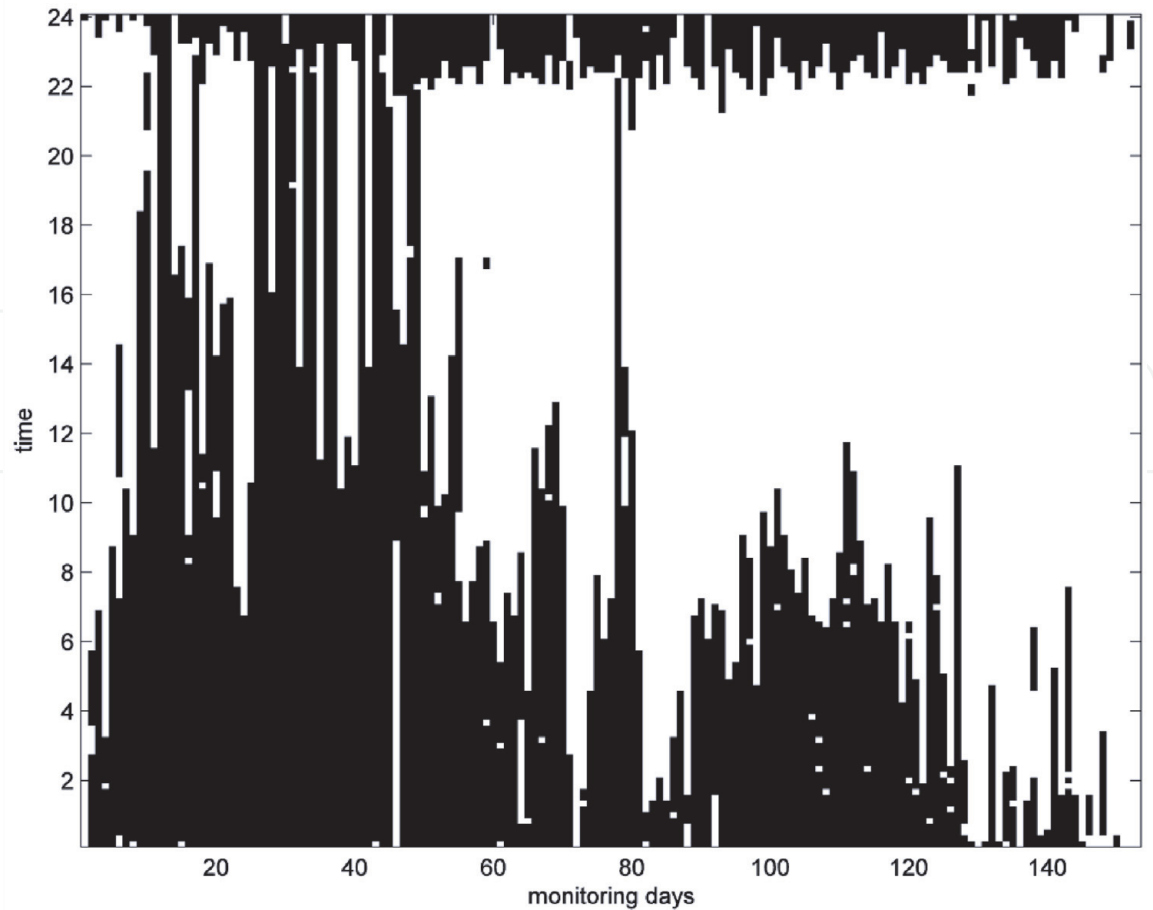


Figure 32.
Daily bed occupancy [45].

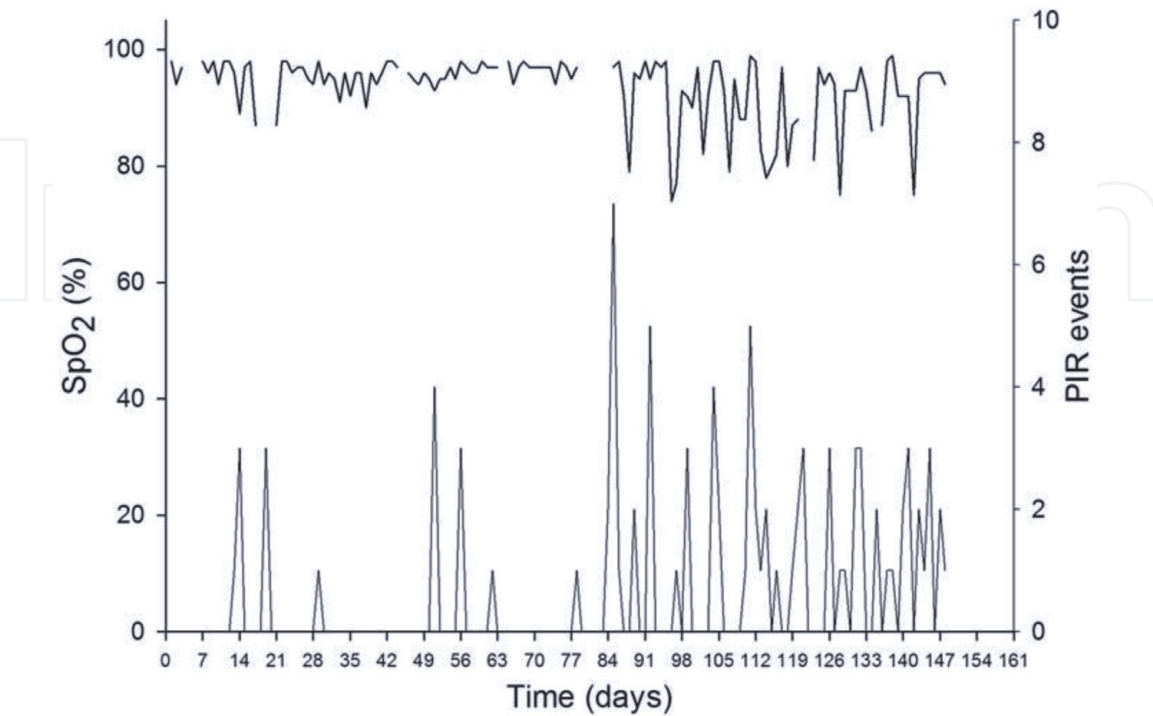


Figure 33.
Incidence of disturbed sleep and low blood oxygen [45].

technology are introducing a range of low-power long range services such as NB-IoT and CAT-M that support direct transmission of data from a device and provide extended battery life.

Telehealth remains beset with devices using proprietary protocols. Although devices may claim to use Bluetooth Low Energy (BLE) as wireless, the data and its format differ significantly between devices and device manufacturers. This locks users into specific devices and applications, which may be acceptable for the consumer market. However it makes it difficult to integrate several devices into a platform to monitor a condition, and many types of device to monitor comorbidities. It also introduces uncertainty to the market regarding continued availability of devices, with consequent loss of investment if a system must be replaced if devices are no longer available.

The situation is not improved by the small number of separate profiles that have been developed for individual medical devices by Bluetooth, and that are fixed in capability. This prevents extensibility and results in proprietary protocols.

There is a great need for protocols that provide semantic interoperability between devices and that are extensible and flexible. The IEEE 11073-20601 [22] base protocol standard and its family of specialisations (IEEE 11073-104xx) with its use of IEEE 11073-10101 nomenclature achieved this goal [66], and is further supported by transparent mapping into enterprise health standards such as IHE PCD-01 and FHIR. However this standard has not been adopted commercially, therefore work has commenced to develop a standard (IEEE 11073-10206) that is based on an abstract version of the object models of IEEE 11073-20601 and that may be used as a guideline to develop other protocols, such as a profile of BLE, that will be semantically interoperable across technologies and thus map transparently to enterprise health standards.

6.3 Algorithms, artificial intelligence and machine learning

Algorithms, artificial intelligence (AI) and machine learning (ML) have been slow to be applied to telehealth. Most telehealth systems continue to use simple thresholds on vital signs data to determine patients at risk of deterioration, which has been shown to have poor performance, resulting in such frequent false alerts that they are often disabled by users and alerts are missed [67].

Patients with COPD often adapt to their condition and will tolerate significantly lower levels of blood oxygen without perceived difference to their health or impact on everyday activities. A simple threshold would determine such patients at risk of deterioration.

Figure 34 shows the daily SpO₂ time-series data for a patient with COPD and the wide variation that is typically observed; short term and long term average are shown, and the vertical dotted lines indicate clinical event.

Using a simple threshold would result in both false negative (value below threshold without clinical event) and false positive (value above threshold during clinical event) indications for this patient.

However when the residual (difference between actual and average) is analysed [68], significant variation is observed, and the standard deviation of the residual is seen to increase significantly during periods of exacerbation (**Figure 35**). Physiologically this might be explained by the patient having a coping mechanism for low blood oxygen, but during exacerbation, this mechanism is overwhelmed or fails, and results in the large variations that are observed, giving a clearer indication of impending deterioration.

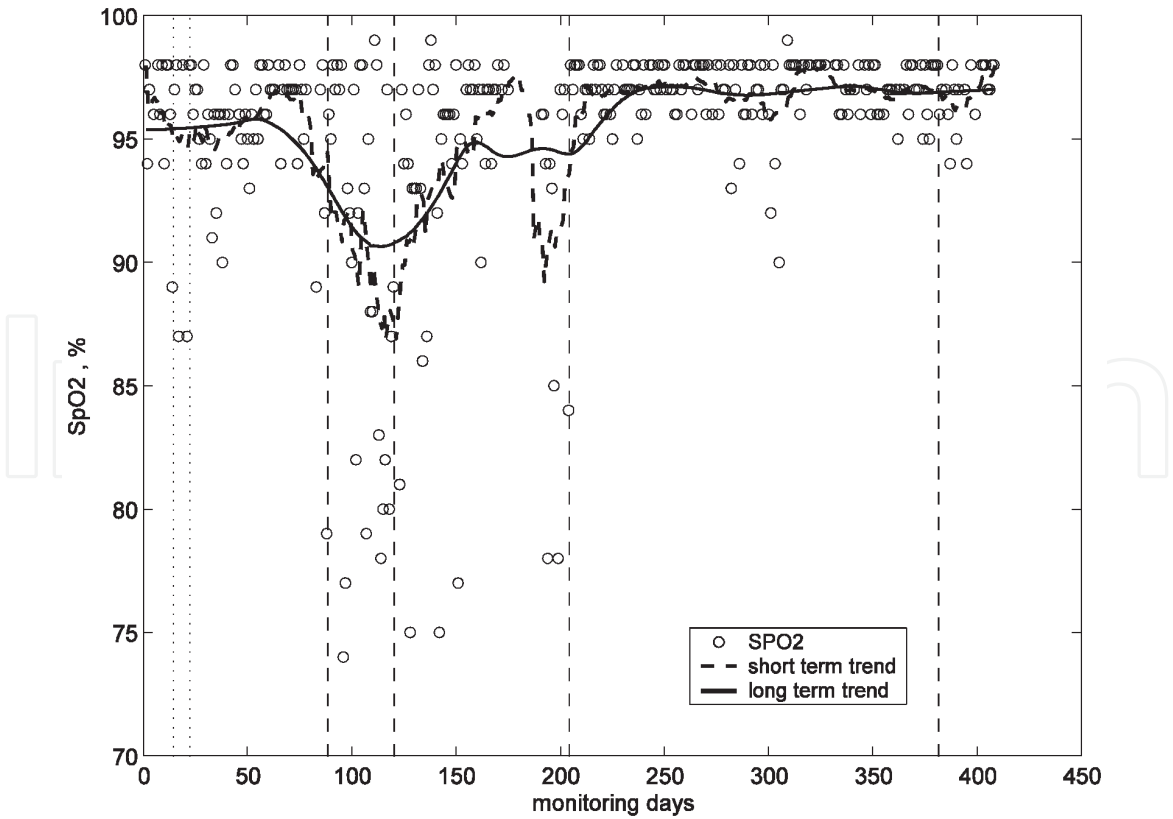


Figure 34.
Daily SpO₂ time-series data for patient with COPD [68].

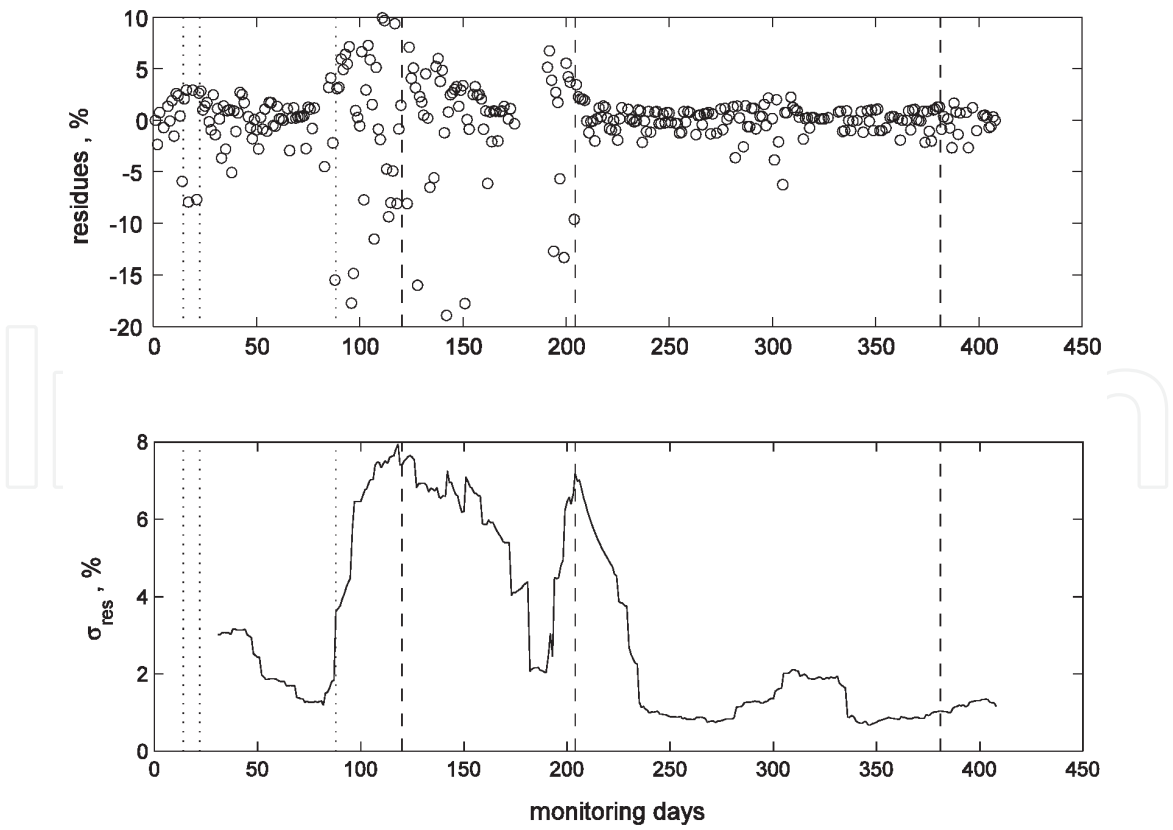


Figure 35.
Residuals (top) and estimates of standard deviation of residuals (bottom) [68].

7. Conclusion

Too often telehealth is seen as a panacea to resolve issues in a failing health service and is applied without consideration of the changes that must be made in order to integrate the telehealth into the existing service in terms of the technology, infrastructure, care pathways, new care services, management, support, training, new and changed roles, patient relationships, and professional relationships.

Telehealth is often promoted as being able to provide cost savings to the health service. Whilst reductions in length of stay, and possibly a reduction in the number of hospital admissions can be shown, resulting in notional savings, it is unlikely that the savings can be realised, as the hospital services will not be reduced. Most likely an organisation will be burdened with the additional costs for the technology and staff and the cost of providing services in the community. Or in cases where services have separate budgets, any saving in one service is not transferred as additional budget to the second. It is therefore essential that a holistic view be taken and all circumstances considered. For example, some organisations reimburse the costs of travel to the patient, and thus this would provide a realisable saving if the patient stays at home. In a single payer system, budget might be transferred, or made available to the organisation providing the telehealth service.

Alternatively a societal view may be taken. Telehealth can be seen as a solution to provide health services to communities and patients where otherwise it would not be available due to remoteness. Telehealth may also be considered to provide cost benefit to society by removing the need for costly travel for patient and relatives, and loss of earnings for time taken to travel and remain with the patient whilst in hospital.

Telehealth often suffers from poor design of the technology. Frequently devices are designed by enthusiastic young engineers to appeal to their imaginings of the needs of a patient; the system is built around the technology with which they are familiar, and does not relate to the needs of the actual user. At worst this means the technology is unusable with real patients (no broadband available, arthritic fingers cannot manipulate a smart phone, technology phobia), or is detested because it must be placed in a prominent position in the home and causes patients to be stigmatised. This problem also applies to procurement, when managers relate to the technology without understanding the needs of the patient; reminders may appear helpful but become irritating after many days of use. Telehealth should be simple and unobtrusive.

Moreover it must be recognised that telehealth is not a treatment, rather it is an approach to elicit relevant information from patients that may be used to support decision support and management. The effectiveness of outcome therefore relies on the services that use and act on that information. This may include telehealth supporting new approaches to deliver care. This may include using primary care and community to manage the patient, and using communication to support joint management and provide continuity of care, or establishing specialist services to manage the patient in the community. The approach adopted requires careful planning for its introduction.

However when implemented effectively, telehealth can confer significant benefit to the patient health, effectiveness of the clinician, and efficiency of the health service.

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