Introduction and Methodology

This literature review is a refinement of the initial review and is an examination of the evidence base for remote telemonitoring and therefore the emphasis has been on identifying key research from the top levels of the evidence hierarchy as defined by the School of Health and Related Research at the University of Sheffield. "The higher up a methodology is ranked, the more robust and closer to objective truth it is assumed to be" (ScHARR). The aim of the literature search was to identify relevant systematic reviews and randomised controlled trials.

Rank	Methodology
1	Systematic reviews and meta-analyses
2	Randomised controlled trials
3	Cohort studies
4	Case-control studies
5	Cross sectional surveys
6	Case reports
7	Expert opinion
8	Anecdotal

Table 1: Hierarchy of Evidence (ScHARR)

A Systematic Review is a method of looking at a number of primary studies which have been identified in a review of the literature according to specific search criteria. Inclusion and exclusion criteria have been set and the identified studies have been evaluated against consistent methodological standards.

A randomised controlled trial (RCT) is a trial where the patients / participants are randomly allocated to an arm of the trial, the two arms being the intervention group and the placebo or usual care group. Those trials which look at an intervention group and a placebo group but the patients

have not been randomly allocated are called non randomised controlled trials and can also be known as other controlled clinical trials.

The methodological approach for the literature search is illustrated in figure 1 and the details of number of articles retrieved are given in table 2.

PubMed was searched individually for each of the main clinical conditions of interest. Each search was run as a MeSH Major Topic in an attempt to ensure the condition was a major element of interest in the identified articles. Each of the individual searches for the clinical conditions was combined into a single result set using the Boolean "OR".

A separate PubMed search was undertaken to address the concept of remote telemonitoring. The terms included in this search were an attempt to be as inclusive as possible at this stage.

The result set for the concept of chronic disease (heart failure, diabetes mellitus and COPD) was combined with the result set for the concept of remote telemonitoring using the Boolean "AND" operator.

Table 2: PubMed Search Terms and Number of Articles Retrieved.

Search Number	Search Term	Number of articles returned
#1	"Heart Failure"[MeSH Major Topic]	43301
#2	"Diabetes Mellitus"[MeSH Major Topic]	178737
#3	"Pulmonary Disease, Chronic Obstructive"[MeSH Major Topic]	16632
#4	#1 OR #2 OR #3	237985
#5	telemedicine OR telecare OR telehealth OR telemonitoring OR "home monitoring" OR "remote monitoring"	11135
#6	#4 AND #5	495
#7	#6 Limits: only items with abstracts, Humans, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review, Controlled Clinical Trial, English	154

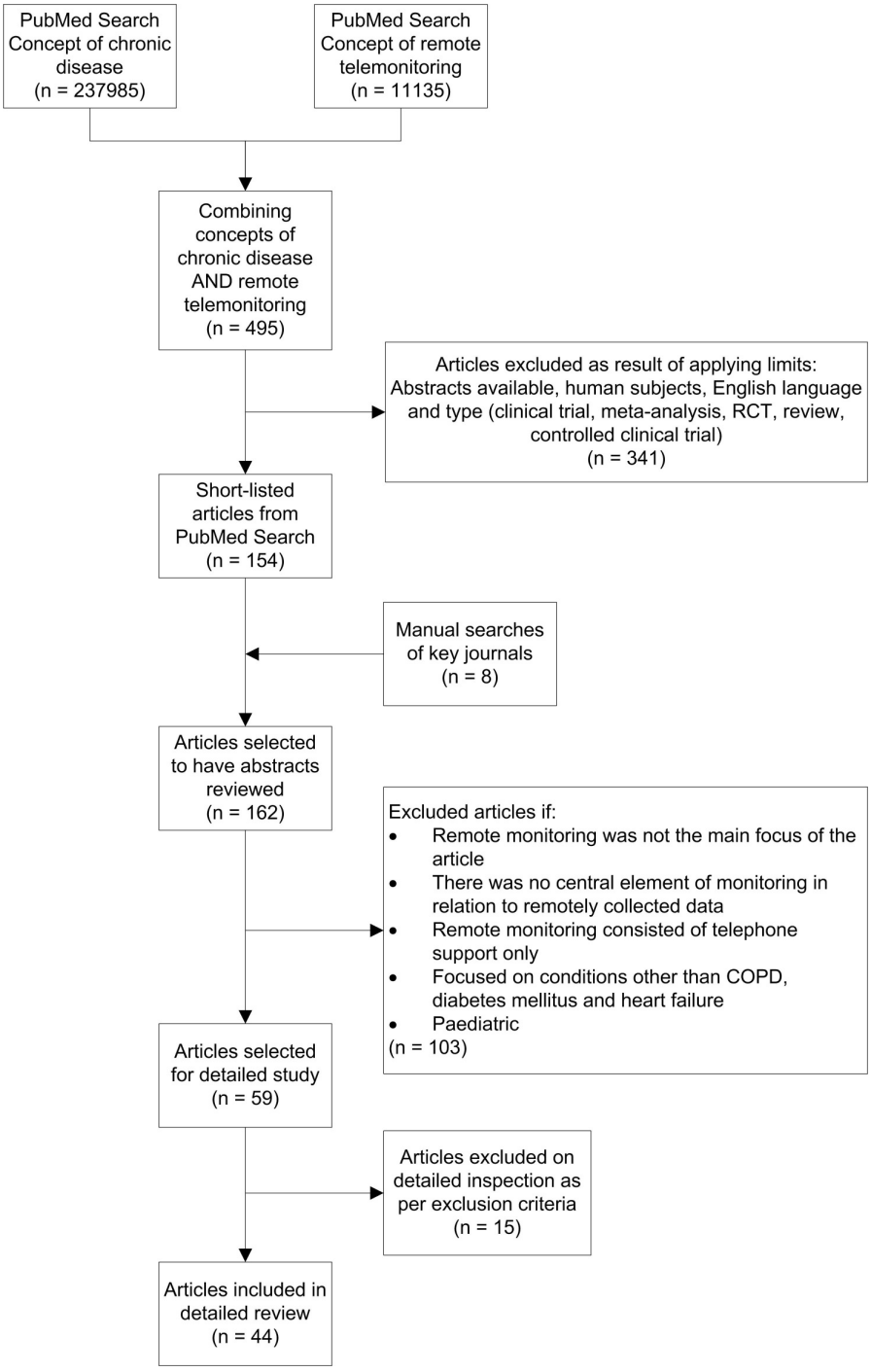


Figure 1: Search methodology

The 495 articles returned from the original combined PubMed search were reduced to 154 by applying several limits. The result set was restricted to those articles that included an abstract, were

in the English language and covered human subjects. Additionally only articles of the following types were included: clinical trial, meta-analysis, RCT, review and controlled clinical trial.

A further 8 articles were identified by hand searching the following journals:

- The Journal of Telemedicine and Telecare
- Telemedicine and e-Health

Abstracts for 162 articles were examined, leading to the exclusion of 103 articles. Articles were excluded from the review if:

- Remote monitoring was not the main focus of the article
- There was no central element of monitoring in relation to remotely collected data
- Remote monitoring consisted of telephone support only
- The article focused on paediatrics or conditions other than heart failure, diabetes mellitus or COPD.

59 articles were studied in detail. 15 of these publications were excluded from the review because it became apparent on detailed study that they met the exclusion criteria.

44 publications are included in the review.

Literature Review

RCT Checklist: Albisser (1996)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Randomised Controlled Trials		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Albisser, A.M., et al.	
Title	"Diabetes intervention in the information age."	
Reference	Med Inform (Lond), 1996. 21(4): p. 297-316.	
Section 1: Internal validity		
In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Adequately addressed
1.2	The assignment of subjects to treatment groups is randomised	Not addressed
1.3	An adequate concealment method is used	Not addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not applicable
1.5	The treatment and control groups are similar at the start of the trial	Not addressed
1.6	The only difference between groups is the treatment under investigation	Not addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Poorly addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study	Not clearly addressed

	dropped out before the study was completed?	
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Poorly addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Poorly addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(-) no indication given
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	No description of inclusion criteria for patients
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect shown is due to the intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	117 recruited from health maintenance organisation. 87 recruited from private practice office.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Characteristics of the patients were not specifically described - entrants were unrestricted in relation to age, gender, socio economic class, type of diabetes, method of treatment, type of medication and method of glucose self management.
3.3	What intervention (treatment, procedure) is being investigated in this study?	Intervention is the use of an electronic information system to facilitate control of blood

	List all interventions covered by the study.	glucose and evaluating if the system is safe to use and/or effective.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Comparisons are made by looking at the blood glucose control of those patients using the electronic system and those patients who are not using the system.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	Patients followed up for 1 year.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Systems utilization statistics. Benefits to patients according to metabolic outcomes, glycated haemoglobin and body weight.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Glycated haemoglobin (glycated Hb) fell significantly showing a drop of 1– 1.3%, $p<0.01$ or $p<0.001$.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Not documented.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study focuses on the safety issue of the use of an electronic device to monitor/ feedback clinical information on a patients blood glucose level and thus provide information on how well a patients condition is

		controlled. It illustrates that there are no observed detrimental effects to patients using the system and also indicates that due to the fact that up to date information on the patients blood glucose measurements are available, the healthcare professionals are in a better position to make changes to the patients treatment regime with the aim of improving the patients diabetic care.

RCT Checklist: Albisser (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (*Include author, title, year of publication, journal title, pages*)	
Author	Albisser, A.M., C.E. Wright, and S. Sakkal
Title	"Averting iatrogenic hypoglycemia through glucose prediction in clinical practice: progress towards a new procedure in diabetes."
Reference	Diabetes Res Clin Pract, 2007. 76(2): p. 207-14.

Section 1: Internal validity

	In a well conducted RCT study:	***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Not addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	0% drop out rate in both arms

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Unclear how randomisation carried out.
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to the intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	22 patients included in the study. 11 patients in each arm of the study.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Community based patients. Age range= 49.9 to +/- 17.6 years. Being intensively treated with insulin. > 1 episode/wk hypoglycaemia. Willingness to report daily results to diabetes center.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Use of telemedicine intervention which would help to avert iatrogenic hypoglycaemia episodes occurring. The remotely

		monitored data is presented on a screen to the healthcare providers enabling predicted pending risks of hypoglycaemia to be identified.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Patients using the system are compared with those patients who do not have access to the system with regard to the number of hypoglycaemic episodes.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	2 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Primary outcome – Frequency of hypoglycaemic episodes. Secondary outcomes include premeal blood glucose, medication dosages taken and glycated HbA1c.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Hypoglycaemia episodes = 0.2+/- 0.3 (0to 1) in the intervention group and 2.0+/- 0.9 (1–3) in the control group.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Not clearly documented.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and*	This study's findings indicate that the more information made available to the clinicians with regard to the patients blood

	indicate how it relates to the key question.	glucose readings, the better the predictive control of hypoglycaemia episodes in patients is achieved. The clinicians are in a better position to advise on treatment options and changes required to the patients treatment regime. The authors in this study have shown that this effect can be achieved in 2 months but the numbers involved in this study are very small.

Systematic Review Checklist: Barlow (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Systematic Reviews and Meta-analyses	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Barlow, J., et al.
Title	"A systematic review of the benefits of home telecare for frail elderly people and those with long-term conditions."
Reference	J Telemed Telecare, 2007. 13(4): p. 172-9.

Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Adequately addressed
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered
1.4	Study quality is assessed and taken into account.	Poorly addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	

Section 3: Description of the study		
3.1	What types of study are included in the review?	RCT, Cohort, Case-control
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	The main outcomes of this systematic review looked at vital sign monitoring and its benefits to individuals and system wide benefits. Looking at the individual benefits the authors identified 18 RCTs and 1 large observational study and from these papers they found that the largest amount of evidence for the use of home telecare in elderly people with long term conditions was available in the clinical areas of diabetes and heart failure with less evidence being available for COPD. For Diabetes 5 of the aforementioned studies showed no significant difference in clinical outcomes occurring from telemonitoring of blood glucose and another 3 studies found significantly improved clinical outcomes. For heart failure improvement in quality of life and reduction in mortality are the main findings. The system benefits shown from this review are that the remote telemonitoring of data is at least as efficient as conventional care and may even reduce the use of health service for those patients with heart failure and COPD. No detrimental effects on patient care are observed in this review.

Cohort Study Checklist: Barnett (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Cohort studies		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Barnett, T.E., et al.	
Title	"The cost-utility of a care coordination/home telehealth programme for veterans with diabetes."	
Reference	J Telemed Telecare, 2007. 13(6): p. 318-21.	
Section 1: Internal validity		
In a well conducted cohort study:		***In this study the criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Adequately addressed
SELECTION OF SUBJECTS		
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Well covered
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	Not addressed
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	Not addressed
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.	Not addressed - made known
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	Not addressed

ASSESSMENT		
1.7	The outcomes are clearly defined.	Adequately addressed
1.8	The assessment of outcome is made blind to exposure status.	Poorly addressed
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	Poorly addressed
1.10	The measure of assessment of exposure is reliable.	Poorly addressed
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	Poorly addressed
1.12	Exposure level or prognostic factor is assessed more than once.	Poorly addressed
CONFOUNDING		
1.13	The main potential confounders are identified and taken into account in the design and analysis.	Poorly addressed
STATISTICAL ANALYSIS		
1.14	Have confidence intervals been provided?	No
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? Code ++, +, or −	(−)
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain	Unclear

	that the overall effect is due to the exposure being investigated?	
Section 3: Description of the study		
3.1	How many patients are included in this study? *List the number in each group separately*	370- site A= 60, site B= 56, Site C= 165, site D= 89 (reference group).
3.2	What are the main characteristics of the study population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Veterans with diabetes, 2 or more hospital admissions or emergency department visits in the 12 months prior to enrolment, >10 medication prescriptions, average age68.2, male(365), Hispanic(175), white(154), black/other(41).
3.3	What environmental or prognostic factor is being investigated in this study?	The cost effectiveness of care co=ordination home telehealth(CCHT) using incremental cost effectiveness ratios(ICERs).
3.4	What comparisons are made in the study? *Are comparisons made between presence or absence of an environmental / prognostic factor, or different levels of the factor?*	Cost effectiveness of care for a cohort of veterans was compared pre and post the introduction of a CCHT programme of care.
3.5	For how long are patients followed-up in the study?	12 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess the impact of the chosen environmental or prognostic factor.*	Cost effectiveness of the care provided measured using ICERs calculated by converting the patients health related quality of life data into quality adjusted life year(QALY) scores and then using costs to construct incremental cost effectiveness ratios(ICERs).

3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk. Include p values and any confidence intervals that are provided.* ***Note****: Be sure to include any adjustments made for confounding factors, differences in prevalence, etc.*	The CCHT programme is shown to be cost effective for at least 1/3 of the veterans in the study.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Funded by a contract from the VA VISN-8 Community Care Coordination Service.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question?*	This study focuses on the analysis of the quality of life scores in order to help address cost effectiveness of the intervention. It does not describe the content of the care coordination home telehealth programme thus the authors do not give enough detail as to whether vital sign monitoring or remote telemonitoring is part of the CCHT programme.

RCT Checklist: Benatar (2003)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Randomised Controlled Trials		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Benatar, D., et al.	
Title	"Outcomes of chronic heart failure."	
Reference	Arch Intern Med, 2003. 163(3): p. 347-52.	
Section 1: Internal validity		
In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Not addressed
1.3	An adequate concealment method is used	Not addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Well covered
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	None

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(-)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	No indication of randomisation
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to the intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	216 patients - 108 in each arm of the study.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Patients admitted to hospital with heart failure, New York heart association(NYHA) class 3 or 4, conventional heart failure symptoms, echo evidence of heart failure ejection fraction<40%, mean age 62.9+/- 13.2, 63%female, 86.1%african American.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	The use of transtelephonic home monitoring devices to measure weight, blood pressure, heart rate and oxygen saturation.

3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Nurse telemanagement, with the patient using the transtelephonic home monitoring devices versus usual home nurse visits.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	3 months post discharge from hospital.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Heart failure readmissions, length of stay and anxiety, depression, self efficacy and quality of life of the patients.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Heart failure readmissions reduced for nurse telemanagement (13 versus 24) p<0.01, shorter length of stay for nurse telemanagement patients (49.5 versus 105 days) p<0.01,mean hospital anxiety and depression score decreased in the nurse telemanagement group from 18.89 to 12.53 (p<.11) compared with a decrease from 17.69 to 15.52 in the nurse home visit group (p<.046), mean quality of life score increased from 16.65 to 20.93 (p<.01) in the telemanagement group and increased from 15.06 to 18.34 in the visit group (p<.01).
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Study funded by grants from the National Institutes of Health, Bethesda, Md.

3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	The findings from this study show that the use of remote telemonitoring has a positive impact on the readmission rates of patients with heart failure, decreasing this rate and also shows a decrease in the length of stay required by a patient who may be readmitted. The sample size used in this study is a reasonable size.

Systematic Review Checklist: Bensink (2006)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Bensink, M., D. Hailey, and R. Wootton	
Title	"A systematic review of successes and failures in home telehealth: preliminary results."	
Reference	J Telemed Telecare, 2006. 12 Suppl 3: p. 8-16.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered
1.4	Study quality is assessed and taken into account.	Adequately addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT, CCT, Cohort, Case-control
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	This systematic review looks at a number of different conditions in which the use of remote telemonitoring has been used. The authors state that the body of evidence for the use of remote telemonitoring is growing and that more, larger scale RCT's are required. This paper is the preliminary findings of the authors. It indicates that conditions most commonly looked at in relation to the use of remote telemonitoring include diabetes, heart failure, heart disease and to a lesser extent chronic lung disease.

Systematic Review Checklist: Bensink (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Systematic Reviews and Meta-analyses	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Bensink, M., D. Hailey, and R. Wootton
Title	"A systematic review of successes and failures in home telehealth. Part 2: Final quality rating results."
Reference	J Telemed Telecare, 2007. 13 Suppl 3: p. 10-14.

Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered
1.4	Study quality is assessed and taken into account.	Well covered
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Well covered
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT, CCT, Cohort, Case-Control.
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	This systematic review is the final analysis of the findings including those presented in an earlier paper. The authors applied a scoring system to rank the evidence base for home telehealth for 25 disease areas. Heart Failure was ranked 2nd, diabetes 4th, chronic disease management 7th and chronic lung disease 16th. The high rating and thus ranking of heart failure and diabetes shows a high quality of evidence in favour of the use of home telehealth/ remote telemonitoring in these conditions.

RCT Checklist: Bergenstal (2005)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Bergenstal, R.M., et al.
Title	"Impact of modem-transferred blood glucose data on clinician work efficiency and patient glycemic control."
Reference	Diabetes Technol Ther, 2005. 7(2): p. 241-7.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Poorly addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	2 patients withdrew consent not indicated which arm they were in

1.9	*All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)*	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(-)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Study does not indicate how patients were randomised
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	47 patients with 23 in the intervention group using a modem and 24 in the control group using the telephone.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean age 44-45, 61-63% female, 50-57%insulin dependent type1, 70-79%insulin required, 96-100%white, 38-39%educated.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Intervention required the use by patients of a modem to transfer their blood glucose results to the health care professional.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or*	The use of modem transfer of blood glucose data to the health care professional(HCP) versus

	between treatment and placebo / no treatment?	telephone phone in by the patient of their blood glucose results.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	4 week follow up period.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	1. The amount of HCP and patient blood glucose communication and transmission time. 2. Number of actual versus scheduled contact attempts needed for patients to transfer information and HCP to provide feedback. 3. HbA1c, blood glucose levels below, within, above targets. 4. Accuracy of transmitted Blood glucose. 5. Level of HCP and patient satisfaction with system.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	The only significant result obtained from the outcomes was the blood glucose data provided by the patient phoning in and self reporting the value showed a 6% error rate.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Grant provided by Roche Diagnostics Corporation.
3.9	Does this study help to answer your key question?	This study shows as presented by the authors no detrimental effect to the use of the remote transfer

	Summarise the main conclusions of the study and indicate how it relates to the key question.	of blood glucose data of patients. The error rate for self reporting of blood glucose data is 6%. The drawbacks to this study include the lack of description of how randomisation was carried out, the small numbers involved in the study and also the short follow up period of the participants.

RCT Checklist: Biermann (2002)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Biermann, E., et al.
Title	"Are there time and cost savings by using telemanagement for patients on intensified insulin therapy? A randomised, controlled trial."
Reference	Comput Methods Programs Biomed, 2002. 69(2): p. 137-46.

Section 1: Internal validity

	In a well conducted RCT study:	***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Poorly addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	10% from telecare dropped out 11% approx. from conventional care

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	*How well was the study done to minimise bias?* Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Patients randomised by lots but 2:1 chance in favour of telecare
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	48 patients with 30 on the intervention arm of telecare and 18 on the control arm of conventional care.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Patient on minimum of 4 insulin injections per day. Average age 30.5+/-11 years for telecare patients Average age 30+/-8.6 years for conventional care.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Intervention is the use of blood glucose meters which transmitted data over a combined modem/interface via the telephone line.

3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	The remote transmission of blood glucose readings via the intervention versus patients receiving conventional care and attending the clinic 50 miles away.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	Follow up after 4 months and after 8 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	HbA1c levels. Patient satisfaction – use of the monitor, travel time and distance travelled.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	HbA1c levels improved in both the telecare and conventional care group and the results were not statistically significant. Patient satisfaction indicated both time and cost savings on travel.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Not clear.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study showed that the HbA1c levels of those patients in the telecare arm improved but so also did the HbA1c levels of those patients on the conventional care arm and the difference in the levels between the 2 groups is not statistically significant.

		The study was unable due to the small numbers involved apply a statistical testing on comparing hypoglycaemia and insulin dose between the 2 groups. Patients reported time saved on travelling to clinics and the costs incurred whist doing this saved those patients at work less time required off.

Systematic Review Checklist: Botsis (2008)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Botsis, T. and G. Hartvigsen	
Title	"Current status and future perspectives in telecare for elderly people suffering from chronic diseases."	
Reference	J Telemed Telecare, 2008. 14(4): p. 195-203.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered
1.4	Study quality is assessed and taken into account.	Poorly addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT, CCT, Cohort.
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	This review is positive in terms of the use of home telecare in relation to patients and health care professionals. The authors comment on several issues from the patients/user prospective such as reduced costs due to time savings and reduced travelling costs. This would indicate that remote telemonitoring is beneficial to patients by reducing their costs and would be helpful in a patient centred service. The authors believe that due to an ageing population, the use of home telecare/ remote telemonitoring could lead to significant benefits.

Systematic Review Checklist: Bowles (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Bowles, K.H. and A.C. Baugh	
Title	"Applying research evidence to optimize telehomecare."	
Reference	J Cardiovasc Nurs, 2007. 22(1): p. 5-15.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Adequately addressed
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Adequately addressed
1.4	Study quality is assessed and taken into account.	Poorly addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		
3.1	What types of study are included in the review?	RCT, CCT, Cohort, Case-Control.

3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	The authors in this review comment that overall generalisations are difficult due to a number of differences in the underlying studies. However they also comment that both patients and health care professionals accept the use of the technology and it can lead to decreased rehospitalisation and length of stay for patients with heart failure and diabetes. The use of telehomecare has a positive effect on self management and control of conditions in particular diabetes.

Systematic Review Checklist: Chaudhry (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Chaudhry, S.I., et al.	
Title	"Telemonitoring for patients with chronic heart failure: a systematic review."	
Reference	J Card Fail, 2007. 13(1): p. 56-62.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Adequately addressed
1.4	Study quality is assessed and taken into account.	Adequately addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT.
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	This systematic review focused on a small number (nine in total) of RCT's looking specifically at remote telemonitoring of patients with chronic heart failure. Six of the RCT's showed findings which suggest a reduction in all cause (14% to 55%) and heart failure hospitalisations (29% to 43%) and a reduction in mortality (40% to 56%). The review did identify negative papers, three in total but indicated that their patient selection for these trials has flaws. One of the papers showed a significant reduction in mortality despite not showing any difference in rehospitalisation rates and a further paper demonstrated a reduction in hospital admissions due to heart failure because of the use of remote telemonitoring.

Systematic Review Checklist: Clark (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Systematic Reviews and Meta-analyses	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Clark, R.A., et al.
Title	"Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis."
Reference	BMJ, 2007. 334(7600): p. 942.

Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Adequately addressed
1.4	Study quality is assessed and taken into account.	Adequately addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	

Section 3: Description of the study		
3.1	What types of study are included in the review?	RCT.
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	The authors in this review showed that remote telemonitoring for heart failure patients can reduce hospital admissions and all cause mortality by nearly one fifth, but had no significant effect on all cause admission. The authors view is that although they have shown substantial and statistically significant benefits with remote telemonitoring for patients with heart failure, they consider it to be a different way of systemically organising effective care. They further concluded that remote telemonitoring may be of particular benefit to patients who have difficulty accessing specialised care because of geography, transport or infirmity.

RCT Checklist: Cleland (2005)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Cleland, J.G., et al.
Title	"Noninvasive home telemonitoring for patients with heart failure at high risk of recurrent admission and death: the Trans-European Network-Home-Care Management System (TEN-HMS) study."
Reference	J Am Coll Cardiol, 2005. 45(10): p. 1654-64.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study	0.6% of nurse telephone support group lost to follow up

	dropped out before the study was completed?	1.8% of home telemonitoring group lost to follow up 7.1% of home telemonitoring group discontinued
1.9	*All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)*	Well covered
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Well covered
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	426 patients made up of 85 usual care arm, 173 nurse telephone support arm and 168 home telemonitoring arm.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	48% aged >70 Mean LVEF of 25%
3.3	What intervention (treatment, procedure) is being investigated in this study?	Use of home telemonitoring with patients twice daily measuring wt, blood pressure, heart rhythm

	List all interventions covered by the study.	and rate with automated devices linked to a cardiology centre.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Home telemonitoring versus nurse telephone support versus usual care.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	240 days follow up.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Primary outcome= days lost because of death or hospitalisation in acute medical/ surgical beds for any reason during 450 days. Secondary outcomes= all cause mortality and optimisation of medication.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Home telemonitoring patients (HTM) spent 26% fewer days in hospital compared with nurse telephone support arm(NTS). HTM led to 10% savings over NTS.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	European Unions Trans European Network Telecom programme and Philips medical systems.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study demonstrates the clinical efficacy and cost savings potential of home telemonitoring as a means of supplementing more traditional care for managing heart failure

		patients. As above HTM improved survival rates by 15% over usual care and led to 26% reduction in hospital days per patient compared with NTS. Because of this an overall 10% cost savings was achieved for HTM relative to NTS.

RCT Checklist: de Lusignan (1999)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	de Lusignan, S., et al.
Title	"A controlled pilot study in the use of telemedicine in the community on the management of heart failure--a report of the first three months."
Reference	Stud Health Technol Inform, 1999. 64: p. 126-37.

Section 1: Internal validity

	In a well conducted RCT study:	***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Well covered
1.3	An adequate concealment method is used	Not applicable
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not applicable
1.5	The treatment and control groups are similar at the start of the trial	Well covered
1.6	The only difference between groups is the treatment under investigation	Well covered
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	20% in control group (1 died cancer, 1 died MI)

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	20 patients, 10 in the telemonitoring arm and 10 in the control group of usual care.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean age 75.1 years. Mean New York Heart Association (NYHA) class 1.75. Diagnosis of heart failure made by a consultant.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	The use of telemedicine equipment to monitor weight, blood pressure and pulse on a daily basis.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Telemedicine versus usual care.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	3 months follow up.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	To test if telemedicine is feasible, reliable and acceptable to patients as a method for managing heart failure.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	70% of telemonitoring group showed improvement in systolic blood pressure. 90% of telemonitoring group showed reduction in their weight. Quality of life of telemonitoring patients improved significantly.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Unclear.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study is a pilot carried out over a period of 3 months looking at whether telemedicine can assist in optimising the management of heart failure. It also looks at the quality of life of patients in the telemedicine group and compares this with the control group. From the results presented value is shown in the use of telemedicine both with control of the patient's condition and their quality of life. The results of the pilot were very encouraging to the authors who in their commentary state that they wish to extend this pilot a further 6 months to assess if the improvement in the patients condition will continue. This study did involve a very small number of patients.

RCT Checklist: de Lusignan (2001)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	de Lusignan, S., et al.
Title	"Compliance and effectiveness of 1 year's home telemonitoring. The report of a pilot study of patients with chronic heart failure."
Reference	Eur J Heart Fail, 2001. 3(6): p. 723-30.

Section 1: Internal validity

	In a well conducted RCT study:	***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Not applicable
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not applicable
1.5	The treatment and control groups are similar at the start of the trial	Well covered
1.6	The only difference between groups is the treatment under investigation	Well covered
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	1 patient out of 10 in the telemedicine group finished after 3 months.

		5 patients died, 2 from telemedicine group and 3 from the control group.
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	20 patients- 10 in the telemonitoring arm and 10 in the control arm.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Average new York heart association(NYHA) class 1.75, Average age= 75.2, 10% patients lived alone, heart failure diagnosed by a consultant, 2 patients in the control group and 1 in the telemedicine group work.
3.3	What intervention (treatment, procedure) is being investigated in this study?	Use of telemedicine where weight, pulse, blood pressure measured and quality of life is measured.

	List all interventions covered by the study.	
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Telemedicine versus usual care.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	1 year.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Is telemedicine beneficial? Are patients willing to monitor themselves for 1 year?
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Results showed that patients are happy to monitor themselves for the year. The results did show that acute events or deterioration in condition were easily predicted.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Hewlett Packard and MSD Pharmaceuticals.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study is a follow on from an initial 3 month pilot which was extended to ascertain if the improvements in patients condition and quality of life identified in the 3 month pilot continued with further monitoring. The results show that patients are happy to use remote telemonitoring devices but the improvements in the patients condition trend did not continue

		and the authors surmise from this that patient selection may have a big impact on results obtained. The authors feel that they were too rigid in their selection criteria and if patients whose heart failure was at an earlier stage of diagnosis were included they feel that these patients would benefit. This RCT involved a very small number of patients.

RCT Checklist: Edmonds (1998)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Edmonds, M., et al.
Title	"Using the Vista 350 telephone to communicate the results of home monitoring of diabetes mellitus to a central database and to provide feedback."
Reference	Int J Med Inform, 1998. 51(2-3): p. 117-25.

Section 1: Internal validity

	In a well conducted RCT study:	***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Poorly addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Poorly addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	2 dropped out - 1 from each arm before trial started

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(–)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	No indication of how patients randomised
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	35 patients– 16 patients intervention group and 17 patients in the control group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Patients attended an endocrinologist clinic. Nil else available.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Use of Vista 350 phone to communicate results of home monitoring of diabetes to a central database and receive feedback summaries.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or*	Vista 350 versus traditional recording in the control group.

	between treatment and placebo / no treatment?	
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	6 month follow up.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Vista 350 acceptable to patients- questionnaires used at 3 and 6 months.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Questionnaires analysed and patients found vista 350 a practical way of recording home monitoring data.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Grant from HEAL Net, Bell Canada and New North Media.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study mainly focuses on whether the vista 350 phone is an acceptable way of capturing diabetic patient data. They used a questionnaire to grade this which indicated a positive response but analysis of the questionnaire did not appear rigorous. The sample size of patients was very small and there was no indication of how randomisation took place which increase bias.

Cohort Study Checklist: Ellery (2006)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Cohort studies		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Ellery, S., et al.	
Title	"Predicting mortality and rehospitalization in heart failure patients with home monitoring--the Home CARE pilot study."	
Reference	Clin Res Cardiol, 2006. 95 Suppl 3: p. III29-35.	
Section 1: Internal validity		
In a well conducted cohort study:		***In this study the criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
SELECTION OF SUBJECTS		
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Poorly addressed
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	Not addressed
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	Poorly addressed
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.	Unclear, 9 patients died

1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	Not addressed
ASSESSMENT		
1.7	The outcomes are clearly defined.	Poorly addressed
1.8	The assessment of outcome is made blind to exposure status.	Not addressed
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	Not addressed
1.10	The measure of assessment of exposure is reliable.	Poorly addressed
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	Poorly addressed
1.12	Exposure level or prognostic factor is assessed more than once.	Not addressed
CONFOUNDING		
1.13	The main potential confounders are identified and taken into account in the design and analysis.	Not addressed
STATISTICAL ANALYSIS		
1.14	Have confidence intervals been provided?	No
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? *Code ++, +, or −*	(−)

2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	From the information given and analysis shown, I cannot be sure that the effect is due to the intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? List the number in each group separately	123 patients.
3.2	What are the main characteristics of the study population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean age 67+/- 9 years, 83% male, 17% female, New York Heart Association(NYHA) class:1(3%), 11(6%), 111(77%), 1V(14%). Ischaemic aetiology 60%, QRS width 158+/- 27ms, SR 53%, paroxysmal AF 22%, other arrthymias 25%.
3.3	What environmental or prognostic factor is being investigated in this study?	Use of remote telemonitoring.
3.4	What comparisons are made in the study? *Are comparisons made between presence or absence of an environmental / prognostic factor, or different levels of the factor?*	Use of remote telemonitoring combined with CRT versus usual CRT(cardiac resynchronisation therapy).
3.5	For how long are patients followed-up in the study?	12 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess the impact of the chosen environmental or prognostic factor.*	Reduction in re hospitalisation.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk. Include p values and any confidence intervals that are*	11 unplanned rehospitalisations, 9 deaths, 16 adverse incidents. In 70% of rehospitalisations- retrospective analysis of

	provided. ***Note****: Be sure to include any adjustments made for confounding factors, differences in prevalence, etc.*	transmitted data via remote monitoring revealed an increase in heart rate at rest and an increase in mean heart rate over the preceding 7 days.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Not clear.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question?*	This study does not present in detail how the patients were chosen nor does it show the statistical analysis of the study. It does however present a finding that by the use of remote telemonitoring and transmission of data, a patient's condition can be closely monitored and trends and changes in their condition can be identified which may prevent an acute unpredicted hospital admission.

Systematic Review Checklist: Farmer (2005)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Farmer, A., et al.	
Title	"A systematic review of telemedicine interventions to support blood glucose self-monitoring in diabetes."	
Reference	Diabet Med, 2005. 22(10): p. 1372-8.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered
1.4	Study quality is assessed and taken into account.	Well covered
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT, Cohort.
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	The authors of this review included 16 trials and 10 cohort studies in their analysis. They have described quality assessing the RCT's using the jaded scale. The authors describe that evidence from cohort studies a well as RCT's strengthens the conclusion that the use of telemedicine in a clinical setting is feasible. The authors describe that with regards to the area of telemedicine's ability of effectiveness in improving HbA1c or reducing costs whist maintaining HbA1c levels, there is not enough evidence currently to substantiate this.

RCT Checklist: Goldberg (2003)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Goldberg, L.R., et al.
Title	"Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: the Weight Monitoring in Heart Failure (WHARF) trial."
Reference	Am Heart J, 2003. 146(4): p. 705-12.

Section 1: Internal validity

	In a well conducted RCT study:	***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	32 patients out of 280 refused follow up data collection or were lost to follow up

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Poorly addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	No indication of how patients were randomised
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Indication is that effect is due to the intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	280 patients- 138 intervention group using Alere Net system, 142 control group and standard care.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	NYHA class 111(75%) or 1V(25%) heart failure, Left ventricular ejection fraction< 35%, mean age= 59+/- 15 and 68% male.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Remote telemonitoring of patients with heart failure using the Alere Net system to monitor daily weight and symptoms.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Use of Alere Net system versus usual care.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	6 month follow up time.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Primary outcome- 6 month hospital readmission rate, secondary outcomes- mortality, heart failure hospital readmission rate, A+E visits and quality of life.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	No difference in hospital admission rates observed. 56.2% reduction in mortality (p <.003) for patients randomised to Alere Net system without an increase in utilisation.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Alere Net grants.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study although not showing any significant difference in the primary endpoint shows a statistically significant reduction in mortality of patients, 56.2% reduction achieved. This reduction is due to the ability of using the Alere Net system to intervene at an earlier stage if a patient's condition is seen to deteriorate. Patients also in the Alere Net group of this study were shown to comply better with their

		medication.

RCT Checklist: Harno (2006)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Harno, K., R. Kauppinen-Makelin, and J. Syrjalainen
Title	"Managing diabetes care using an integrated regional e-health approach."
Reference	J Telemed Telecare, 2006. 12 Suppl 1: p. 13-5.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Adequately addressed
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	Not clear

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect is due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	175- 101 intervention ehealth group, 74 control usual care group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	The 2 groups did not differ in the proportion of type1 and type 11 diabetics. The 2 groups were of a similar age.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	ehealth application with a diabetes management system and home care link.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	ehealth group versus control group/ usual care.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	12 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Level of HbA1c Level of plasma fasting glucose. Level of cholesterol- total, serum LDL and triglycerides.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	HbA1c decreased in both study groups, the difference between the groups was small but the HbA1c was lower in the ehealth group than the control group. Diastolic Blood pressure, fasting plasma glucose, serum total cholesterol, serum LDL and triglycerides all lower in the ehealth group.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Not clear.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study shows that by using an ehealth type of intervention, care is not compromised and the patient's condition is controlled as well as face to face visits. This study did not indicate the funding stream. The numbers involved in the study are a reasonable size. No detrimental effect is shown to patients using the ehealth provision of care.

Systematic Review Checklist: Jaana (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Systematic Reviews and Meta-analyses	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Jaana, M. and G. Pare
Title	"Home telemonitoring of patients with diabetes: a systematic assessment of observed effects."
Reference	J Eval Clin Pract, 2007. 13(2): p. 242-53.

Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered
1.4	Study quality is assessed and taken into account.	Poorly addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT, CCT.
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	The authors comment that close management and monitoring of diabetes in several studies have resulted in significant decrease in HbA1c. They also comment that the close management approach seems to have significant positive impact on patient's attitudes towards their illness and helps empower patients and educate patients about their own condition. They state that economic and structured impacts of telemonitoring are still at an early stage. The authors comment that larger studies over longer time frames are required to further assess this promising patient management approach with regard to efficacy and cost effectiveness.

RCT Checklist: Jerant (2001)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Jerant, A.F., R. Azari, and T.S. Nesbitt
Title	"Reducing the cost of frequent hospital admissions for congestive heart failure: a randomized trial of a home telecare intervention."
Reference	Med Care, 2001. 39(11): p. 1234-45.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Well covered
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Well covered
1.6	The only difference between groups is the treatment under investigation	Well covered
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	2 patients died - telephone group

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	37 patients- 13 telecare arm, 12 telephone arm, 12 usual care arm.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	English speaking, >40 years age, primary hospital admission diagnosis of heart failure, active telephone line, patient has a primary care provider.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Home telecare unit delivered via a 2 way video conference device with an integrated electronic stethoscope.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Personal aviva telecare unit which transmits vital signs versus nurse telephone versus

		usual care.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	6 month follow up.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Primary outcome- chronic heart failure(CHF) related readmission charges during the 6 month period. Secondary outcome- all cause readmissions, A+E visits and associated charges.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Mean CHF related readmission charges 86% lower in telecare group and 84% lower in the nurse telephone support group than in usual care. The between group difference was not statistically significant. Secondary outcome= CHF related A+E visits significantly reduced (p=.0342) and charges(p=.047) then usual care.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Funded by UCD School of Medicine Hibbert E Williams Research grant.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study shows positive results in relation to remote telemonitoring. The results indicate that the primary outcome of a reduction in CHF readmission charges is achieved. It also achieved the secondary outcomes of a reduction in A+E visits and

		all cause readmission charges. The nurse telephone follow up results were equivocal to the telemonitoring and both show that follow up of patients on discharge with chronic heart failure is beneficial. This RCT is small in numbers of patients and duration of follow is 6 months. This study also highlights that home telecare may not offer incremental benefit beyond telephone follow up and is more expensive.

RCT Checklist: Kashem (2008)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Randomised Controlled Trials		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Kashem, A., et al.	
Title	"Managing heart failure care using an internet-based telemedicine system."	
Reference	J Card Fail, 2008. 14(2): p. 121-6.	
Section 1: Internal validity		
In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	Unclear

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Unsure how patients randomised.
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	48 patients- 24 telemedicine and usual care and 24 usual care.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean age 53.2+/-2 years, male 72%, Caucasian 61%, African American 39%./ Left ventricular ejection fraction measured, NYHA class 11, 111, 1V with > 1 hospital admission in the past 6 months.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Internet based telemedicine system which provides frequent surveillance and increased communication between heart failure patients and their provider at hospital.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Telemedicine system versus usual care to communicate with patients.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	1 year.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Office visits, emergency dept visits, hospitalisation, telephone calls, number of internet communications.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Usual care=74 phone calls, telemedicine= 88 phone calls + 1887 telemedicine data messages. Emergency room visits lower in the telemedicine group (T=5), usual care group (uc=12) p<.05. Hospital admissions T=24 uc= 40 p=.025. Total hospital days T=84, uc=226 p<.005. Unscheduled clinic visits T=13 uc=13 p=ns.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Not clear.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	In this study the telemedicine group have fewer attendances at A+E and fewer hospital admissions than the usual care group. The number of communications in the telemedicine group was higher than the usual care group and this may be the cause of the reduction in hospital admissions and A+E attendances associated with the telemedicine group as the patients change or deterioration in condition could be managed at an earlier stage thus preventing admission. This study is small in numbers and the patient population chosen may have brought some bias as the predominance is white males and a younger age range.

RCT Checklist: Kashem (2006)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Kashem, A., et al.
Title	"Web-based Internet telemedicine management of patients with heart failure."
Reference	Telemed J E Health, 2006. 12(4): p. 439-47.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	1 patient in telemedicine group transplanted 1 patient usual care group died

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Not clear how patients identified
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect is due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	36 patients- 18 telemedicine arm, 18 usual care.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	NYHA class 2to 4, hospitalisation in the past 6 months, mean age 56.1+/- 12.6years, 66.7% male, 66.7% Caucasian, 27.8& African American, 5.6% Hispanic. Mean ejection fraction 23.9+/- 17.6%.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Internet based store and retrieval telemedicine system to communicate with heart failure patients and healthcare providers- web based, allows frequent surveillance of heart failure patients.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or*	Use of telemedicine internet based system to communicate with heart failure patients versus usual care. Cost effective method

	between treatment and placebo / no treatment?	of patient/ physician communication.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	8 month period follow up.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Clinic phone calls, scheduled clinic visits, unscheduled clinic visits, hospitalisations, hospital days.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Clinic phone calls(T=39,uc=21 p=.025) Unscheduled visits(T=3,uc=5 p=ns) Scheduled visits(T=11,uc=7 p=ns) Total hospital days(T=44,uc=133 p<.05) Hospitalisations(T=9,uc=18 p=.025)
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	National Institutes of Health grant.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study is an initial follow up of the chosen patients after 8 months. These patients form part of another study which will be followed up after 12 months. The results show hospitalisations and total hospital days are reduced by using telemedicine. The number of scheduled and unscheduled visits between the telemedicine group and usual care group is not significant. The numbers in this study are small.

RCT Checklist: Kim (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Kim, H.S.
Title	"A randomized controlled trial of a nurse short-message service by cellular phone for people with diabetes."
Reference	Int J Nurs Stud, 2007. 44(5): p. 687-92.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Well covered
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Well covered
1.6	The only difference between groups is the treatment under investigation	Well covered
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	5 out of 30 intervention group dropped out 4 out of 30 control group dropped out

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	51 patients- 25 intervention group, 26 control group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Patients able to carry out blood glucose self testing and self injection of medication, access websites and own mobile phone. Mean age 47.5, mean BMI 24.5, mean duration diabetes 5.2 years.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Patients in the intervention group accessed a website using a cellular phone or the internet and input blood glucose levels daily. The patients were sent optimal recommendations by cellular phone and internet.

3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Use of educational intervention using the internet and SMS cellular phone versus usual care.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	12 weeks.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Blood glucose concentration close to normal range 2HPMG
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Intervention group mean decrease in HbA1c of 1.15%.Control group mean increase HbA1c .07% p=.005. Intervention group showed mean change 4.7mmol/l p<.05 in 2HPMG, not significant for control group.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Korea research grant funded by the Korean government.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study is positive and shows that the patients accessing the website via the internet or mobile phone had an improvement in their HbA1c and 2HPMG compared with usual care. This is a positive step in the direction of the use of telemedicine to help control diabetes mellitus. Also by using this method convenience to patients is improved. This study involved small numbers of

		patients and patients excluded if they could not access websites nor own a cellular phone.

RCT Checklist: Ladyzynski (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Ladyzynski, P. and J.M. Wojcicki
Title	"Home telecare during intensive insulin treatment-- metabolic control does not improve as much as expected."
Reference	J Telemed Telecare, 2007. 13(1): p. 44-7.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	Unclear

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Not clear how patients randomised
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	30 patients- 15 patients in intervention group of telecare, 15 patients in control group of usual care.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Patients pregnant. Type 1 diabetics.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Data reporting via home telecare system which stored blood glucose values and integrated with simple electronic logbook. The data was automatically transmitted via the telephone network every night.

3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Telecare group versus usual care group.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	180 days- telecare group. 176 days- control group.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Metabolic control. Insulin dose adjustments.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Significantly lower variability of glycaemic control in telecare, thus showing more accurate implementation of physician's strategy. Other metabolic controls showed no significant difference. Insulin dose adjustment is similar.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Research grant from state committee for scientific research sponsored by Bayer diagnostic division.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study shows that the use of home telecare intervention is advantageous in lowering the variability in glycaemic control but other outcomes showed no significant difference to usual care. The numbers looked at in this study are small and it is unclear how they are randomised to each group. Not a lot of information is available as to

		the characteristics of the patient population which consisted of pregnant ladies.

Systematic Review Checklist: Louis (2003)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Louis, A.A., et al.	
Title	"A systematic review of telemonitoring for the management of heart failure."	
Reference	Eur J Heart Fail, 2003. 5(5): p. 583-90.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Adequately addressed
1.4	Study quality is assessed and taken into account.	Poorly addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Well covered
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT, Cohort.
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	This review examined several randomised control trials and observational studies involving telemonitoring for the management of heart failure. 18 observational studies and 6 RCT's showed positive findings in the use of telemonitoring such as reduced hospital bed occupancy and patient acceptance and compliance with telemonitoring. 2 RCT's showed telemonitoring of vital signs and symptoms help facilitate early detection of deterioration in the patient's condition and can reduce hospital readmission rates and length of stay. 1 RCT showed a significant reduction in mortality via the remote telemonitoring of patients' weight and symptoms in heart failure.

Systematic Review Checklist: Martinez (2006)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Martinez, A., et al.	
Title	"A systematic review of the literature on home monitoring for patients with heart failure."	
Reference	J Telemed Telecare, 2006. 12(5): p. 234-41.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered
1.4	Study quality is assessed and taken into account.	Well covered
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Well covered
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT, CCT, Cohort.
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	The authors in this review conclude that there is evidence to show that home telemonitoring is reliable and has several advantages. They consider home telemonitoring to be a proven intervention that is ready for wide scale rollout and anticipate that rollout would lead to a better quality of life for patients. The authors report that in 23 out of 42 articles, home telemonitoring of heart failure patients leads to a reduction in the number of hospital admissions. They report on reviewing the articles that remote telemonitoring of heart failure patients leads to a significant reduction in mortality and an improvement in quality of life for patients.

Systematic Review Checklist: Meystre (2005)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Meystre, S.	
Title	"The current state of telemonitoring: a comment on the literature."	
Reference	Telemed J E Health, 2005. 11(1): p. 63-9.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Poorly addressed
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Poorly addressed
1.4	Study quality is assessed and taken into account.	Poorly addressed
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Poorly addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Not clear how papers selected and type of study included.
Section 3: Description of the study		

3.1	What types of study are included in the review?	Unclear
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	The author reports that from reviewing the literature telemonitoring allows- reduction of complications from chronic disease due to better follow up care, provide health service care without utilisation of a hospital bed, reduction in patient travel time and time off work. The author believes that telemonitoring is a way of responding to the new needs of home care in an aging population.

RCT Checklist: Montori (2004)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Montori, V.M., et al.
Title	"Telecare for patients with type 1 diabetes and inadequate glycemic control: a randomized controlled trial and meta-analysis."
Reference	Diabetes Care, 2004. 27(5): p. 1088-94.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well controlled
1.2	The assignment of subjects to treatment groups is randomised	Well controlled
1.3	An adequate concealment method is used	Well controlled
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Well controlled
1.6	The only difference between groups is the treatment under investigation	Well controlled
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well controlled
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	2 patients out of 15 from intervention (13.3%) 1 patient out of 16 from control

		group (6.25%)
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well controlled
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	31 patients- 15 intervention group, 16 control group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Type 1 diabetes, intensive insulin therapy, HbA1c>7.8%.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Telecare- glucometer transmission with feedback.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or*	Telecare versus control (glucometer transmission without

	between treatment and placebo / no treatment?	the feedback).
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	6 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Primary outcome- 6 month HbA1c.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Telecare patients showed a lower HbA1c to the control group(8.2 versus 7.8% p=.03) Nurses spent 50 more minutes/patient giving feedback to telecare group.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Mayo Foundation with a research grant to Y.C.K. Roche Diagnostics.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This trial shows that the use of the intervention (transmission of blood glucose levels with nurse follow up feedback) did not have a significant effect on the control of HbA1c versus the control group. This study had very small numbers involved.

RCT Checklist: Nguyen (2006)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Randomised Controlled Trials		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Nguyen, H.Q., et al.	
Title	"Exercise and symptom monitoring with a mobile device."	
Reference	AMIA Annu Symp Proc, 2006: p. 1047.	
Section 1: Internal validity		
In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Adequately addressed
1.2	The assignment of subjects to treatment groups is randomised	Poorly addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Poorly addressed
1.6	The only difference between groups is the treatment under investigation	Poorly addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Poorly addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	Unclear

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Poorly addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	No indication how patients were randomised
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Uncertain.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	6 patients in the intervention arm of eDSMP (internet based program), unclear numbers in the other arm.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean age 73+/- 6, COPD sufferers, internet users.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Web based dyspnoea self management programme (DSMP)- mobile device delivered automated prompts.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or*	This study focuses on the eDSMP group looking at responses rate and response time for both

	between treatment and placebo / no treatment?	exercise and symptom.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	6 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Response rate Response time
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Response rate 83.9% exercise, 82.3% symptom. Response time 15.8% exercise, 20.2% symptom.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Robert Wood Johnston Health e Technologies Institute.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	The authors report a lot of difficulty in the hardware used in this pilot study. The pilot involves a very small number of patients and this will have an impact on the results which are equivocal.

Systematic Review Checklist: Pare (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004		
Methodology Checklist: Systematic Reviews and Meta-analyses		
Study identification (Include author, title, year of publication, journal title, pages)		
Author	Pare, G., M. Jaana, and C. Sicotte	
Title	"Systematic review of home telemonitoring for chronic diseases: the evidence base."	
Reference	J Am Med Inform Assoc, 2007. 14(3): p. 269-77.	
Section 1: Internal validity		
In a well conducted systematic review:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	A description of the methodology used is included.	Well covered
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered
1.4	Study quality is assessed and taken into account.	Well covered
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Well covered
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
Section 3: Description of the study		

3.1	What types of study are included in the review?	RCT, CCT, Case-control
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	In this systematic review the authors consider the use of telemonitoring in 4 types of chronic disease. Results revealed 18 articles looking at pulmonary disease, 17 articles looking at diabetes, 16 articles looking at cardiac disease and 14 articles looking at hypertension. In total the authors reviewed 65 articles that examined the outcomes of home telemonitoring programmes. Their findings were positive stating that home telemonitoiring may help empower patients about management of their conditions, produce reliable and accurate data and potentially help improve control of the patient's medical condition. It does state that further studies are required in order to build on the evidence base.

RCT Checklist: Pinna (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Pinna, G.D., et al.
Title	"Home telemonitoring of vital signs and cardiorespiratory signals in heart failure patients: system architecture and feasibility of the HHH model."
Reference	Int J Cardiol, 2007. 120(3): p. 371-9.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	18 patients dropped out of study - not clear which group 15 patients died - not clear

		which group
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	461 patients- 160 usual care, 301 telemonitoring which is further subdivided into 106 monthly nurse contact, 94 nurse and weekly cardiorespiratory telemonitoring (health care professionals blinded), 101 nurse and weekly cardiorespiratory telemonitoring.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Age>18<85 years, NYHA class 2to4, LVEF<40%, 1 or more hospital admissions with heart failure in the previous 12 months.
3.3	What intervention (treatment, procedure) is being investigated in this study?	Self managed home telemonitoring of vital signs and respiration.

	List all interventions covered by the study.	
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Usual care of heart failure patients with 3 home based remote telemonitoring interventions.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	12 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Patients at home self manage all telemonitoring and transmission devices.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	81% of all practicable vital signs transmitted. Patient compliance is high.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	European Community funded trial.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This home or hospital heart failure study demonstrates that home telemonitoring is feasible and that patient compliance was high.

Cohort Studies Checklist: Roglieri (1997)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Cohort studies	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Roglieri, J.L., et al.
Title	"Disease management interventions to improve outcomes in congestive heart failure."
Reference	Am J Manag Care, 1997. 3(12): p. 1831-9.

Section 1: Internal validity

	In a well conducted cohort study:	***In this study the criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
SELECTION OF SUBJECTS		
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Adequately addressed
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	Poorly addressed
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	Adequately addressed
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.	Not clear
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	Poorly addressed

ASSESSMENT		
1.7	The outcomes are clearly defined.	Well covered
1.8	The assessment of outcome is made blind to exposure status.	Not addressed
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	Not addressed
1.10	The measure of assessment of exposure is reliable.	Adequately addressed
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	Adequately addressed
1.12	Exposure level or prognostic factor is assessed more than once.	Adequately addressed
CONFOUNDING		
1.13	The main potential confounders are identified and taken into account in the design and analysis.	Poorly addressed
STATISTICAL ANALYSIS		
1.14	Have confidence intervals been provided?	No
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? *Code ++, +, or −*	(+)
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain	Effect due to exposure.

	that the overall effect is due to the exposure being investigated?	
Section 3: Description of the study		
3.1	How many patients are included in this study? *List the number in each group separately*	Unclear.
3.2	What are the main characteristics of the study population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean ejection fraction= 38.7, mean age= 75.6, NYHA class= 2.7.
3.3	What environmental or prognostic factor is being investigated in this study?	Impact of telemonitoring of patients post hospitalisation follow up and provider of education.
3.4	What comparisons are made in the study? *Are comparisons made between presence or absence of an environmental / prognostic factor, or different levels of the factor?*	Comparison made between the intervention in pure chronic heart failure group and chronic heart failure related diagnosis versus 1 year previous.
3.5	For how long are patients followed-up in the study?	12 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess the impact of the chosen environmental or prognostic factor.*	Hospital admission rates, readmission rates, length of stay, total hospital days and emergency room utilisation.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk. Include p values and any confidence intervals that are provided.* ***Note****: Be sure to include any adjustments made for confounding factors, differences in prevalence, etc.*	Admission rate decreased by 63% (p=.00002), 30 day +90 day readmission rate decreased 75% (p=.02) and 74%(p=.004). Average length of stay for patients with chronic heart failure related diagnosis was significantly reduced among both plan

		participants and programme participants (p=.001).
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	NYLCare Health Plans of New York Inc.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question?*	This study shows analysis of participants after 12 months of a 24 month study. It shows that with the use of telemonitoring hospital admission rates and length of stay and emergency room attendances are reduced.

RCT Checklist: Ross (2006)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Ross, S.E., et al.
Title	"Adoption and use of an online patient portal for diabetes (Diabetes-STAR)."
Reference	AMIA Annu Symp Proc, 2006: p. 1080.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Poorly addressed
1.3	An adequate concealment method is used	Not addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not addressed
1.5	The treatment and control groups are similar at the start of the trial	Not addressed
1.6	The only difference between groups is the treatment under investigation	Not addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Poorly addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	Not clear

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Not addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Randomisation not clear
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	328 patients- 163 intervention arm, 165 control arm.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean age= 59.2, 45% female, 19% safety net insurance.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Portal providing personalised self management information.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Use of personalised portal versus portal providing generic diabetes self management information.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	10 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Characteristics of patient users, whether including personalised content promotes sustained use.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Use of system- 772 days intervention group versus 319 days in control group (p=.001). In intervention group 39% set goal to improve health, 42% reviewed lab results and 30% reviewed clinical notes.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Unclear.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study was presented at AMIA 2006 symposium and the information obtained for this template came from the symposium proceedings. It is unclear how patients were chosen to participate and how they were randomised. The results as presented are positive to personalised self management diabetes information in helping to control and manage symptoms.

RCT Checklist: Schwarz (2008)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Schwarz, K.A., et al.
Title	"Telemonitoring of heart failure patients and their caregivers: a pilot randomized controlled trial."
Reference	Prog Cardiovasc Nurs, 2008. 23(1): p. 18-26.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	Usual care arm 11/51 (21.6%) Usual care + telemonitoring 7/51 (13.7%)

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Method of randomisation unclear.
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	102 patients- 51 usual care, 51 usual care plus telemonitoring.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Age>65 years, 52% female, NYHA class 2, 3 or 4 heart failure, functionally impaired in at least 1 activity of daily living or one instrumental activity of daily living(IADL) necessitating assistance of family care giver.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Use of electronic home monitoring and usual care.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or*	Electronic home monitoring and usual care versus usual care.

	between treatment and placebo / no treatment?	
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	90 days.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Hospital readmissions, emergency dept visits, costs, days to readmission, quality of life, depression and caregiver mastery forms.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Telemonitoring by electronic home monitoring did not reduce rates of hospitalisation, emergency dept visits, cost of care or depression. Did not increase care giver mastery, quality of life or days to readmission.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Grant from National Institute of Nursing research, National Institute of health and the Ohio Board of Regents.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study is a pilot study which was carried out over 90 days. The results did not show any benefits for the use of remote telemonitoring but the authors do comment that no detrimental effects were shown. The study involves small numbers and follow up is over a short period of time.

RCT Checklist: Shea (2007)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Shea, S.
Title	"The Informatics for Diabetes and Education Telemedicine (IDEATel) project."
Reference	Trans Am Clin Climatol Assoc, 2007. 118: p. 289-304.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Well covered
1.3	An adequate concealment method is used	Adequately addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Adequately addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	248 (14.9%): 144 from intervention arm, 104 from usual care arm

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	1665 patients- 844 intervention group and 821 in the control usual care group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Age>55 years, 98% participants black/Hispanic, 69% Medicaid-eligible.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Telemedicine case management, home telemedicine unit (HTU).
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Telemedicine case management versus usual care.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	1 year.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	HbA1c, blood pressure, low density lipoprotein (LDL).
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Mean HbA1c level decreased in the intervention group- 7.35% to 6.97% and compared to usual care the net adjusted reduction was .18% (p=.006). Net adjusted result for systolic and diastolic blood pressure was 3.4mmHg p=.001+1.9mmHg (p<.001). Total cholesterol and LDL cholesterol, net differences were 11.06mg/dl+9.5mg/dl (p<.001) for both.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Funded by CMS(Centres for Medicare and Medicaid Services)
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study involving a large numbers of participants and follow over a 12 month period showed positive results in the use of telemedicine for the case management of diabetes. It shows an improvement in HbA1c, BP and LDL cholesterol levels in older patients with diabetes mellitus at 1 year compared to the usual care which the control group

		received.

RCT Checklist: Shultz (1992)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Shultz, E.K., et al.
Title	"Improved care of patients with diabetes through telecommunications."
Reference	Ann N Y Acad Sci, 1992. 670: p. 141-5.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Adequately addressed
1.2	The assignment of subjects to treatment groups is randomised	Poorly addressed
1.3	An adequate concealment method is used	Not addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not addressed
1.5	The treatment and control groups are similar at the start of the trial	Poorly addressed
1.6	The only difference between groups is the treatment under investigation	Poorly addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Poorly addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	10 dropped out - medical problems thought to be unrelated to the study or because they declined to continue

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Not applicable
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Unclear how randomised
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect is due to the intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	30 patients- 10 intervention group and 10 in the control group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Diabetics, Insulin users, High glycoheamoglobin in the last 18 months.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Use of modem transmission of blood glucose readings.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Intervention of modem transmission of blood glucose data versus usual care.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	15 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Glycohaemoglobin levels.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Intervention group showed glycohaemoglobin dropped significantly (p<.003) as compared to the control group where no overall change was found.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Department of Veteran Affairs Health Service Research and Development grant.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study was a double crossover design. It involved a small number of patients but results found that glycohaemoglobin showed a significant reduction in the intervention group using the integrated home monitoring system as opposed to usual care and logging blood glucose levels in a diary. The home monitoring system had a greater impact on glycohaemoglobin.

RCT Checklist: Spaeder (2006)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Spaeder, J., et al.
Title	"Rapid titration of carvedilol in patients with congestive heart failure: a randomized trial of automated telemedicine versus frequent outpatient clinic visits."
Reference	Am Heart J, 2006. 151(4): p. 844 e1-10.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Well covered
1.3	An adequate concealment method is used	Adequately addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Adequately addressed
1.5	The treatment and control groups are similar at the start of the trial	Well covered
1.6	The only difference between groups is the treatment under investigation	Well covered
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	2 withdrew - 1 telemedicine arm, 1 clinic only 1 patient was withdrawn from telemedicine arm due to violation

		of eligibility criteria
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Well covered
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(++)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect is due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	49 patients- 25 telewatch intervention group, 24 clinic only control group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Age >21, NYHA class 2 and 3, left ventricular systolic dysfunction, tolerating afterload reducing therapy and not receiving B Blocker therapy.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Intervention is looking at if the use of the automated telemedicine system could facilitate carvedilol titration.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or*	Telemedicine system titration versus clinic only attendance titration.

	between treatment and placebo / no treatment?	
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	3 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Titration time of carvedilol.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	No significant difference in mean final dose of carvedilol between clinic only and telemedicine p=.52. Time to reach final dose of carvedilol was significantly shorter in the telemedicine group p<.001. 5 adverse incidents in the study, 4 of which were in the telemedicine group p=.29, however telemedicine prospectively detected 2 adverse events.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	unclear
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study shows that patients requiring titration of a drug to a maintenance dose can be monitored closely using telemedicine and the time to reach final dose, maintenance dose of the drug carvedilol is shorter than if the patients had attended a clinic on a regular basis to obtain the same results. The study was randomised and blinded. It did involve small numbers of patients and due to the specific nature of the intervention and primary outcome the time frame for review is appropriate.

RCT Checklist: Trappenburg (2008)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Trappenburg, J.C., et al.
Title	"Effects of telemonitoring in patients with chronic obstructive pulmonary disease."
Reference	Telemed J E Health, 2008. 14(2): p. 138-46.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Not applicable
1.3	An adequate concealment method is used	Not applicable
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not applicable
1.5	The treatment and control groups are similar at the start of the trial	Not applicable
1.6	The only difference between groups is the treatment under investigation	Well covered
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	33% intervention group- reasons given are technical, lack of motivation, death, moving into area and could not continue. 12% control group- death, no

		response to follow up questionnaire.
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Not applicable
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Well covered
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	Not randomised
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	101 patients intervention group, 64 patients in control group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Age>45 years, post bronchodilator FEV1 <50% predicted, reversibility <10% of predicted normal FEV1 after inhalation of a bronchodilator.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Home based telemonitoring device- health buddy. The health buddy (HB) provides daily symptom surveillance by a case manager and education to enhance disease

		knowledge and self management.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Use of the health buddy versus usual care.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	6 months.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Health related quality of life, health care consumption measured via medical records.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Health related quality of life measured via a questionnaire showed no significant changes were observed. The health buddy group showed significant reduction in hospital admission rates (HB= -.11+/- 1.16) versus (control +.27+/- 1.0) p=.02. Total number of exacerbations (HB -.35+/-1.4) versus (control +.32+/-1.2) p=.004.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Grant from Dutch Asthma Foundation.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study is a non randomised control trial. It shows a positive response to the use of telemedicine for remotely monitoring patients with COPD and showed a decrease in health care utilization at follow up of 6

		months. The intervention group showed a decrease in hospital admissions and exacerbations of COPD.

RCT Checklist: Tsang (2001)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Tsang, M.W., et al.
Title	"Improvement in diabetes control with a monitoring system based on a hand-held, touch-screen electronic diary."
Reference	J Telemed Telecare, 2001. 7(1): p. 47-50.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Poorly addressed
1.3	An adequate concealment method is used	Not applicable
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Not applicable
1.5	The treatment and control groups are similar at the start of the trial	Poorly addressed
1.6	The only difference between groups is the treatment under investigation	Poorly addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	1 failed to complete the study as defaulted during follow up

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Poorly addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	Crossover study
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Randomisation unclear
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	20 patients- 10 in the intervention group and 10 in the control group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Unclear in the paper as to the patient characteristics.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Computerised diabetes monitoring system which conveyed dietary information- recorded meal portions and blood glucose readings.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Intervention group and the computerised diabetes monitoring system and usual care.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	Each group used the intervention for 3 months. 6 months in total for the cross over study.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Glycaemic control, computerised diabetes monitoring system acceptance.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	HbA1c reduction of .825% achieved during intervention period compared with the control period. 95% patients found the computerised diabetes management system easy to use. 63% found it useful.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Grant from Health Services Research Committee.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study is a cross over randomised control trial which involves a small number of patients and each group allocated and reviewed for only 3 months. Despite this the study shows an acceptance of the diabetes management system and also shows that HbA1c is reduced in the intervention group.

RCT Checklist: Whitlock (2000)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Whitlock, W.L., et al.
Title	"Telemedicine improved diabetic management."
Reference	Mil Med, 2000. 165(8): p. 579-84.

Section 1: Internal validity

	In a well conducted RCT study:	***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	None reported

1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Randomisation unclear
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	28 patients- 15 intervention group and 13 in the control group.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean age= 63 Male/female= 11/7 Average HbA1c= 9.5 Average total body weight= 217llb.
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	Home telemedicine consultation.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Home telemedicine consultation versus usual care.

3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	3 month follow up.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Can telemedicine improve a patients ability to self manage diabetes? Lab studies. Total body weight.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Intervention group mean HbA1c reduction=16%(9.5 to 8.2%), mean weight reduction (214.3 to 206.7) pounds.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Grant 1997 from the Office of the Assistant Secretary of Defence, Health affairs to evaluate applications of Telemedicine Technology in the Management of the high cost of Chronic Disease.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study involves small numbers of patients who are followed up for a short period of time. The findings show a mean reduction in HbA1c and mean reduction in weight over the 3 months indicating a positivity towards the use of telemedicine to help improve patients ability to self manage their diabetes.

RCT Checklist: Woodend (2008)

Checklist Methodology is copyright Scottish Intercollegiate Guidelines Network, March 2004	
Methodology Checklist: Randomised Controlled Trials	
Study identification (Include author, title, year of publication, journal title, pages)	
Author	Woodend, A.K., et al.
Title	"Telehome monitoring in patients with cardiac disease who are at high risk of readmission."
Reference	Heart Lung, 2008. 37(1): p. 36-45.

Section 1: Internal validity

In a well conducted RCT study:		***In this study this criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	Well covered
1.2	The assignment of subjects to treatment groups is randomised	Adequately addressed
1.3	An adequate concealment method is used	Poorly addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Poorly addressed
1.5	The treatment and control groups are similar at the start of the trial	Adequately addressed
1.6	The only difference between groups is the treatment under investigation	Adequately addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Adequately addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	9 patients in the telehomecare arm and 6 patients in the usual care arm were lost to follow up at 1 year. 9 patients with heart failure and 3 patients with

		angina died.
1.9	*All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)*	Adequately addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Adequately addressed
Section 2: Overall assessment of the study		
2.1	How well was the study done to minimise bias? Code ++, +, or –	(+)
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	Randomisation unclear
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	Effect due to intervention.
Section 3: Description of the study		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	249 patients- 121 heart failure and 128 angina. Heart failure patients divided into 62 telehomecare and 59 usual care and angina patients divided into 62 telehomecare and 66 usual care.
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	Mean age= 66, 75% male, NYHA class 2, 3, 4. Angina class 1 or greater, read and write English or French, live within 100km by road of the University of Ottowa Heart Institute.
3.3	What intervention (treatment, procedure) is being investigated in this study?	Intervention of telehomecare which involves videoconference with the nurse and daily

	List all interventions covered by the study.	transmission of weight and blood pressure.
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	Telehomecare versus usual care.
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	3 month follow up and 1 year follow up.
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	Readmission, healthcare resource use, morbidity and quality of life.
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	Patients with angina- 51% reduction in number of admissions per patient in telehomecare versus usual care, p=.02 and 61%reduction in the number of days spent in hospital p=.04. No significant difference between patients with heart failure in the number of admissions. Patients with heart failure spent 28% fewer days in hospital than usual care but the result is not statistically significant. Patients with angina at 1 year had significantly fewer hospital admissions than usual care p=.02, hospital admission rates reduced by 45% and the number of days spent in hospital did not significantly differ in the 2 groups. In heart failure patients no significant difference was

		shown between the telehomecare and usual care patients with hospital admission and days spent in hospital at 1 year.
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Richard Ivey Foundation, The Change Foundation and an unrestricted education grant from Merck- Frosst Canada.
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	This study shows high patient satisfaction to video conferencing with a nurse and telemonitoring of vital signs in patients with heart failure and angina and also shows an improvement in quality of life.

Discussion

The primary focus of this literature review was to assess the existing evidence base on the use of remote telemonitoring in the management of three chronic conditions: heart failure, diabetes mellitus and COPD. The aim of ECCH is to have 5000 patients with chronic diseases having access to remote telemonitoring services by 2011.

The three chronic conditions chosen as the initial focus for ECCH were selected on the basis of the burden they place on the population of Northern Ireland.

A systematic review of the literature identified a total of 44 articles on remote telemonitoring which focused on at least one of the chronic conditions of interest. Each of these 44 publications was assessed using critical appraisal frameworks developed by the Scottish Intercollegiate Guidelines Network (SIGN). In total three frameworks were used: checklist for systematic reviews, checklist for RCTs and checklist for cohort studies.

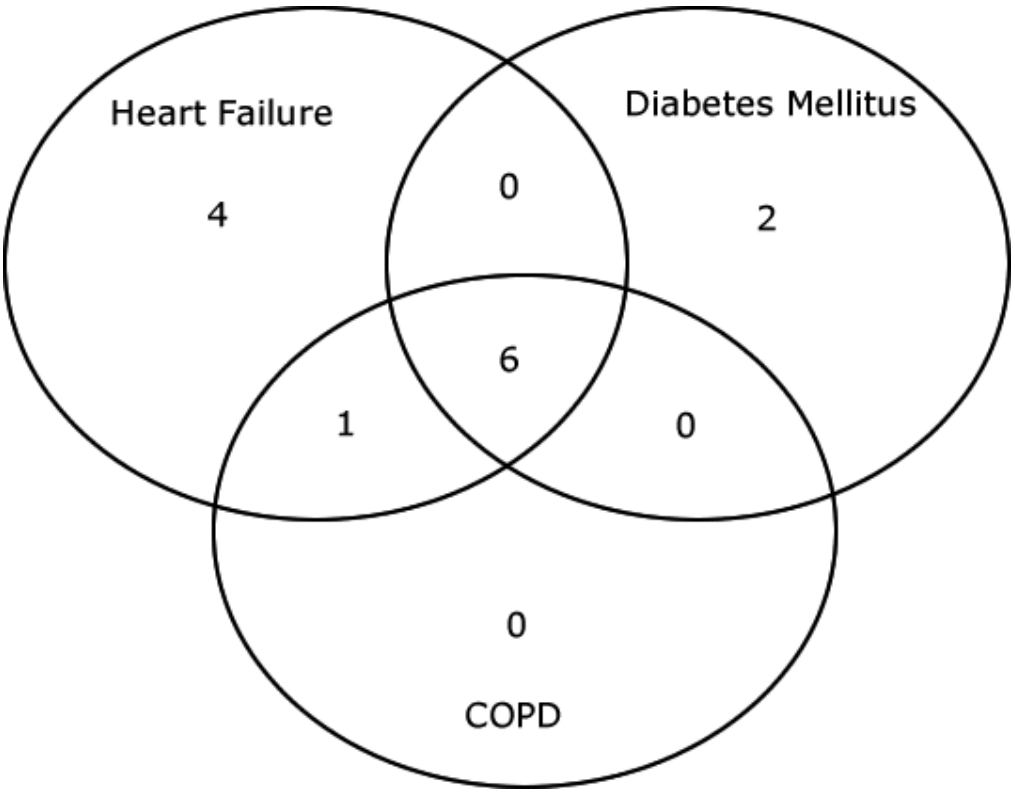
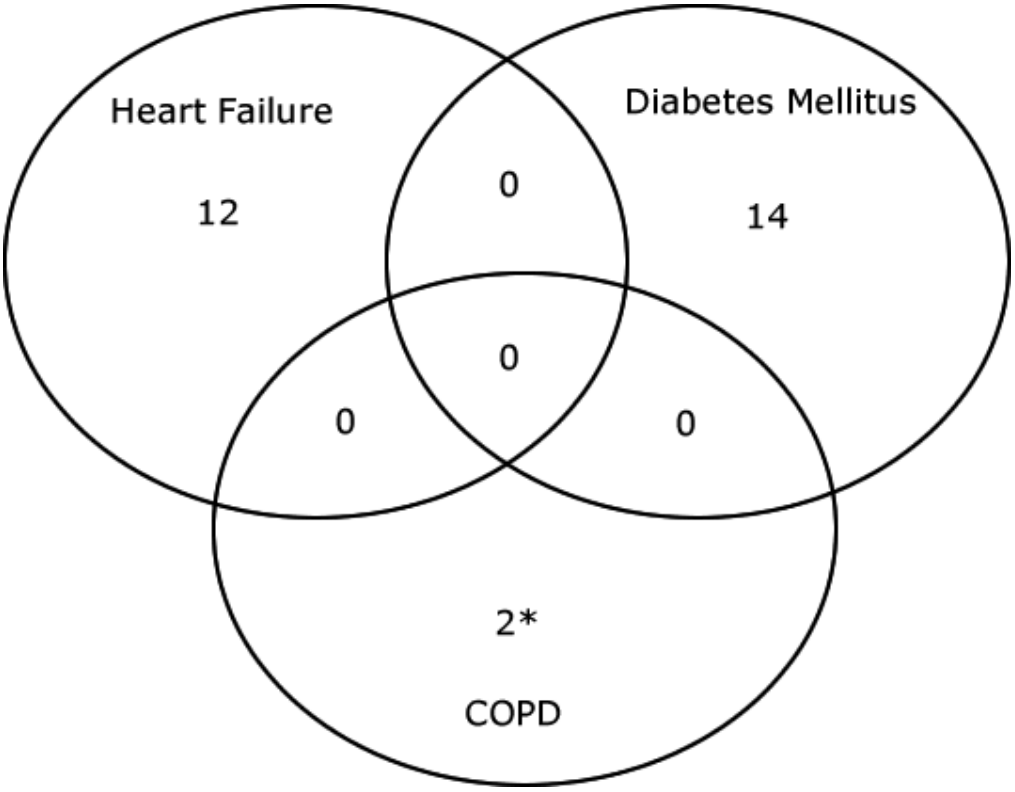


Figure 2: Number of identified systematic reviews by chronic condition

In total 13 systematic reviews were identified that considered remote telemonitoring in the management of at least one of the chronic conditions of interest. Four of the systematic reviews

looked exclusively at heart failure, two at diabetes mellitus, while one of the reviews considered both heart failure and COPD. Six of the systematic reviews identified included studies covering each of the chronic conditions of interest.



*one study was non randomised

Figure 3: Number of identified RCTs by chronic condition

Figure 3 illustrates the coverage of clinical conditions by the RCTs identified in the literature search. 12 RCTs addressed the use of remote telemonitoring in heart failure, while 14 RCTs covered its use in the management of diabetes mellitus and only two in COPD.

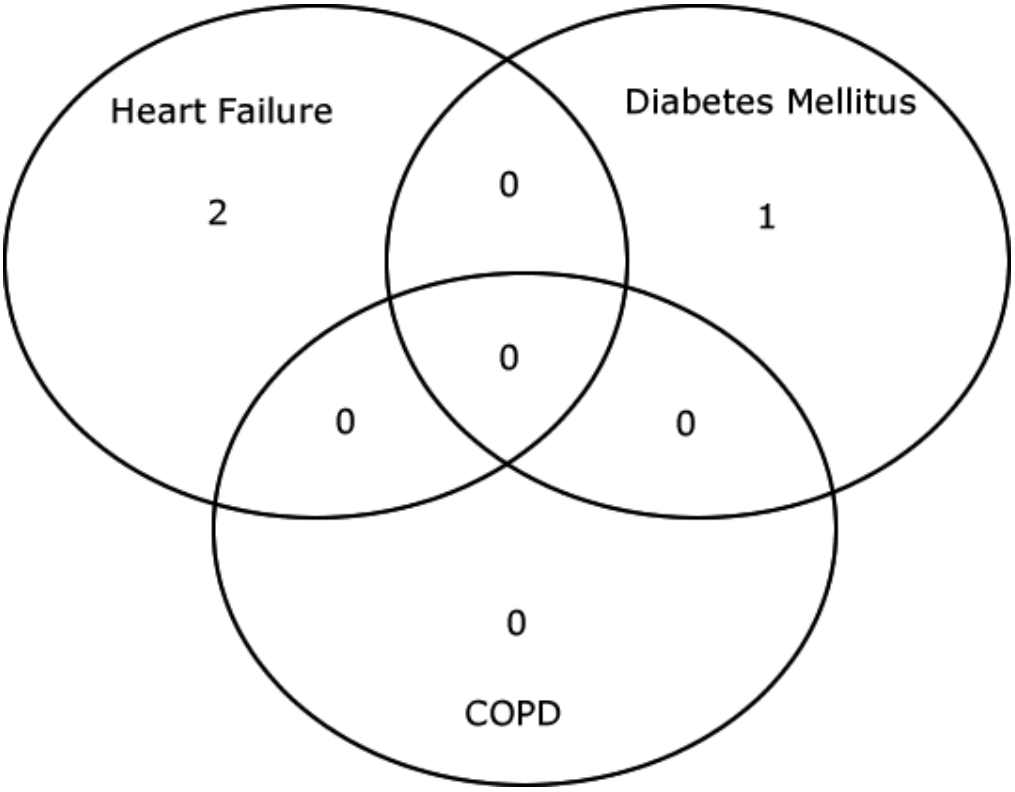


Figure 4: Number of identified cohort studies by chronic condition

Progressing down the hierarchy of evidence, three cohort studies were identified which looked at the use of remote telemonitoring in heart failure or diabetes mellitus.

Evidence Base for Remote Telemonitoring in Heart Failure

Well conducted systematic reviews are considered to offer the highest quality of evidence available from the medical literature.

The literature review identified a total of 11 systematic reviews that addressed the use of remote telemonitoring in the management of patients with heart failure. Four of the systematic reviews exclusively looked at heart failure; one also addressed COPD while a further six addressed all three chronic conditions of interest.

Critical appraisal of the systematic reviews revealed that ten of the reviews were of high quality and that only the review that jointly considered heart failure and COPD had methodological flaws. The paper by Meystre et al did not provide details on the types of study included in the review nor how the papers were selected for the review.

All four systematic reviews that exclusively considered remote telemonitoring in the management of heart failure patients concluded in favour of its use. Clarke et al found that remote

telemonitoring reduced hospital admissions in patients with heart failure and also lead to a one fifth reduction in all cause mortality. They also concluded that the use of remote telemonitoring could improve access to services for patients where geography, transport or infirmity of the patient limited access. Chaudhry et al also found that the use of remote telemonitoring in heart failure patients led to reduced hospital admissions and a reduction in mortality. Louis et al similarly found reduced mortality, fewer hospital admissions and reduced length of stay. Louis et al also commented on the acceptance of telemonitoring by patients. The review by Martinez et al made perhaps the strongest conclusions in favour of the use of remote telemonitoring for heart failure patients. The review concluded that remote telemonitoring in heart failure was a proven intervention and ready for wide scale roll out.

The six systematic reviews in which heart failure was not the sole focus made similar findings to those reviews in which heart failure was the only condition considered. The two systematic reviews by Bensink et al, which were really an extension of a single review, ranked numerous conditions in terms of the evidence base supporting the use of remote telemonitoring. Heart failure was ranked the second most strongly supported area behind smoking cessation. The review by Paré et al additionally concluded that the use of remote telemonitoring may help empower patients in terms of management of their condition.

Applicability to a Northern Ireland Context

In summary there is a strong evidential base in favour of the use of remote telemonitoring in the management of patients with heart failure. In Northern Ireland heart failure is a significant cause of morbidity and mortality. The strong consensus in conclusions reached in the high quality systematic reviews identified, demonstrates that the findings are applicable to the Northern Ireland population. In particular because the roll out of remote telemonitoring has ministerial support which is important in ensuring that the required infrastructure will be put in place.

Evidence Base for Remote Telemonitoring in Diabetes Mellitus

In addition to the six systematic reviews that included publications covering all three of the chronic conditions of interest, two systematic reviews were identified that exclusively considered the use of remote telemonitoring in patients with diabetes mellitus. Farmer et al concluded that the use of remote telemonitoring in a clinical setting is feasible. Jaana et al concluded that the remote telemonitoring of diabetic patients can result in a significant decrease in HbA1c for monitored patients. They also concluded that remote telemonitoring can have a positive impact on patients' attitudes towards their illness and help empower and educate patients about their illness.

The six other systematic reviews correlate well with these two reviews. The Bensink review ranked diabetes mellitus fourth highest in their assessment of conditions for which the evidence supported a role for remote telemonitoring.

Applicability to a Northern Ireland Context

Northern Ireland has a rising prevalence of diabetes mellitus. The literature has demonstrated acceptability by patients of the remote telemonitoring approach. The potential for using remote telemonitoring to help empower patients fits very well with the health agenda in Northern Ireland which has a goal to place the patient at the centre of the care process.

Evidence Base for Remote Telemonitoring in COPD

There is little evidence currently to support the use of remote telemonitoring in the management of COPD. No systematic reviews were identified that exclusively considered remote telemonitoring in COPD patients. The Bensink review ranked chronic lung disease sixteenth in its scoring of the evidence base available to support remote telemonitoring in various conditions.

The other systematic review identified that considered COPD along with heart failure was of poor quality.

Only two clinical controlled trials were identified that considered remote telemonitoring in COPD. One was non randomised and the other was very small in size with only six patients. The non randomised trial did show a positive response to the use of remote telemonitoring in patients with COPD, showing a decrease in health care utilisation.

Applicability to a Northern Ireland Context

There is a paucity of existing studies addressing the use of remote telemonitoring for COPD patients. Until more studies are published it is not possible to conclude either for or against the use of remote telemonitoring in COPD patients.

Existing Remote Telemonitoring Pilots in Northern Ireland

Several telemonitoring pilots are underway in Northern Ireland. Each of five Health and Social Care Trusts in Northern Ireland is currently running its own pilot. The pilots involve the use of remote telemonitoring in heart failure, diabetes mellitus and COPD. Some of the pilots are also investigating the use of telecare for dementia patients.

Conclusions

The published literature at present does not include enough studies to enable definitive conclusions to be drawn on all three of the chronic conditions of interest. The evidence base is conclusive in favour of the role of remote telemonitoring in the management of patients with heart failure. Published studies are also generally supportive of the role of remote telemonitoring in patients with diabetes mellitus. In particular the evidence is supportive for diabetic patients requiring insulin initiation and also in high risk pregnancies.

There are insufficient studies published to date to allow conclusions to be drawn on the role of remote telemonitoring in COPD patients. However the pilot studies currently underway in Northern Ireland and in England may provide further evidence either for or against the use of remote telemonitoring in COPD patients. These pilot projects will need to be evaluated carefully to ensure appropriate conclusions are drawn.

None of the 44 identified studies, included in this review, found adverse effects resulting from the use of remote telemonitoring in any of the chronic conditions of interest. There was also a general consensus among studies that remote telemonitoring lead to better use of scarce resources e.g. by enabling highly skilled nursing staff to take greater numbers of patients on to their caseloads. Triaging of patients also enables clinicians to maximise the use of appropriate skill mix for individual patients.

The roll out of the remote telemonitoring services planned by ECCH does offer the potential to improve the treatment offered to patients with chronic conditions living in Northern Ireland. The investment in remote telemonitoring services in Northern Ireland, if properly implemented and evaluated from the outset, also has the potential to contribute to the body of evidence available on the use of remote telemonitoring in chronic conditions.

Bibliography

SCHARR Systematic Reviews Hierarchy of Evidence. School of Health and Related Research, The University of Sheffield.