The Whole System Demonstrator Programme

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Whole System Demonstrator Publications


Whole System Demonstrator Programme
Executive Summary of Findings

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Background

Over the coming decades, extended life expectancy and low fertility will result in a shift in the old age dependency ratio in many countries including the United Kingdom, with a greater proportion of the population at retirement age than at working age. Projections indicate that in the UK, the population aged over 65 will increase from 17% to 25% between 2010 and 2035. Despite some positive changes in levels of old age disability and years of self-reported good health, greater numbers of older people living with long term conditions are likely to present major challenges for health and social care systems in the years ahead. In the current context of economic pressures and a desire to secure efficiency savings, there is significant interest in the potential for technology to reduce utilisation of health services in older people with long-term conditions and social care needs, while improving the quality and cost-effectiveness of care.

Part of the then UK government's response to this need was to fund the Whole System Demonstrator (WSD) Evaluation to investigate the effects of two broad classes of telemonitoring technologies on a comprehensive range of outcomes in regions of England that had undergone “Whole Systems Redesign”. Whole systems redesign refers to a process that aims to produce more integrated working practices across the NHS (health care) and Local Authorities (social care) at the organisational and routine delivery levels. Whole Systems Redesign aims to produce integrated services that deliver more effective health and social care through improved sharing of information and coordinated care plans, and to supplant the traditional model for delivery of care by encouraging care in the home through increased use of Community Matron case management and self-care management.

Telehealth (TH) and Telecare (TC)

There are a number of relevant types of telemonitoring technology; the focus of these studies was on TC and TH technologies. Telehealth requires active participation of patients to measure vital signs using peripheral devices whereas Telecare monitors without the need for patient input.
Telecare describes a system that allows remote and automatic monitoring that does not require any active involvement of individuals’ personal health and safety (e.g. mobility, falls) and home environment (e.g. floods, fires) in order to manage the risks of independent living or provide prompt emergency responses. The monitored sensors installed for intervention participants in the WSD TC Trial were tailored to individual needs and could include movement sensors, falls sensors, bed/chair occupancy sensors, enuresis sensors, smoke alarms, heat sensors and flood detectors. Telehealth differs in that it allows the remote exchange of data between a patient (at home) and health care professionals (at a Monitoring Centre) to assist in the management of existing long-term conditions (chronic obstructive pulmonary disease, diabetes, heart failure). The telehealth system used in the WSD TH Trial requires active participation by users to measure vital signs using peripheral devices tailored to their clinical needs and could include a blood pressure monitor, blood glucose monitor, blood oxygen monitor and weight scales.

The WSD evaluation trial was designed to address some of the shortcomings of previous research by conducting two large, methodologically rigorous, multicentre RCTs across three socio-demographically distinct regions of England (rural Cornwall; rural/urban Kent; urban Newham). Each WSD Site had undergone Whole Systems Redesign prior to the start of the WSD Evaluation. Each Site comprises one (Cornwall, Newham) or two (Kent) health authority regions (i.e. Primary Care Trusts) and geographically superimposed Local Authorities. The aim was the development of integrated care plans to deliver care more effectively to these patient populations. Each cluster RCT included a nested questionnaire study (the WSD TH Questionnaire Study and the WSD TC Questionnaire Study) to allow assessment of patient- and carer-reported outcomes (e.g. HRQoL, anxiety, depressive symptoms, functional ability, self-care behaviour) and quality-adjusted life years based cost-effectiveness. Additional qualitative studies of purposive subsamples explored patients’, carers’, healthcare professionals’ and healthcare organisations’ experiences of TH or TC. Collectively, the WSD Evaluation was the largest and most comprehensive investigation of TH and TC to date.
WSD Evaluation Design

The WSD evaluation trial was a large scale, multi-site study of the implementation, impact and acceptability of two new technologies, telecare and telehealth, in the context of routine delivery of NHS care. The evaluation was principally a cluster-randomised controlled trial (RCT) of TH and a second RCT on TC versus usual care in patients with long-term conditions or social care needs. The aim was to assess the effectiveness and cost-effectiveness of (a) TH in the management of patients with long-term health conditions, and (b) TC in the management of patients with social care needs.

As with any pragmatic trial, the proposed design was a compromise between methodological, ethical and policy issues. The optimal assessment of the cost-effectiveness of a new health technology is a randomised controlled trial, and this was the initial basis for all design discussions. However, sites highlighted the importance of designing a trial that had the support of stakeholders, and therefore individual randomisation of patients was unlikely to be acceptable. To address these concerns a cluster randomised trial design was used.

Although many services provided to patients (especially those with social care needs) are delivered outside primary care, general practices were used as the unit of allocation because they are stable organisations involved in the care of all patients in each site. General practices were randomised so that eligible patients within their populations would receive access to one technology (i.e. either TH or TC). Each practice would thus provide intervention participants for one technology and control participants for the other. This ensured equity of access existed at the level of the practice population, and that no practice was asked to risk randomisation to a no-treatment control where all patients would be denied access.

The three sites each had a local WSD Project Team responsible for implementation in line with the protocols provided by the WSD Evaluation Team. WSD Project Teams’ responsibilities included: identifying and recruiting eligible participants; installing and maintaining TH and TC devices for intervention participants; training participants (and professionals) in the use of the TH and TC; providing Monitoring
Centre services; providing usual health and social care to all participants; and providing local organisational and management resources as required to support the two trials.

General practices were randomised for treatments; each provided one technology (TH or TC) and controlled participants for the other intervention (TC or TH), ensuring equity of access to advanced assistive technology at the level of the practice population. Consenting practices were allocated to the intervention and control groups by the trial statistician using a centrally-administered minimisation algorithm that aimed to ensure comparability across trial arms in terms of practice size, deprivation, proportion of patients from non-White ethnic groups, prevalence of diabetes, COPD and HF, and WSD Site. There was no blinding for practices, participants or assessors.

The introduction of a complex suite of telemonitoring technologies and the associated service changes raised more questions than could be answered with a conventional trial alone. The proposed cluster trial was used as a structure, around which a wider evaluative process was designed in line with current convention regarding the assessment of complex interventions. The research questions were:

- Does the introduction of TH or TC result in a reduction of service utilisation and costs of care?
- Does the introduction of TH or TC result in improvements in quality of life, well-being, self-care, and carer burden (clinical effectiveness)?
- What are the economic consequences of introducing TH/TC (Cost-effectiveness)?
- What organisational factors impact sustainable adoption and integration of TH/TC?
- To explore user and carer perspectives, including views on existing services; interaction with service providers; and attitudes to TH/TC, including reasons for declining to take part.
- To explore TH and TC professionals' attitudes, including engagement and perceived barriers and facilitators to operationalising TH/TC.
Methodology

Service use

Analysis of service utilisation relied on electronic data extracted from administrative data sets, with the aim of tracking service use for (a) up to three years pre-intervention and (b) 12 months post-intervention. Person-level data on hospital use were collected from four NHS primary care trusts (Newham, Cornwall, Eastern and Coastal Kent, and West Kent) while person-level data on use of primary care were collected from general practices across the three sites. This data included emergency and elective inpatient admissions; inpatient bed day use; outpatient attendances and accident and emergency visits; primary care utilisation (including GP encounters); prescription drugs; and community matron visits. Where possible, data about social care use of those receiving TC or TH have also been collected based on information from the local authorities. All data sets were anonymised at source to protect patient confidentiality, and then linked to show use of care in individuals. Over a billion rows of data were cleaned, linked and assembled into large data sets. For a more detailed account of how data sets were assembled, and the implementation of case-mix adjustments (see Steventon et al., 2012).

Clinical effectiveness

Evaluations of clinical effectiveness required assessment through questionnaires recording patient reported outcomes (PROs) in a patient subgroup recruited for both TH and TC trials, although most measures in the WSD TH and TC Questionnaires Studies were self-reported. The WSD TH and TC Questionnaire Studies (nested within the main study and utilising its group allocations) assessed the impact from the patient’s perspective using self-reported measures for quality of life, psychological outcomes and acceptability of services along with measures of behaviour and attitude. The latter included an assessment of self-care behaviours and attitudes towards the technology. Outcomes and processes were assessed at the level of the individual with long term conditions: Chronic obstructive pulmonary disease (COPD), diabetes, or heart failure. At baseline, the outcome measures were self-completed by participants with a trained researcher on hand to explain or clarify the meaning of particular questions or assist questionnaire completion if participants were physically unable to do so. Following the baseline interview, two further
assessments were conducted and PRO measures were collected at short-term (4-months) and long-term (12-months) follow-up. These assessed quality of life, anxiety and depressive symptoms, all of which are common among patients with the long term conditions covered, as well as processes and attitudes. Participants who had not returned their questionnaire at 12 months were contacted to arrange an interview.

**Cost-effectiveness**

Patients who were assessed using PRO measures were also assessed for health utilisation measures to provide a more comprehensive assessment of clinical and cost-effectiveness. This assessment was also carried out through self-reported questionnaires. Trained interviewers administered the Client Services Receipt Inventory (CSRI) (Beecham and Knapp, 2001) at three time points to collect information needed to calculate health and care costs. The CSRI was administered as part of the questionnaire study and participants were assessed by interview at baseline and as a self-reported questionnaire four and 12 months after randomisation. Participants who had not returned their questionnaire at 12 months were contacted to arrange an interview. Unit costs were calculated for the TH and TC interventions, drawing on key informants' reports, financial and administrative data provided by the sites' project teams. The information was used to build detailed descriptions of TH and TC production processes in 2009/10. The sites provided details of the TH/TC equipment used by trial participants. Annuited costs of base units and peripherals used by individual participants were added to a per-participant, per-site average cost of monitoring, installation and maintenance to give a unit cost of TC equipment support. The intervention costs thus calculated partially capture variation between participants, but do not reflect, for instance, different patterns of sensor activations. We attached nationally-applicable unit costs (at 2009/10 prices) to self-report service use data collected by CSRI. Costs were calculated for the 3-month period prior to 12-month follow-up and multiplied by four to provide a yearly equivalent for the cost-effectiveness analyses.

The economic evaluation adopted a health and social services perspective. The TH and TC analyses examined the relationship of quality-adjusted life years (QALY) to
health and social care costs, taking a net-benefit approach. Net-benefit captures the monetary value of a gain in outcome associated with the intervention at a given willingness-to-pay (WTP), net of the additional cost of the intervention aimed at achieving the outcome. Multi-level regression models explored the relationship between outcomes and costs, clustering at the level of the general practice. Regression results were used to estimate incremental cost-effectiveness ratios, representing the extra cost of a one-unit gain in outcome associated with the addition of TH or TC to standard care, and to create cost-effectiveness acceptability curves (CEAC) showing the likelihood that the intervention is cost-effective over a series of alternative thresholds of societal WTP for additional improvements in outcomes. WTP values examined in the analyses included the £20,000 to £30,000 per QALY range (NICE, 2008).

Sensitivity analyses were conducted to investigate whether the assumptions of the main analyses were robust to two assumptions about cost parameters – equipment and support costs. In the TH analyses, we examined equipment price decreases of 50% and 80%, and support costs of a service working at a higher capacity, of 1000 service users per site. In the TC analyses, we examined the effect of assuming a lower cost of TC support of £260 per annum and a 50% price decrease for TC equipment.

**Exploring service user, carer and professional perspectives**

This qualitative evaluation, performed as part of the WSD study, assessed the views and experiences of patients; service users (including carers); and the interaction between service users, carers and professionals of TH and TC packages. A multi-method approach was adopted in order to fulfil these aims, and each subgroup was addressed differently. To assess the impact on patients and carers (including both trial participants and a sample of those who were invited to join the trial but chose not to enter), semi-structured in-depth interviews were carried out. Observation also documented the introduction and use of technologies in patient and service users' homes within the context of other management practices, caring relationships and interactions with professionals. Those receiving the intervention were also subject to follow-up interviews (mixture of face-to-face and telephone) at multiple time-points. The sample included 19 potential participants who declined to take part in the trial.
and 58 cases from the intervention arm of the trial who were followed throughout the trial.

An additional focus was professional attitudes on the use and implementation of TC and TH, including perceived costs and benefits. The impact of TC and TH on frontline staff was also explored, including changes to established work practices. Perceived barriers and facilitators to utilising TH and TC, and education and training needs for implementation were also assessed. Key professionals directly involved in the delivery of TC or TH at all three WSD sites were subject to semi-structured in-depth interviews at baseline and 12 months follow-up where possible. The sample for these interviews included 50 TH participants, 33 of which also completed the follow-up interview; and 31 TC participants, 12 of which completed the follow-up interview after 12 months.

Service delivery and organisation

An organisational evaluation, in parallel with service delivery implementation and a randomised controlled trial was conducted in order to better understand the interconnections existing between policy, organisational environments, contextual influences (e.g. history of remote care involvement at each site), and the programme intervention itself. A particular focus was understanding the interaction of organisational factors that would assist in the successful large scale implementation of remote care. The context, mechanisms, and outcome relationships between different stakeholders across the system was explored, by asking ‘what makes sense and works?; for whom?; and under what conditions?’. A fundamental challenge for the sites was the anticipated tensions between differing organisational priorities:

1. to maintain an effective, high quality intervention to create robust scientific evidence on the technologies in use and
2. to establish practices and systems to foster sustainable use of the technologies in the future and nationwide, beyond the WSD programme.
Case-studies of the three sites forming the UK Department of Health’s Whole Systems Demonstrator (WSD) Programme were undertaken. Qualitative research techniques were used to obtain data from various sources, including semi-structured interviews, observation of meetings prior to the launch of WSD as well as over the course of the programme, and a document review. Participants were managers and practitioners involved in the implementation of remote care services.

**Telehealth results**

**Service Use**

Patients’ service use and cost were assessed in the full sample of 3,154 patients (98% of those recruited). Over the 12 month trial, patients allocated to receive the TH intervention had fewer emergency hospital admissions. They experienced an average of 0.54 emergency admissions per person, compared with 0.68 per person for control patients – a difference of around 20 per cent. Furthermore, over the twelve months, 4.6 per cent of intervention patients died compared with 8.3 per cent of controls. These differences in emergency admissions and mortality were statistically significant, so were unlikely to have been caused by chance. However, although intervention patients experienced 20 per cent fewer emergency admissions than controls, these reductions were from a low base. Differences corresponded to 0.14 admissions per person over 12 months. The control group appeared to experience more emergency hospital admissions shortly after being recruited into the trial compared with previously. The reasons for this increase are unclear but it is possible that trial recruitment processes affected admissions.

**Cost-effectiveness**

Cost effectiveness was assessed in the Questionnaire sample. At baseline 1,573 participants provided data in the questionnaire study (TH n=845; usual care (UC) n=728). At short term (ST) follow-up, the overall response rate was 62.7% (986/1,573); and at long term (LT) it was 61.9% (974/1,573). Costs were available at both the baseline and the 12-month follow-up for 965 people (534 TH and 431 usual care).
For intervention patients, the overall costs of hospital care (including emergency admissions, elective admissions and outpatient attendances) were £188 per patient less than those for controls. However, this cost difference was not statistically significant. Service use data were available for 841 TH and 728 usual care participants at baseline and for 534 TH participants and 431 usual care participants at 12-month follow-up. In the three months prior to 12-month follow-up, unadjusted health and social care costs (including intervention costs) were £1,390 (SE £102) for the controls and £1,596 (SE £89) for the intervention participants. The average yearly cost of the TH intervention (including both support and equipment costs) for these participants was estimated as £1,847 (SE £11.3).

The results of the net benefit analyses indicated that there was a small QALY gain for the intervention group (0.012), and that the extra cost of this gain was £92,000. The probability of cost-effectiveness of TH at a Willingness to Pay (WTP) of £30,000 was low, at 11%. The adjusted difference in annual total costs between groups was £1110. In sensitivity analyses reducing the costs of equipment by 80%, or assuming a higher capacity, the intervention group’s costs remained higher than those of the controls. Combining these scenarios, the difference between groups was less than in the base case, at £109. The incremental cost effectiveness ratio (ICER) was lower, at £12,000 per QALY. Assuming a WTP of £30,000 per QALY, the probability that the TH intervention was cost-effective was 61%.

Total health and social care costs of the TH group were higher than those of the controls. QALYs were similar in both groups. The probability of cost-effectiveness - judged by the £30,000 threshold willingness-to-pay used as a reference by NICE - was relatively low. Total costs were quite sensitive to the costs of the intervention, as witnessed by lower cost per QALY estimates in the sensitivity analyses and similar costs between intervention and control groups.

**Patient and carers outcomes**

**Descriptive Statistics**

Two basic forms of analyses were conducted on patient reported outcomes: a) A Complete Case Cohort which included 48.3% (759/1,573) of participants and b) An
Available Case Cohort which included 76.4% (1,201/1,573). Some differences were apparent between the TH and usual care groups in these analyses. In addition, a per protocol analysis was conducted which assessed the impact of the TH devices when used appropriately (i.e. efficacy analysis).

Treatment Effectiveness and Efficacy

Intention-to-treat analyses of quality of life outcomes and psychological wellbeing (anxiety and depression) multilevel modelling was used to control for the BL score of the respective outcome measures, key covariates (e.g. age, gender, LTC diagnosis) and the intra-cluster correlation. Analyses results showed that trial arm, time and their interaction were not significant for all measures of Quality of life and Psychological wellbeing in either the Complete Case Cohort or the Available Case Cohort. Analyses for adjusted effect sizes for trial arm (TH vs. UC) suggested both cohorts at ST and LT failed to reach the trial-defined clinical effect. The per protocol analyses using multilevel modelling also generated no significant main effects of trial arm (TH vs. UC) or time (ST vs. LT) for any outcome measure. There were no adverse events or side effects related to any of the TH devices reported in the intervention group throughout the course of the trial.

Levels of self-care

We examined whether the functions of TH (e.g. regular patient monitoring of clinical indicators; timely contact with healthcare providers when clinical readings breach individual parameters) led to improved patient self-care behaviour and self-efficacy. In the analyses of data from the WSD TH Questionnaire Study, there was no effect of TH on generalised self-efficacy, self-care self-efficacy or self-care behaviour over the 12-month trial period. These findings were consistent across a series of sensitivity analyses (intention-to-treat vs per protocol; available case cohort vs complete case cohort). Although the TH regimen appears to contain several elements common to effective (face-to-face) self-management interventions (e.g. goal setting; self-monitoring of behaviour and outcomes of behaviour; feedback of disease markers; disease-specific education), the failure to find any effect on behaviour suggest that the limited behaviour change techniques used in the WSD
study were not adequate to produce clear changes in self care behaviour or the cognitions associated with improved self-care. One important challenge for the future will be to develop ways of implementing effective behaviour change strategies using TH as a tool for delivery.

Refusals

Active rejection of the TH intervention was the most frequent reason for withdrawal (13% of TH participants). Patient rejection is a potential barrier to the widespread deployment of TH. Trial-related, health, socio-demographic, cognitive, emotional and behavioural factors were examined. Patients diagnosed with diabetes, as opposed to heart failure or chronic obstructive pulmonary disease, and patients’ beliefs about the acceptability of the TH service predicted whether or not they withdrew from the trial. Key to predicted continued participation in the TH arm of the WSD trial were beliefs that it resulted in increased accessibility to care, greater satisfaction with equipment and fewer concerns about the privacy, safety and discomfort associated with using TH equipment. These findings suggest that an intervention that incorporates and responds to these issues may alleviate some potential concerns regarding use of TH and increase continued use.

Telecare results

Service use

The analysis focused on 2,600 people with social care needs, comparing TC with usual care (UC). Patients were followed up for 12 months and analyses were conducted as intention-to-treat, focusing on the proportion admitted to hospital within twelve months. Secondary endpoints included mortality; rates of secondary care use (seven different metrics); contact with general practitioners and practice nurses; proportion admitted to permanent residential or nursing care; weeks in domiciliary social care; and notional costs. Results indicated that 46.8% of intervention participants were admitted to hospital, compared with 49.2% of controls. Unadjusted differences were not statistically significant (odds ratio 0.90, 95% CI, 0.75 to 1.07, p=0.211). Though they reached statistical significance after adjusting for baseline
covariates but this was not replicated when adjusting for predictive risk score. Secondary metrics including social care use were not statistically significant.

The study found a very low proportion of control participants (3.2%) had been admitted to permanent residential and nursing care by twelve months, therefore benefits may only materialise over longer time periods than this trial. Further, effects might vary according to the characteristics of participants. For example, participants receiving falls detectors may have shown greater reductions in hospital admissions for falls than the entire sample. This study was, however, not designed to address these questions. Telecare as implemented in the Whole System Demonstrator trial did not lead to reductions in service use, at least in terms of results assessed over twelve months.

**Cost-effectiveness**

Cost effectiveness was analysed through the Questionnaire study which assessed 1189 participants, with 639 (53.7%) in the UC group and 550 (46.3%) in the TC group. The response rate was 45.0% (535/1189) at ST and LT 64.2% (763/1189) at LT. Both baseline and 12-month follow-up costs were available for 753 participants (375 intervention and 378 control).

Health and social care costs (including intervention costs) in the three months prior to 12-month follow-up, not adjusting for case-mix, were £1,822 (SE £133) for controls and £2,227 (SE £140) for intervention participants. The mean annual cost of support and equipment for these participants was estimated at £791. Adjusted, costs of the intervention group were £1014 (CIs -525, 2553) higher than those of the controls in the principle analyses.

The regression results suggested that there was a very small QALY gain for the TC group (0.003). The cost of a QALY gained by the addition of TC to standard health and social care was £297,000. Assuming a WTP of £30,000 per QALY, the probability that the TC intervention was cost-effective was 16%. In the sensitivity analysis assuming a lower cost for TC support, the cost per QALY gained was £173,000; at a WTP of £30,000 the probability of cost effectiveness was slightly
higher than in the main analysis, at 30%. Combining lower-cost support and lower equipment costs scenarios, the cost per QALY gained was estimated as £161,000 and the probability of cost-effectiveness of TC at a £30,000 WTP was only slightly higher, at 31%.

Service costs in the TC group were not lower than in the controls, and there was little difference between the groups in QALY gain over 12 months. A package of second-generation TC equipment and associated monitoring service did not constitute a cost-effective alternative to usual care, assuming a commonly accepted willingness to pay for QALYs.

**Patient outcomes**

Participants and carer outcomes were assessed in the questionnaire sample described in the previous section. Sample participants were approximately 74 years with the majority classified as white British/Irish. They had on average one comorbid condition and the majority (64.8%) had received little formal education. The intervention group received, on average, just short of 4 pieces of TC kit (excluding the base-box and personal pendant alarm).

Analyses revealed a significant trial-arm effect on SF12 MCS and time effects on EQ5D and depression scales. Parameter estimates indicate that being a member of the TC trial-arm increases the SF12 mental component score overall by about 3 points (after the intra-cluster correlation, all covariates and data hierarchy are taken into account), as indicated by the EMMs of the MCS scale of the UC (mean=40.52) and TC groups (mean=43.69, p=0.017).

Across the sample, the EQ-5D score indicates that health status was reduced overall from short-term (mean=0.332) to long-term (mean=0.283; p=0.002); and the CESD-10 scale that depressed mood increased from short-term (mean=1.226,) to long-term (mean=1.287, p=0.032). Of note is the lower levels of depressed mood in the TC group (mean=1.187) compared to the UC group (mean=1.326) which was close to significance (p=0.050). Sensitivity analyses (per-protocol, complete cases, excluding covariates) indicated similar trends.
Costs for the TC group, including intervention costs, were £1014 higher per annum than the control group in the principal analyses. The probability that a decision maker would find the intervention cost-effective at a willingness-to-pay of £30,000 for an additional QALY was about 16%. The probability that the intervention was cost-effective did not reach 50% even assuming a willingness-to-pay of £90,000 per QALY.

**Carer Outcomes**

At baseline 242 carers completed questionnaires (usual care = 124 (52.5%), TC = 118 (47.5%) and, of these, 199 (75.1%) also completed at least one follow-up assessment (Available Case Cohort) and 118 (44.5%) completed both follow-up assessments (Complete Case Cohort). The carer sample was largely White (96%), female (80%), and living with (90%) or married to the patient (82%). On average, carers were approximately 6.5 years younger than the patient and reported fewer than half their number of comorbidities. This study of the effects of patient TH on carer outcomes over 12 months found no statistically significant effects on quality of life, anxiety, depressive symptoms, caregiver strain or the carer-reported number of hours the patient could be safely left unattended. Some authors have argued that carers have negative expectations regarding TC (Bardsley et al., 2012) and may be dubious regarding its potential benefits (Dinesen et al., 2008) but the current findings indicate that, on average, carers of patients with TC do not report reduced QoL or carer strain compared to carers of patients without TC. Thus, contrary to previous concerns, our findings suggest that, on average, the introduction of TC is unlikely to lead to worse carer outcomes.

**Rejection of Telecare**

The passive monitoring of TC was not actively refused in significant numbers to require further exploration (0.73%). The most frequent reason for TC withdrawal was due to mortality and this applied to 5.85% of the sample.
Patients’ and carers’ responses to the introduction of technology (Qualitative Study)

People who declined participation in the trial

There was a common perception that utilising TH requires prior technological expertise and special skills. However, the research indicated that the way technology was first introduced could impact upon perceptions of technical competency. Adoption of TH was often perceived to potentially undermine existing ways of managing and coping with long-term conditions and that it could be disruptive and constraining in everyday life. Adoption of TH and TC were commonly associated with people who were very sick, old and frail. Consequently, adoption of these interventions was perceived by some to signify ‘giving up’ and accepting deterioration. A small number of carers felt that the person they were caring for was too sick or too dependent on them or healthcare staff to benefit from use of the interventions. There were also concerns that TH and TC could impact negatively on provision of services and on existing relationships with professionals.

People who received telehealth in the trial

The majority of patients who were recruited to the trial had a positive experience of TH as part of on-going service provision, especially when use was tailored to suit individual circumstances.

Use of TH varied over time and according to disease burden. For example, those with high disease burden often valued TH as enabling better crisis management and emergency care; whereas those with less severe problems were more likely to value TH as a means of enabling better preventive self-care. A small number of participants felt that service provision and relationships with professionals were adversely affected by the intervention, but many participants valued the new service provision and new relationships with professionals associated with TH. The latter was especially noticeable when there was some continuity of contact with monitoring staff.
Technical problems in conjunction with communication barriers seemed to be associated with some cases where participants did not fully engage with the intervention. A small number of TH recipients found the intervention to be burdensome and disruptive to existing management. The design and specific features of the different pieces of equipment had some bearing on acceptability and how it was used. For example, a TV based intervention often occupied a very different place in the home and facilitated a degree of interaction amongst family members. Also, some people received information via the equipment and others did not. Telehealth recipients valued peer support regarding use of the intervention where this was facilitated, for example via coffee mornings in the urban site of Newham.

People who received telecare in the trial

Recipients of TC and especially their carers valued the sense of reassurance gained by presence of the various sensors and alarm systems. Experiences of TC users were different to TH users because it was mostly experienced in passive terms, as something functioning in the background of daily life and as an emergency back-up system. Whilst participants valued TC in providing ‘peace of mind’, they also emphasised the importance of ‘human care’. Telecare could only be additional to the tangible care they received from others. Emergency pendants were often kept in various places in the home rather than worn. A small number of service users found false alarms to be disruptive.

Professionals’ responses to the introduction of technology

Telehealth staff

Nurses

The vast majority of nursing staff described TH goals in terms of personal benefits to patients, such as improving independence and quality of life. A few mentioned organisational and economic objectives, such as reducing unnecessary or unplanned hospital admissions. Some patients were perceived as more suitable candidates for TH than others, and several interviewees had reservations about the use of time and resources on patients who were relatively active and healthy.
Nurses were often concerned that older and frail patients would not be willing or suitable candidates for the intervention. However, in some cases these perceptions changed over time where they found examples of such patients managing well with the intervention. Most nursing staff reported that TH enabled professional development and specialism because they acquired new skills and tended to have prime responsibility for the TH intervention. Telehealth was viewed to facilitate a more systematic approach to patient care although some felt there was need for further refinement of the technology to overcome some technical problems.

Nurses often described the positive impact of TH on time management. However, they also felt that TH should be seen as one of multiple options to support patients rather than a solution to staff shortages and funding problems. Some nurses were concerned that TH could generate additional unplanned work and make extra demands on their time. Nurses frequently stressed that TH should not replace face-to-face contact with patients.

**General Practitioners**

GPs acknowledged and sympathised with organisational and policy goals to reduce economic costs associated with long-term health and social care needs. On the whole, GPs were less convinced than the nurses about the patient benefits of TH, and were concerned TH could over-medicalise and cause unnecessary anxiety. GPs were concerned that TH would add an additional burden to their workload and even where they had capacity to access TH records, in the main they did not engage. Some GPs were concerned about processes that might undermine their professional autonomy and diagnostic skill.

**Telecare Staff**

Telecare staff tended to view TC as facilitating improved quality of life for service user. The TC professionals considered most service users to be already familiar with technologies such as the pendant lifeline and so already aware of the benefits of TC. They also felt that few service users had concerns that the equipment would intrude...
on their privacy. Although the monitoring service required regular and routine attention to incoming data, the work did not require just passive monitoring and reacting to a screen. Variety and interest came from routinely visiting clients, carrying out assessments of client equipment needs and the need to liaise with equipment installers.

Whilst TC involves increasingly standardised and process driven operations, the TC technology leaves operatives with discretion as to how to proceed once the alert has come through to the monitoring site. Responses are determined partly by protocols but also by common sense judgments, on the job training and informal discussions with colleagues. When TC workers receive and respond to an alarm or alert, some report inadequate arrangements for obtaining assistance for the client. Inadequate responses from services are a source of stress. Service providers did not consider the interface with health to be salient or particularly important. They had little interaction or collaboration with the health service generally and specifically had little interest in or knowledge of TH.

**Telecare and Informal Carers**

Informal carers who bear the brunt of responsibility for looking after the frail elderly have been found to have poorer quality of life and report significant burden of care. The level of carer burden has been found to relate to the likelihood of admission to a care home. The study assessed the potential benefits of social care recipients’ receipt of TC on attenuating the level of caregiver strain. It was considered that this may occur through reducing worry and pressures to monitor the care recipient.

Telecare was not found to have an impact on carer burden. The findings however, suggested a small effect of TC in maintaining mental health quality of life over time for carers. Mental Health Quality of life showed a small decline in those not receiving TC.
Organisational Issues

The research programme investigated implementation lessons across the three WSD trial sites and in six additional sites not forming part of the trial.

A key finding was that delivering a major service change such as remote care in a period of financial cutbacks and NHS and local authority reforms requires strong leadership and vision, commissioning support and good communication across key health and social care partners to increase stakeholder engagement. Within the WSD Programme, constantly shifting organisational priorities and staff turnover impeded wider engagement with the TH and TC agenda, which was often viewed as misaligned with local policies, care processes and staff working practices.

Building a shared language and long term strategic vision to support mainstream implementation was important, and across all locations the involvement of clinical champions in the management and delivery of the programme helped address NHS and local authority concerns and increased clinical engagement.

Many staff, originally sceptical about the efficacy of TH services, became enthused and excited by the innovation as their knowledge and interaction with the technology increased. The provision of the ‘right’ type and level of evidence was important in influencing attitudes towards TH.

However, while participation in the WSD and in TC and TH projects in other sites instilled staff with a sense of enthusiasm, this tended to fade as organisational priorities shifted and workload increased. Changes in senior management also impacted on the implementation process. At inception, changes in leadership were accommodated, but as the programme progressed this resulted in a loss of focus, with delays in the programme delivery.

Whole system working was not a large part of the culture of WSD staff, nor was a ‘whole system’ transformation of care services around remote care seen as desirable by many frontline staff. The introduction of remote care did not change the underlying structure of care delivery. Across all sites, TH was frequently seen as a
‘standalone service’, separate from other organisational roles and established care processes.

**Discussion, Conclusions and Implications**

This discussion is designed to pull together the findings of the WSD programme; to relate some of these to recent findings in the area; to draw conclusions; and suggest some of the implications for the use of assistive devices in both health and social care. Specific discussions on each of the areas of the WSD study have been reported earlier. As the evaluation involved two large RCTs and distinguished between TH and TC, these two aspects of assistive devices will be distinguished before considering assistive devices in general.

**Telehealth**

In the context of the WSD Evaluation, TH describes a system that allows the remote exchange of data between a patient (at home) and Healthcare professionals (at a Monitoring Centre) to assist in the Management of an existing long-term condition(s) (COPD, diabetes, and heart failure). The peripheral devices used by intervention participants in the WSD TH Trial to monitor vital signs were tailored to their clinical needs and could include blood pressure monitor, blood glucose monitor, blood oxygen monitor and weight scales. These devices require active participation from the user in assessing, sending and in many cases receiving information.

**Quality of the Evidence in 2013**

Since the time of WSD’s inception a large amount of research has been conducted in the area. A simple Pubmed search of ‘telehealth’ revealed 390 papers on the subject since 2009, which is probably an underestimate of the amount of work undertaken.

The WSD study started in 2008. At this time a number of questions were directed at the quality of existing evidence on both TH and TC. Several reviews of their
effectiveness had been published both within specific disease areas (Chaudhry et al., 2011) (Barlow et al., 2007a) (Bergmo, 2009) and across different areas (Farmer et al., 2005) (Cruickshank et al., 2010). However, much of the available literature referred to pilot projects and the assessment of the impact of these devices on short-term outcomes (a few months). Furthermore, the majority of studies did not meet robust evaluation standards. Very few of the studies assessed the longer-term or routine use of such technologies.

A consideration of the systematic reviews at the time indicated areas of concern in this research. One systematic review of 24 trials of interactive health communication applications (Roland et al., 2005) most closely relate to what is defined here as telehealth. In the review, TH was found to have a significant positive effect on knowledge, social support, behavioural outcomes (e.g. calorific intake, exercise and medication taking) and clinical outcomes (e.g. asthma symptoms, HbA1c levels and body mass index). Another systematic review of TC and TH interventions reported an emerging evidence base for the clinical effectiveness of TH technologies aimed at vital signs monitoring but insufficient high quality evidence for the effectiveness of TC applications such as safety and security monitoring (Billings et al., 2006).

These methodological concerns regarding the quantitative evidence in specific areas remain. To illustrate an ongoing concern regarding studies in the area the example of research in COPD will be used.

At the outset in WSD, we identified the poor quality of studies both in terms of design and also in relation to the number of participants. This situation has been remarked on in a systematic review of TH studies in COPD published in 2013 where it is stated that the vast majority of the studies are small and lack a control group (Pedone et al., 2013). To gather reliable data in COPD using a common measure of outcome such as the dyspnea scale of the CRQ and a two group parametric test (t-test) on this continuous outcome assuming an effect size of 0.3 (medium-small effect size), would require 176 per group (352 total). The larger studies in COPD utilising only the telephone tend to have approximately 180 participants. Studies are smaller where home telemonitoring and transmission is more extensive, where they tend to have approximately 90 participants. Some examples of recent studies that continue to
report inadequate numbers of participants to have any confidence that their findings are reliable include (Pecina et al., 2013) n=166; (Dinesen et al., 2012) n=105; (Pedone et al., 2013) n = 99; (De San Miguel et al., 2013) n =99; (Sicotte et al., 2011) n = 46; (Lewis et al., 2010) n = 40.

In contrast to these studies, numbers in the WSD full study and questionnaire study were 1,577 and 578 participants respectively, which is more comparable to the studies listed above. It is clear that size of the studies remain a persistent limitation to the evidence base as findings will not be reliable with numbers that are insufficient.

The assessment of costs and differences between a group who receive TH are critical to any understanding of the impact of these devices. The data from the WSD study showed evidence of reductions in hospitalisation and reductions in mortality in the TH group. These findings are complex, and as discussed above, they are subject to interpretation as the data indicated substantial changes in the control group. For the use of TH to generate genuine reductions in mortality and hospitalisation, it is useful to speculate on the mechanism that may have been in operation in the WSD trial. There are a number of possibilities including that the devices prompted an early warning leading to a intervention that successfully managed a health problem. Alternatively, it may be that the technology impacts on the behaviours of either the patients, or the wider health system in the ways they react to emerging health problems. In both cases they may reduce deterioration in health, which in turn result in reduced hospitalisation and mortality in the TH group.

It was unfortunate that it was not feasible in the WSD study to examine clinical changes that may presage a significant deterioration in any systematic manner as this would have provided clearer evidence whether TH as used in the WSD trial provided this early warning of deterioration. It is recommended that data on the clinical changes that patients experience when on TH are carefully assessed as this will provide information on the mechanism of TH, as well as enable careful review of the timings of interventions in relation to the triggers for action resulting from monitoring. This should be a focus in future studies especially where single conditions are examined.
We now focus on PROMS and in particular Quality of Life. At the outset of the study, some argued that the use of TH would lead to social isolation and diminution of quality of life. Overall, the WSD study failed to find any significant changes in either generic or specific quality of life. Despite many studies being small, most have in general, confirmed the WSD study findings of no improvements in the majority of Quality of Life indices (Pinnock et al., 2013a). Whilst quality of life is a critical and recognised way of assessing the patients’ perspective, it is important to consider whether TH could be expected to show improvements in QoL following the introduction of equipment, and if these do occur, when they may manifest. We have argued that TH should not be introduced to improve quality of life but do consider that it should be assessed to ensure no reduction in Quality of Life. This assertion is based both on the evidence but also on the expectation of changes in these measures when they are examined closely, coupled with a view of how the introduction of TH may work.

If we assume the mechanism in WSD that brought about reductions in admissions and mortality was earlier detection and intervention, it might be useful to examine whether early detection and feelings of security would lead to subsequent improvements in Quality of Life. The contents of the generic questionnaire used in the WSD (SF-12 & EQ5D) examined physical and mental health symptoms and their impact on the individual. It is unlikely that a system of early detection would have an impact on restrictions in activity or any improvement in Physical Health QoL. Whilst it may provide some reassurance, it is unlikely that in the face of a major health problem it would vastly impinge on mental quality of life or measures of psychological well-being. The disease specific questionnaires lead to a similar conclusion. The CRQ Scale for COPD focuses on how shortness of breath has influenced a range of activities and responses, the MHLHF examines the extent to which Heart Failure symptoms impact on a range of activities and the Diabetes Health Profile examines the impact on Diabetes in general on activities. Whilst all three disease specific scales include a few items on mood it is, as with the generic scale, unlikely that a system of early detection would lead to improvements in quality of life.
One question is that if the WSD trial followed patients for significantly longer than 12 months, would some changes have resulted in QoL differences between the TH and control groups? It may be that in a longer follow up of TH, any early detection and intervention of exacerbations may lead to improved health outcomes and these may result in improved QoL. This issue will need further evidence to be gathered. Although the WSD study focused on QoL and Psychological wellbeing, it could be argued that the most apparent difference in services using assistive devices is in patient and family perceptions of the quality of care they receive, and in many cases the convenience the service offers them. These types of outcomes were not assessed in the WSD study and would be worthwhile to consider in future deployments.

**Cost and cost effectiveness of Telehealth**

The findings reported in WSD on TH failed to find support for the introduction of TH on the basis of cost effectiveness using NICE guidelines specifying the threshold required. Given that the WSD and many other studies failed to find any improvement in Quality of Life, this has repercussions for cost effectiveness analyses based on quality of life. Whilst there are clear advantages of using a quality of life measure in order to provide comparability across conditions and interventions, the question raised above of QoL’s appropriateness, along with the failure to find any QoL changes in TH, raises questions of the utility of these measures in TH. This has repercussions for any assessment of cost effectiveness based on QALYs. In WSD, finding little change in any Quality of Life measure makes it difficult to establish a cost effectiveness advantage to TH.

**Sustainability of Telehealth – self care behaviours**

One key issue raised in this report is whether self care behaviours change with the introduction of TH devices. We characterised two models: one where increased surveillance with timely intervention occurs; and another in which participants alter their self care behaviours (Antonicelli et al., 2008, Koff et al., 2009). This suggestion is supported by our analysis of self-care behaviours and also the theoretically
deduced cognitions that would precede changes in self-care behaviours reported above. No evidence was found for any change in self-care behaviour in the WSD TH study. In speculating as to why this was the case, it is important to recognize that the WSD programme did not specifically include a component to address changing behaviours of patients. We have argued here and elsewhere (Ciere et al., 2012b) that if sustainable change is to be achieved in chronic disease and in the introduction of TH, then careful integration of behaviour change techniques to promote self-management should be integrated with the introduction of TH.

**Contextualising the introduction of Telehealth**

To put the studies into context it important to recognise the inherent variability in the ways in which the integration of TH into chronic disease may occur. TH is essentially designed to detect worsening health status and to implement timely interventions so as to reduce hospitalisations and thereby reduce costs. Studies present a range of issues, including the different types of technology employed (ranging from telephone through to monitoring of vital signs such as oxygenation). In some studies, monitoring of information by a health care professional occurs on all days and at all times, whilst others monitor at specific times or only in the working week (9 – 5). In some studies, the monitoring performed has been well integrated into a care pathway and the working patterns of the staff adapted to cope with the new technology. However in many TH interventions the TH components are bolted on to existing services. This variability is important as it implies that any evaluation of the impact of TH requires a careful examination of how the technology was incorporated into care. Because of this variability, asking the simple question, “Does telehealth work?” is not helpful in any examination of the potential role of TH technologies.

**Professional Changes in Telehealth**

Organisational change will need to consider the value attached to the professional client relationship and how this will evolve by remote care and monitoring. The differences between the relationship between nurses/health care professionals and patients when carrying out care using the telephone has been well illustrated (See
Table 1, Face-to-face versus telehealth care services.

Table 1: Face-to-face versus telehealth care services

<table>
<thead>
<tr>
<th>Face-to-face services</th>
<th>Telehealth-care services</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Physical proximity</td>
<td>▪ Digital proximity</td>
</tr>
<tr>
<td>▪ intermittent monitoring</td>
<td>▪ daily monitoring</td>
</tr>
<tr>
<td>▪ open communication</td>
<td>▪ protocol-driven communication</td>
</tr>
<tr>
<td>▪ medical interventions and advice</td>
<td>▪ control and advice</td>
</tr>
<tr>
<td>▪ nurse/HCP as counsellor</td>
<td>▪ nurse/HCP overseeing</td>
</tr>
<tr>
<td>▪ self-care as option</td>
<td>▪ self-care as obligation</td>
</tr>
<tr>
<td>▪ Contextualised</td>
<td>▪ Individualised</td>
</tr>
<tr>
<td>▪ Personalised care that considers</td>
<td>▪ Immediate care that considers</td>
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<td>condition as illness</td>
<td>condition as disease</td>
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In the WSD trial, the nurses were found to be more supportive of TH. A less favourable view was expressed by GPs, who were not very engaged in the process. Many GPs had preconceptions as to how TH would work and what it would do to their practice of medicine and their patient relationships. Whilst not arising directly from the findings - although apparent at the set-up of WSD - the concerns of professionals will need to be taken into account with any roll out of TH. The planning required to integrate TH into healthcare will necessitate careful consideration as to how devices are to be integrated into care pathways, along with changes that may occur in the relationship between professionals and their clients/patients. Time to gather support for these changes from all professional groups and to obtain agreement for newly designed care pathways will be necessary. One of the lessons from WSD and other healthcare innovations is the need for detailed preparatory work to be undertaken.

Telecare

Unlike TH, TC requires much less engagement of users. In the context of the WSD Evaluation, TC describes a system that allows the remote, automatic and passive
monitoring of individuals’ personal health and safety (e.g. mobility, falls) and home environment (e.g. floods, fires) in order to manage the risks of independent living or provide prompt emergency responses. The monitored sensors installed for intervention participants in the WSD TC Trial were tailored to individual needs and could include movement sensors, falls sensors, bed/chair occupancy sensors, enuresis sensors, smoke alarms, and heat or flood detectors.

Participants in the TC trial were selected on the basis of prior use of services or need which included night sitting in receipt of care, mobility difficulties, cognitive impairment with a carer as well as being at risk for falling. The group was elderly with the full sample having a mean age of 75 years. Importantly, they reported on average slightly over one chronic condition, slightly over three quarters had visited the GP, and approximately one sixth had experienced a hospital admission in a three month period. In addition, forty percent were severely economically deprived. This group as defined here largely consisted of the frail elderly group commonly targeted for TC interventions with devices that were deployed in the WSD TC study.

The TC devices can be mapped to four broad functions: monitoring a person’s functional status (such as a pendant, bed or chair occupancy sensors, fall detectors), home security (bogus caller buttons, property exit sensors), and home environment (carbon monoxide detectors, flood detectors), and “stand-alone” devices that do not send alerts to the monitoring centre (big button telephones, key safes) but facilitate the TC package. Telecare users received an equipment package including a base unit and pendant/bracelet and at least one of 27 types of TC sensor/device. In the questionnaire study, all participants had at least one “functional monitoring” sensor and more than half had stand-alone devices. Only 14% had any safety and security monitoring sensor.

Cost and cost effectiveness of telecare

During the 12 month study, admission to hospital was 46.8% for TC participants compared to 49.2% of controls. This absolute difference of -2.4% (relative difference of -4.8%) was significant in only the analysis which adjusted for baseline characteristics (p = 0.042). This did not provide much support for the success of TC
devices in preventing hospital admissions. This however is not the key outcome most look for with TC devices. The main focus for TC interventions is usually that the devices provide support for continued independent living and the avoidance or delay in admission to care homes. The proportion who progressed to care homes in the study was extremely small (3.1% and 3.2%) and did not differ between those who received TC and the control group. The rate of admission to care homes within the trial follow up was small and although data is lacking on yearly risk of admission, it is unlikely that a follow up of 12 months would be adequately powered to detect any difference in admission rates to care homes due to their low frequency.

As the potential major cost savings in TC may occur with reduction in care home admissions, future costs and cost effectiveness studies of TC will need a longer follow up period. The costs associated with TC varied considerably by site. This reflected the different project management and arrangements for monitoring and responding to TC activations. This is important as it suggests that the organisational arrangements around TC requires review if TC is to become cost-effective. Overall, the findings indicated that the deployment of TC and associated monitoring services did not constitute a cost-effective alternative to usual care, assuming a commonly accepted willingness to pay for QALYs. The probability of gaining a QALY at a societal willingness-to-pay of £30,000 was 16%.

**Quality of Life and Psychological well being**

It has been a frequently stated assumption that TC has the potential to enable the elderly to remain safely at home with limited assistance and that this will enable them to maintain their QoL. In addition, that the reassurance of being monitored may increase perceptions of safety and thereby reduce anxiety and stress (See e.g. (Taylor and Agamanolis, 2010)). The findings in the WSD study suggest that TC may limit or ameliorate declines in mental health quality of life as measured by a generic HRQoL measure (SF-12) and potentially depressive symptoms (CESD-10) that are apparent in the absence of TC. These occurred in the absence of any changes in Physical QoL (SF12-PCS). While it must be recognised that the clinical significance of the effect is small, they are consistent with previous findings (Beale et al., 2010,
Roush and Teasdale, 2011). One possible interpretation is that these effects reflect increased perceptions of safety and security and that these benefits could constitute a particular focus of the potential benefits for the introduction of TC.

**Telecare and Informal Carers**

Informal carers who bear the brunt of responsibility for looking after the frail elderly have been found to have poorer quality of life and report significant burden of care. The level of carer burden has been found to relate to the likelihood of admission to a care home. The WSD study also assessed the potential benefits of social care recipients’ use of TC on attenuating the level of caregiver strain, although this was not the primary reason for introducing TC. It was considered that this may occur through reducing worry and pressures to monitor the care recipient.

Telecare was not found to have an impact on carer burden. The findings however, suggested a small effect of TC in maintaining mental health quality of life over time for carers. Mental Health Quality of life showed a small decline in those not receiving TC. Telecare may therefore have the potential to limit the reductions in mental health quality of life over time in informal caregivers. A focus on this aspect of quality of life could be further enhanced in future deployments by recognizing that TC should be designed with the carer in mind.

**Issues common to both Telecare (TC) and Telehealth (TH)**

**System Changes - Fiscal flows**

Although not specifically addressed in the WSD studies, significant adjustment in most healthcare environments will be required if the key evidence presented here and elsewhere to utilise TH is to be persuasive. These adjustments are in relation to ensuring that appropriate incentives are put in place to reward TH deployment and its use, and that these are commensurate with, or exceed those in operation for current face to face healthcare. If cost savings occur, then incentives can also be linked to clinical and patient outcomes. Measuring effectiveness and cost-effectiveness of a shared care pathway encompassing both TH and TC services needs to include shared goals or outcomes that are sensitive to detect changes
within the co-ordinated care system. For example, a cost saving and clinical impact on emergency care in health services might not be detected in other services, reduce mortality and lead to increased social care needs of older people living at home for longer. In addition, a cost saving in one service may lead to a cost increase in another. Therefore, for TH and TC to be implemented as a system there needs to be alignment of financial and clinical incentives across different services.

Resistance for participants to use TH and TC devices

The WSD study presented evidence about the likelihood of people refusing assistive devices and the reasons why they refuse. What was clear from the quantitative evidence is that refusals were greater in TH where participants had to play a more active role in the monitoring of their status and thus transmission of data. In TC, the demands placed on participants by devices are low as they are on the whole passive subjects of monitoring. The TH findings make it clear that those who rejected TH did not view the devices as having a particular value for them in terms of improving access, and felt they invaded their privacy; all of which contributed to lower satisfaction. These results were complemented by the qualitative findings which showed that people refused equipment as they felt having the devices would increase perceptions of dependency. Such views indicate the importance of tackling the issue of how the service and devices are perceived (e.g. beliefs about what the devices have to offer and their demands) when introducing prospective users to them.

Another issue to address is overcoming some of the concerns of users and carers regarding the operational aspects of equipment in a time of financial constraints and reductions in service provision, where accepting the devices is feared to lead in a reduction in (face to face) service. A further more controversial issue to be considered when looking at a widespread roll out of TH and TC is the need for evidence. One argument warranting serious consideration is whether the introduction of many of these forms of technology is simply reflecting the modernisation of the health and social care system. Indeed, the healthcare system is often compared to other large social systems such as the banking and travel industries. Both have
changed beyond recognition with the introduction of new technologies, revolutionising the experience for both staff and customers. The evidence is overwhelming of a public shift to new technologies. In 2011, only 9% of Americans continued to use an offline travel agent to book travel, and 75% of the US population reported using online banking. Yet extending the modernization argument to the introduction of TH and TC is problematic as the manner in which these devices are integrated into healthcare appears critical to their impact. This makes it necessary to examine the integration of TH and TC.

**Introducing TC and TH: Perceptions of Managers and Professionals**

Overall, the professional perception of TH was positive. It was viewed as providing an effective, low risk form of patient care that would enhance patient health awareness and self-management, as well as providing prompt and appropriate responses to patients with Long Term Conditions. Concerns were expressed regarding the appropriateness of TH for some patients such as those with very severe conditions. Nurses were in general very supportive of these devices and felt they had the potential to enhance their work and careers. In contrast, GPs were found to be have limited knowledge of TH in the WSD study. They expressed some scepticism about the usefulness of monitoring data and were concerned that it may affect their workload.

Telecare was generally supported by all staff. They saw the devices as potentially enhancing the safety of the frail or vulnerable, promoting the maintenance of independent living and providing reassurance for family and informal carers. In the WSD deployment of assistive devices, little action was required by GPs, and this is likely to be the main reason for their lack of engagement and appreciation of TH. This was considered as a potential weakness in the deployment of devices in the WSD. Given the role GPs play in access and involvement of patients (including the frail elderly) in the community, it is critical to win their attention and support in any future large scale deployment of TH. In addition, their services must be integrated into the care pathways for TH and TC.
Organisational Issues

Organisational Change

It has become increasingly recognised that the introduction of remote care requires significant organisational change for it to be successful. In the WSD study, the different ways in which the organisations dealt with the introduction of TH and TC varied. As we state earlier:

“The impact of telehealth may be intricately linked to wider issues about how health systems operate. There is always the question of whether effects are due to the technology or the way it was implemented, and telehealth has been described as a disruptive technology in that it requires different ways of working for some professional groups.”

This issue was recognised by the managers and the clinicians in the sites. One manager stated:

“The process is quite new, the technology is new, just the way of thinking is new, that remote monitoring changes the whole way you operate.”

An original aim of the WSD was to help facilitate a higher level of integration between Health and Social Services. While this did happen in some areas, the wholesale integration of health and social care did not take place in the sites, and most often the TH services were added to existing care services. The evidence from WSD and other work suggests that it is unreasonable to assume that the mere introduction of the technology would lead to an integration of services or wholesale changes to existing services. Certainly any expectation that may have been held by some that the WSD programme – and the evidence gained via the RCT – would lead to clear reorganisation and integration of services was misplaced. In fact, the RCT appears to have constrained the service as it reduced flexibility and change while it was being developed. Recognising the complexity of making organisational changes in a complex system such as health, with its clear firmly embedded professional relationships is well recognised, and reinforced by the experience of the WSD.
Key challenges in the implementation of remote care

The timing and manner of any introduction of remote care is likely to have a profound effect on its likely success. In the WSD study, the technologies were introduced in the context of a rapidly changing policy environment. As well as concern over financial cutbacks in both Health and Social Services, staff in the sites faced shifting organisational priorities and structures, and there was staff turnover. This negatively influenced ongoing staff engagement in supporting TH and TC.

Within the WSD, we found that implementation was supported in organisations where there was a clear vision and strong leadership. In the context of TH, the role of clinical champions and clinical leaders was significant in addressing concerns and led to increased engagement of clinical staff. For any future deployment of TH and TC, the findings suggest a clear vision, leadership and champions with appropriate expertise is needed to gain support across the organisations involved. It is also important to note that there was lack of clear evidence on the benefits or best models of whole system working through integrated health and social care services. Coupled with the requirement of the RCT for separate TH and TC arms, it was therefore unlikely that the WSD would ever drive greater integration. Efforts to achieve greater integration across health and social care around TH and TC are more likely to succeed if it is seen as a priority and is embedded within integration programmes from the outset.

Finally there are questions over the timing and targeting of who receives these technologies. One key concern is that only subsets of uses show the full benefits, yet there are no hard and fast rules to identify these individuals. Moreover definitive studies of patient sub-types require large numbers of cases to produce significant findings.

Limitations

Limitations to Generalisability

There are important limitations to the generalisability of research in the area. Besides variability in design, each intervention has several areas where differences are likely
to occur making any accumulation of the research problematic. These include:

1. the devices deployed
2. the sample recruited
3. the way the care pathway was defined
4. the multiple and diverse understandings of what integration and whole system working is and how it should be implemented in the context of assistive technology
5. the devices integrated into the care pathway
6. the specific nature of the intervention.
7. the efficacy and effectiveness of any control condition

Recognising that TH and TC are complex interventions requiring subtle changes in process and redesign of the care system is likely to have a big influence on the outcome being measured. In essence, the question originally posed in WSD was, ‘do these devices work to improve patient outcomes and reduce costs in whole system working?’ . This should now be changed to be more context specific, ‘Do these devices - when integrated into care - work to improve patient and participant outcomes and reduce costs in the context whole system working?’.

In addition to these limitations, this study explored only home based devices, yet there is now an increasing focus on mobile ones. This will influence who may be recruited as mobile devices are more suited to a younger, possibly working age population. The current evidence on the impact of these devices remains poor (See e.g. (Baron et al., 2012)).

Organisationally, much variation can be introduced into the system, and the range of changes possible go beyond this report. However the cost implications of alternative means of distribution of equipment and service delivery needs careful consideration in any future system. Devices were left permanently with participants in the WSD study. Alternative models have the potential to significantly reduce equipment costs by rotating devices between participants (introducing them at specific times of need – e.g. after a flare or incident, when more careful monitoring is warranted). The rationale for removing equipment from participants requires careful planning and
communication to ensure the commitment of patients, families and health care professionals is maintained. Plus the risk remains that important changes in patients will be missed. Such models do not embed devices in the culture of care.