Value of Telemonitoring and Telemedicine in Heart Failure Management

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Abstract

The use of telemonitoring and telemedicine is a relatively new but quickly developing area in medicine. As new digital tools and applications are being created and used to manage medical conditions such as heart failure, many implications require close consideration and further study, including the effectiveness and safety of these telemonitoring tools in diagnosing, treating and managing heart failure compared to traditional face-to-face doctor–patient interaction. When compared to multidisciplinary intervention programs which are frequently hindered by economic, geographic and bureaucratic barriers, non-invasive remote monitoring could be a solution to support and promote the care of patients over time. Therefore it is crucial to identify the most relevant biological parameters to monitor, which heart failure sub-populations may gain real benefits from telehealth interventions and in which specific healthcare subsets these interventions should be implemented in order to maximise value.

Keywords

Telehealth, telemedicine, heart failure management, remote patient monitoring, digital medical tools, telemonitoring.

Disclosure: The authors have no conflicts of interest to declare.

Received: 28 March 2017 **Accepted:** 4 July 2017 **Citation:** *Cardiac Failure Review* 2017;**3**(2):116–21. DOI: 10.15420/cfr.2017:6:2

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Telehealth is a multiform term embracing the applications of telematics to medicine, in order to enable diagnosis and/or treatment remotely through a set of communication tools, including phones, smartphones and mobile wireless devices, with or without a video connection.[1]

Until a few years ago, digital applications in medicine were restricted to the use of data obtained from electronic health records (EHR), but, in more recent times, the technological context has notably expanded: the number of existing internet-connected mobile devices has roughly doubled every five years. This phenomenon will probably lead to the simultaneous operability of around 50 billion devices by 2020.[2]

Sensors

Sensors are tools that are capable of detecting, recording and responding to specific inputs coming from a physical setting (e.g. a patient's vital signs) and are increasingly embedded in smartphones and other mobile devices. Recording and quantifying biological variables by means of sensors is generating large digital datasets that are suitable for transmission in real-time to healthcare and non-healthcare professionals. Computer applications arising from these phenomena are potentially numberless and will probably drive changes in both doctor–patient relationships and healthcare economic scenarios. Several insurance companies have already introduced better money premiums for customers who demonstrate regular use of smartphone applications aimed at illness prevention.[1]

Some issues that will need to be addressed in the near future concern patient privacy and data safety.[3] As the practice of selling personal data to third parties for commercial purposes has come to light, increased attention has focused on data security of digital platforms and mobile devices.[4,5] Several reports published recently have revealed a concerning lack of details regarding the way that personal data is managed by telehealth application developers.[5] The Global Privacy Enforcement Network has disclosed that around 60 % of the applications they evaluated exhibited criticisms regarding privacy issues, as they did not properly inform users how their personal data would be used and the number of personal questions asked was considered inappropriate.[6]

Heart Failure Epidemiology

Heart failure (HF) is a common clinical syndrome associated with high morbidity and mortality. It is a major public health problem, with a prevalence of over 5.8 million people affected in the US, and over 26 million people worldwide.[7] In the US and in Europe, HF prevalence ranges from 1.1 % to 2.2 % in the general population. Most of the HF burden is situated in people aged over 65 years, who account for more than 80 % of deaths and prevalent cases in the US and in Europe.[8,9] The lifetime probability of developing HF is believed to be one in five.

Notwithstanding the historical equation that attributes HF genesis to a reduced left ventricular ejection fraction (LVEF), it has been shown that, in real medical practice, HF with preserved LVEF is more prevalent than HF with reduced LVEF in patients over 60 years of age (median prevalence 4.9 % and 3.3 %, respectively)[10]. Despite recent advances in the diagnosis and treatment of HF with reduced LVEF, management of HF with preserved LVEF is debated, and both types of HF still carry substantial morbidity and mortality, with 5-year mortality rates that are in some cases comparable to those of some cancers with a poor prognosis. In addition, HF is a leading cause of hospitalisation and hospital readmission worldwide. Data from the ARNO Observatory have shown a hospitalisation rate in HF of 2.8 patients per 1000,[11] which represents 1–4 % of all the hospitalisations in the US and Europe.[12] Moreover, 30-day readmission rates of HF patients range from 19 % to 25 % and have been reported to be up to 50 % at 1 year,[13] even if discrepancies between actual causes of HF admissions (frequently attributable to comorbidities) and hospital diagnoses from clinical records (usually assigned to decompensated HF) have increased the possibility of an overestimation of HF-related hospital readmission rates.[14] Nonetheless, one of the most challenging issues for the healthcare systems nowadays is finding innovative ways to reduce the high hospital admission and readmission rates of patients with HF.[13]

Purposes and Goals

Some studies have shown that some interventions aimed at improving the management of patients with HF after hospital discharge, in particular, periodic monitoring of symptoms/signs and reviews of pharmacological therapy, are related to a significant decrease in hospital readmission rates.[15,16] However, the heavy economic costs related to the systematic organisation of patient follow-ups after hospital discharge have pushed the development of remote monitoring systems for the continuous control of clinical variables, such as blood pressure, oxygen saturation, heart rate, electrocardiogram and intracardiac/pulmonary pressure. The implementation of these monitoring tools has been hypothesised to augment medical control over the unstable syndrome of HF in order to prevent decompensations and to concurrently gain time and resources when compared to traditional care.

Artificial Intelligence as a Clinical Support Tool for HF Care

A development in computer science that could be applied in future HF management is artificial intelligence (AI). In cardiology, AI is being investigated in the application of domains that span from clinical decision support systems to imaging interpretation. Some machine learning (ML) techniques allow computers, whether "trained" with wide datasets that have been previously correctly classified and labelled by doctors, to "learn" and develop autonomous (and sometimes inscrutable) rules in order to apply the learned classifications to new inputs as far as these new inputs are similar enough to those included in the training datasets. This process is mainly focused on the development of automated decision support systems aimed at diagnostic or predictive prognostic purposes. However, an appropriate classification of telemedical systems based on ML techniques is lacking and profiles of patients who could benefit most from ML-based telemedicine solutions are unknown and need to be adequately investigated.[17]

Prevention and treatment of disease exacerbations and promotion of patient self-empowerment are the main objectives of telemedicine in HF. Individual characteristics of patients with HF obtained from the analysis of a large number of EHR may allow the identification of those patients at higher risk of negative outcomes who could most likely benefit from individualised medical treatments. For example, the Seattle Heart Failure Model is an ML-based framework for calculating mortality risk in HF that examines multiple clinical features obtained from EHR to predict HF prognosis and incorporates the potential impact of HF therapies on patient outcomes.[18] The Seattle Heart Failure Model was developed at the Mayo Clinic, where an ML risk prediction model was trained with routinely collected clinical data obtained from EHR. This decision support system showed a potential usefulness in the identification of patients with HF at higher risk of negative outcomes, but presented barriers to implementation (it was time consuming, expensive, required doctor familiarity with computers and did not account for clinical variables that could not be included as part of the collected data).[18] Proper management of follow-up in HF patients is considered critical to reduce common causes of re-hospitalisation, that can lead to worse outcomes and increasing costs to patients and society.[19] In this setting, ML techniques could be potentially valuable in remote monitoring of high-risk HF patients.

Results of Clinical Trials of Telemedicine in HF

The 2016 European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic HF recommend for the first time "remote patient monitoring" of HF patients with a recommendation of grade IIb, Level of Evidence B.[20] In HF patients, telemonitoring is mainly focused on predicting acute decompensation episodes that are usually associated with fluid congestion and require optimisation of therapy. Clinical practice guidelines on chronic HF recommend daily weight measurements and include a warning alert when an increased weight of more than 2 lbs in a day is observed.[20] However, even if body weight trend is rightly considered a critical element to predict decompensations, sensitivity and specificity of body weight variability alone as a proxy of total body water has revealed to be an inaccurate predictor of HF decompensations.[21] Other variables have been explored in the Multisensor Monitoring in Congestive Heart Failure (MUSIC) and Sensitivity of the InSync Sentry OptiVol Feature for the Prediction of Heart Failure (SENSE-HF) trials.[22,23] In the MUSIC study, a multisensor, non-invasive external device was used to measure and remotely transmit bio-impedance, heart rate, respiratory rate and volume, physical activity duration and intensity, and body posture. Investigators used a development cohort to identify a single or a multiparameter reliable algorithm based on three main components: fluid index, breath index, and personalisation parameters. Use of all three parameters yielded a sensitivity of 65 % and a specificity of 90 % in predicting acute HF decompensations. The failure rate of the device used in MUSIC was shown to be approximately 45 %, reflecting the need for further improvements.[22]

In the SENSE-HF study, performed on patients with chronic systolic HF who had been implanted with cardiac implantable electronic devices (CIED), an intrathoracic impedence-derived fluid index (intrathoracic impedence was measured between the lead and the pace maker's case) consistently showed low sensitivity and low positive predictive value for hospitalisation prediction.[23] Other studies have assessed the effectiveness of remote monitoring through CIED (cardiac resynchronisation therapy with or without defibrillator function) in reducing clinical decompensations, overall mortality or hospitalisations in HF patients.

In the Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators (EVOLVO) study, 200 patients with chronic systolic HF and a mean age of 66 years were randomised to remote monitoring (through CIED) of intra-thoracic impedance, atrial arrhythmias and ICD-shocks versus usual care (scheduled visits every 4 months). A significant reduction of emergency visits in the remote monitoring group was observed when compared to usual care.[24]

More recently, in the Implant-Based Multiparameter Telemonitoring of Patients with Heart Failure (IN-TIME) trial, 716 HF patients with a mean age 65 years and a mean LVEF of 26 %, who had been previously implanted with CIED, were randomly assigned to a telemonitoring strategy or a control "standard care" group: in the active arm patient data were transmitted and reviewed both by the study investigators and by a central monitoring unit (composed of trained study nurses and supporting physicians). A clinical response (standardised telephone call or additional clinical care) was undertaken at the discretion of investigators. After 1 year, a modest benefit was observed in a clinical composite score (all causes of death, overnight hospital admission for HF, change in New York Heart Association (NYHA) class and change in patient global self-assessment).[25]

In the Optimization of Heart Failure Management using OptiVol Fluid Status Monitoring and CareLink (OptiLink HF) study, conducted in ICD carriers with severe systolic HF randomised to have fluid status alerts or usual care, no significant effect was detected in the composite endpoint of all-cause of death and cardiovascular hospitalisations.[26] Some authors have speculated that alerts may even be responsible for a delay in the detection of clinical deterioration, with a consequent postponement of appropriate treatment.

In the multicentric Remote Management of Heart Failure Using Implantable Electronic Devices (REM-HF) study, which enrolled patients with a mean age of 70 years who had been previously implanted with CIED, no significant difference was detected between the CIED remote monitoring group (using weekly downloads) and the usual care group with respect to the primary endpoint of death for any cause or unplanned hospitalisation for cardiovascular reasons. A concern in this study has been raised by the report that approximately 70 % of the patients in the intervention group underwent additional actions that were driven by the results of remote monitoring. This result, whether interpreted in light of the observed lack of effect on outcomes, highlights the potential risks of medicalisation and overtreatment that may arise from inappropriate use of remote monitoring strategies.[27]

Aside from CIED, the basic concept of care that is extended beyond traditional healthcare settings is also well captured by the phone call monitoring strategies wherein patient compliance, symptoms, vital signs, and weight are followed remotely.[28–30] The Randomised Trial of Telephone Intervention in Chronic Heart Failure (DIAL) study was one of the first trials investigating structured telephone support (STS) in 1,518 HF patients randomised to an STS intervention group or to a control "usual care" group.[15] In the intervention group, dedicated nurses phoned patients every 14 days and adjusted the frequency accordingly thereafter for a year. Predetermined standardised questions were used to assess dyspnea/fatigue, daily weight monitoring, oedema progression, dietary/drug compliance and physical activity. Nurses were only allowed to change the diuretic dose and recommend a non-scheduled medical consultation. Nurses used a computer-aided software system to keep a log of conversations and receive reminders for phone calls. All study subjects were followed at the study centres on a 3-month basis irrespective of unscheduled visits and phone calls. Most of these patients had systolic dysfunction and NYHA class II-III symptoms. Overall, the intervention group had fewer hospital readmissions both in the short term and even at 1–3 years after stopping intervention. Mortality was similar in both groups. At the end of the study the intervention group had a better quality of life score than the usual care group.

Similarly, in a meta-analysis, Inglis et al. reviewed 16 studies investigating STS interventions and detected a non-significant trend towards improved mortality with STS versus usual care (RR 0.88 [95 % CI 0.76–1.01], p=0.08), but a significant 23 % reduction of HF hospitalisations (RR 0.77 [95 % CI 0.68–0.87]).[31] Of the 16 studies considered, six reported improved quality of life with STS in both overall and physical scores on the Minnesota Living with Heart Failure Questionnaire and on the Kansas City Cardiomyopathy Questionnaire.

The Telemonitoring to Improve Heart Failure Outcomes (Tele-HF) study randomised 1,653 subjects within 30 days of an HF hospitalisation to a telephone-based interactive voice response system or usual care. The voice response system included a series of questions related to general health and HF symptoms, with patients entering their responses using their telephone keypad.[32]

The Trans-European Network – Home-Care Management System (TEN-HMS) study attempted to identify whether home telemonitoring was able to improve outcomes compared with nurse telephone support and usual care.[33] Home telemonitoring consisted of twice-daily patient self-measurement of weight, blood pressure, heart rate, and heart rhythm with automated devices linked to a cardiology centre. The structured telephone support consisted of specialist nurses who were available to patients by telephone. Primary care physicians delivered usual care. The primary endpoint was days lost for death or hospitalsation with nurse telephone support (NTS) versus home telemonitoring (HTM) at 240 days. At the end of the study, the number of admissions and mortality were similar among patients randomly assigned to nurse telephone support or home telemonitoring. Patients randomly assigned to receive usual care had higher 1-year mortality than patients assigned to receive NTS or HTM, but with a weakly meaningful difference (p=0.032).

A smaller study by Goldberg et al.[34] reported a 10.4 % absolute and 56.2 % relative reduction in mortality in a monitoring system using only symptoms and weight monitoring.

Another large telemonitoring study which evaluated feasibility and perception of the Telemedical Interventional Monitoring in Heart Failure (TIM-HF) trial[35] used Bluetooth technology to transmit weight, blood pressure, heart rhythm, and a self-assessed health status over a mobile telephone connection. Apart from structured monthly phone calls, physician-led medical support was available 24 hours a day, 7 days a week. Intervention was provided based on set standards on an ongoing basis. A total of 710 patients were randomised to the monitoring system or to usual care. Compliance in the intervention arm was high: 81 % had at least 70 % daily data transmission. However, follow up at 26 months showed no difference in overall mortality, cardiovascular mortality, or hospitalisations.[35] A pre-specified subgroup analysis for the TIM-HF trial pointed out that specific characteristics of patients (i.e. a depression model of Patient Health Questionnaire [PHQ-9]<10 or a prior HF decompensation or an ICD implantation), could be associated with better outcomes in mortality (only the subgroup with PHQ-9<10) and numbers of days lost due to hospitalisation for HF or death.[36]

Findings from two Cochrane meta-analyses including studies up to 2015[37,38] have shown that, compared with usual care, STS can reduce all-cause mortality at a follow-up of 6–12 months, and can reduce HF-related hospitalisations. The recent Better Effectiveness After Transition – Heart Failure (BEAT-HF) study,[39] one of the largest trials in telemonitoring in HF, also needs to be mentioned. This is a multicentre randomised controlled trial conducted at six academic medical centres in California, which compared usual care with a telehealth-based care transition intervention for older patients (n=1457, median age

73, 664 [46.2 %] female, 316 [46.2 %] African-American) discharged home after in-hospital treatment for decompensated HF.

Patients assigned to the telemonitoring intervention group were scheduled to receive nine telephone coaching calls over a 6-month period, generally from the same nurse, who had access to patient medical histories and medication records. All telephone calls covered content reinforcing the pre-discharge education materials. Patients were asked to use the telemonitoring equipment daily to transmit their weight, blood pressure, heart rate, and responses to three questions about symptoms, which were sent via cellular bandwidth to a secure server and accessed daily by the telephone call centre nurses. Readings that exceeded predetermined thresholds triggered nurses to telephone the patient so that they could investigate potential causes. When symptoms were of concern, patients were encouraged to contact their health call centre. Nurses also called patients who had stopped transmitting data to determine why and to encourage them to resume daily monitoring. Only 61.4 % (439 of 715) and 55.4 % (396 of 715) of patients randomised to the intervention were more than 50 % adherent to telephone calls and telemonitoring. This study, characterised by very poor adherence, found that a combination of remote patient monitoring with care transition management did not reduce all cause readmission at 180 days after hospitalisation for HF when compared to usual care. Hospitalisations in the first 30 days and 180-day mortality were also not reduced with telemonitoring intervention.

Few studies have assessed the effectiveness of remote monitoring to promote cardiac exercise training in stable HF patients, the so-called "telerehabilitation". In patients with stable HF, exercise training can improve life quality, symptoms, exercise capacity and hospitalisations. According to the 2016 ESC HF guidelines, all stable HF patients should undergo exercise training (class I level A).[20] However, a gap has been identified between this recommendation and a lack of specific instructions about physical training. In this context, telerehabilitation has been advocated by some authors as a way to improve adherence and a practical way to promote regular exercise training in stable HF patients.[40] One randomised trial on telerehabilitation in HF patients showed that an 8-week home-based telemonitored rehabilitation program based on walking training resulted as effective as an outpatient-based standard cardiac rehabilitation program and provided similar improvements in life quality.[41] Another randomised trial, which included patients with CIED, compared an 8-week home-based telerehabilitation program to usual care (which did not include specific exercise programs except for lifestyle advice). This study showed better life quality and better 6-walk test distances in the telerehabilitation group, but results could have been affected by disparities in the extent of intervention between the groups.[42]

In summary, randomised clinical trials about telehealth interventions in HF have disclosed conflicting results regarding the ability of these interventions to reduce mortality and hospitalisation rates. Trials comparing remote telehealth interventions to usual care are nonetheless hardly comparable because of differences in the remote interaction processes, choice of monitoring systems and measured variables.[43] Even in the most recent trials, little information is available on which specific therapeutic interventions have been adopted in response to abnormal changes of vital parameters and which measures have been taken to check whether patients were able to understand and follow the instructions received. Therefore, a large heterogeneity exists among current studies designs and outcomes because of the use of different monitoring techniques and differences among the clinical profile of the patients studied. For example, of the four different non-invasive remote monitoring strategies employed (STS, telemonitoring, videophone and interactive voice response device), only STS and telemonitoring have demonstrated in a few studies a reduction in all-cause mortality and HF-related hospitalisation.[37,38] Moreover, although several clinical trials and two meta-analyses have demonstrated a benefit with the above strategies in mortality reduction and in HF-related hospitalisations, the impact of STS and telemonitoring in HF is not univocally considered to be cost-effective. Nevertheless, when compared to the uncommon chance of access to multidisciplinary intervention programs, that is frequently hindered by economic, geographic and bureaucratic barriers, non-invasive remote monitoring may be a solution to support and promote the care of HF patients over time, especially during the tricky early discharge phase after a hospitalisation. In view of the above-reported complex and heterogeneous literature, it is crucial to identify the most relevant biological parameters to monitor, which HF sub-populations may gain real benefits from telehealth interventions and in which specific healthcare subsets these interventions should be implemented in order to maximise their value. For example, a meta-regression analysis on the effectiveness of telehealth programs in patients with chronic HF showed significantly greater effectiveness in reducing mortality and hospitalisations in HF patients at higher risk.[44] Another meta-analysis related the lowest mortality index for telehealth programs in HF with the promptness of feedback actions (interventions performed within 1 day of a change in the patient's vital signs). Moreover, the complex literature on telehealth also seems marked by methodological issues, like publication bias and poor recruitment in clinical trials.[45] For example, in the TELE-HF study, 14 % of patients assigned to telemonitoring never used the system and by the final week of the study period, only 55 % of the patients were still using the system at least three times a week.[33] As an appropriate adherence to a given intervention can contribute to an adequate external validity of the studies, improvement of adherence represents a key element of the future research on telehealth.

In the end, it has been hypothesised that a "judicious and flexible use" of technology could exist in daily clinical practice, but it might not have been intercepted by too strict and inflexible study protocols that are not able yet to fit real world settings.[45]

Barriers to Implementation

The clear-cut reimbursement restriction of telehealth services is one of the biggest hurdles to their dissemination. In the US, while some insurance programs related to Medicaid – each one with remarkable restrictions – reimburse telehealth services in 48 states, Medicare limits reimbursements to those areas where an inadequate supply of healthcare services has been clearly established. It has been estimated that Medicare paid around five million dollars for telehealth services in 2012, which is less than 0.001 % of its expenditure.[1]

The second barrier to telehealth dissemination concerns the replacement of traditional face-to-face evaluations with digital ones, highlighting some of the critical issues related to the quality of doctor–patient relationship, to the potential incompleteness of "touch-free" virtual objective examinations and, in general, to the care process itself. Moreover, the fragmentation of care that would probably be delivered by heterogeneous and non-interconnected professionals may result in patients receiving different and possibly conflicting recommendations for identical clinical pictures. With regard to legal issues, physicians who operate in the context of telehealth are not yet requested any specific accreditation: in some countries, as in the US, however, doctors need to provide verifiable references to be allowed to practice telehealth, but difficulties can arise in practicing outside the state where a physician obtained their license.[1]

Costs and Sustainability

Telemedicine is believed to have the potential to improve costs related to healthcare.[1] Direct-to-consumer telehealth, such as patient–physician meetings via videoconference, may become an efficient way to deliver care as it could reduce costs to both the patient (e.g. travel expenses, work loss, etc.) and healthcare systems. Nonetheless, the scientific literature lacks studies in good methodological quality about the comprehensive economic evaluations of telehealth services. A recent review on the cost/effectiveness of telemedicine use in chronic HF concluded that, without full economic analyses, the cost-effectiveness of telehealth interventions in chronic HF remains very difficult to be reliably determined.[46] Otherwise, a recent sensitivity analysis showed that cost savings of telehealth programs are most sensitive to patient risk (i.e. more cost-effective in higher risk patients).[47] This further underlines the importance of an adequate risk stratification of patients included in clinical studies on telehealth.

Moreover, concerns have been raised about some of the potential unintended consequences of telemedicine medical encounters. Despite their hypothesised efficiency, virtual medical visits may paradoxically have physicians schedule more future virtual visits than they would in traditional face-to-face encounters, with a consequential unexpected increase in healthcare costs.[48]

A recent study analysed commercial claims data on 300,000 patients to explore patterns of spending for acute respiratory illnesses. The study concluded that direct-to-consumer telehealth may increase access to care by making it more accessible and convenient for some patients, but at the same time it may also increase utilisation and healthcare expenditure.[49] In the above study, costs were lower for patients who underwent direct-to-consumer telehealth visits but increased overall because of a noticeable rise in the number of new utilisations. The authors estimated that only 12 % of direct-to-consumer telehealth visits replaced visits to other providers, but 88 % were new utilisations.[49] Despite the above concerns, no sufficient and reliable evidence is available about cost-effectiveness of telehealth services, and therefore no informed decision at a policy level about delivery of such services will be well-grounded until evidence becomes available.

Patient Participation

A recent policy statement of the American Heart Association on telemonitoring-based management of HF has suggested that effective programs need timely data, appropriate staff, and a feedback loop to patients with sufficient empowerment to understand and follow the proposed interventions.[50] Participation of patients to the HF care process is a basic need for the success of any management program and particularly for a telemonitoring-based approach. Self-management support may be a key to the implementation of telehealth models and requires the active participation of patients. For example, in a qualitative study led with interviews, it was observed that non-video telehealth technologies fostered the sharing of personal information and a non-judgemental attitude in patients, but each contact between a telehealth professional and a patient required a skilful negotiation of the relationship to engage the patient as an "expert of their own illness".[51] In addition, it has been pointed out recently that HF self-management may be associated with reduced hospital admissions only in a subgroup of patients with HF (i.e. patients under 65 years of age), whereas in other subgroups (patients with moderate or severe depression), involvement in self-management may be even associated with a reduced survival rate.[45] Again, careful stratification of patients enrolled in clinical studies seems to be a pivotal pre-requirement for a valuable application of telehealth to different healthcare contexts.

Need for a New Approach

In recent times, technological developments have expanded to the medical sector, with the ambitious objective to gain a dominant role in the future of healthcare improvements. Some authors,[52] in the wake of evidence-based medicine, but also according to ethical *primum non nocere* and economic issues, have highlighted that new technologies, such as telehealth models, should be evaluated in methodologically sound and reproducible studies and compared to usual care before being approved and implemented in medical practice. Nonetheless, even this may turn out to be an insufficient approach. Indeed, Greenhalgh et al,[52] by recalling the principle of the philosopher Heidegger that technology has its maximum value when it helps achieve "what matters to us", have underlined that the use of technological tools in healthcare must be only considered in the precise context of the physical, material and symbolic spaces in which they are applied and perfectly embedded in the social and cultural contexts in which they must operate. This perspective could overcome the old dichotomy between "high tech" and "high touch" and potentially lead to the development of technologies that are natural extensions of both the patient's and doctor's intents and are not felt by users as obligations or as a waste of time.

Based on results of a qualitative study performed on 40 people with comorbidities aged 60 to 98 years, the ARCHIE framework[52] has suggested requirements that any new technology applied to healthcare should meet before implementation. In particular, telehealth products should be "anchored in what matters to users; realistic about the natural history of illness, continuously co-created (developing and adapting solutions in an ongoing way with those who are using them), underpinned by strong human relationships and embedded in social networks; integrated using the principles of computer-supported cooperative work (maximising mutual awareness and mobilising knowledge and expertise across the network)".[52]

Conclusion

The essential premise for any technological solution applied to health is the real (not theoretical or experimental) fulfilment of individual needs for whom that product had been conceived. This implies a shift from standard blinded "one size fits all" models to open personalised ones. We believe that such perspective represents a necessary starting point for future research on telehealth that is focused on a real supporting role for suffering people. ■

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