How will telemedicine change clinical practice in chronic obstructive pulmonary disease?

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Abstract: Within telehealth there are a number of domains relevant to pulmonary care: telemonitoring, teleassistance, telerehabilitation, teleconsultation and second opinion calls. In the last decade, several studies focusing on the effects of various telemanagement programs for patients with chronic obstructive pulmonary disease (COPD) have been published but with contradictory findings. From the literature, the best telemonitoring outcomes come from programs dedicated to aged and very sick patients, frequent exacerbators with multimorbidity and limited community support; programs using third-generation telemonitoring systems providing constant analytical and decisionmaking support (24 h/day, 7 days/week); countries where strong community links are not available; and zones where telemonitoring and rehabilitation can be delivered directly to the patient's location. In the near future, it is expected that telemedicine will produce changes in work practices, cultural attitudes and organization, which will affect all professional figures involved in the provision of care. The key to optimizing the use of telemonitoring is to correctly identify who the ideal candidates are, at what time they need it, and for how long. The time course of disease progression varies from patient to patient; hence identifying for each patient a 'correct window' for initiating telemonitoring could be the correct solution.

In conclusion, as clinicians, we need to identify the specific challenges we face in delivering care, and implement flexible systems that can be customized to individual patients' requirements and adapted to our diverse healthcare contexts.

Keywords: chronic care, e-health care, telecare, telemonitoring

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Introduction

Chronic obstructive pulmonary disease (COPD) is associated with a high cost burden.[1] Modern information communication technologies offer new options for delivering remote specialized healthcare, amongst which telemonitoring, a complex intervention that includes both the electronic transmission of patient information to the healthcare system and the follow-up response by a healthcare professional. Telehealth has been defined as the use of information and communication technologies (ICT) to deliver healthcare services and transmit medical data over long and short distances.[2] It encompasses a wide variety of technologies such as videoconferencing, internet platforms, store-and-forward devices, streaming media, and terrestrial and wireless communication. Telehealth may be used for a wide range of purposes: to decrease the demand on existing hospital and healthcare services; reduce the cost of care; measure treatment adherence; identify disease worsening; improve accessibility to services; and to extend the reach of services to remote locations. Telehealth is therefore a broad concept that involves diagnosis, treatment, monitoring, education and prevention. Within telehealth there are a number of domains relevant to pulmonary rehabilitation:

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(1) Telemonitoring: the use of ICT to monitor patients at a distance.
(2) Teleassistance: the provision of clinical care at a distance using ICT.
(3) Telerehabilitation: the use of ICT to provide clinical rehabilitation services at a distance.[3]

Rationale for telehealth in COPD

The rationale for telemonitoring development in patients presenting with COPD with or without chronic respiratory failure is related to progressive aging of the patient population, carrying with it an increased burden of care at home; technological advances; increased healthcare consumption and the need to cut costs; difficulties associated with hospital discharge; early remote detection of signs and symptoms of COPD chronic respiratory insufficiency decompensation;[4] tailoring and monitoring at a distance of mechanical ventilation and providing education reinforcement for the patient and caregiver; and an opportunity to improve the access to pulmonary rehabilitation for aging populations in many developed countries and reduce patient-related barriers to attendance.[5]

Telehealth opportunities

There are several opportunities related to e-health: telemedicine (TM) with diagnosis at a distance based on spirometry tracing, teleconsultation, telemonitoring of biological signals, decision support systems, teletherapy, teleevaluation, telecare, telerehabilitation, telecoaching/mentoring, teleconference and second opinion calls.[6] The different generations of e-health, as thy have evolved, have proposed the following: measurements transferred to the care provider asynchronously (by store-and-forward protocols) (first generation); synchronized data transfer (automated algorithms can recognize important changes but delays can occur if the systems are not active 24 h/day) (second generation); and constant analytical and decisionmaking support in which monitoring centers have full therapeutic authority 24 h/day, 7 days/week (third generation). The level of technology for an optimized e-health is available, but so far no one platform has proven its superiority over another. For this reason, the correct level of technology to use needs to be determined according to each individual patient, and it should be safe, feasible, effective, sustainable and flexible to the patient's condition.

Clinical findings

To date, the evidence as to whether telemonitoring is really effective in COPD seems inconclusive and contradictory. For this reason authors have proposed an 'authors review' based on a search of EMBASE, CINALH, PubMed, PsychINFO and Scopus databases using the following keywords: telemonitoring and COPD, TM and COPD. Papers published between 2003 and 2017 in English language were considered. The first author assessed the identified RCT studies for appropriateness. Among 395 papers, 46 randomized controlled trials (RCTs) were considered as appropriate for analysis.

In the last decade, several studies have been published on the effects of various telemanagement programs for patients with COPD.[7–53] Table 1 summarizes the RCTs on TM which showed positive results. Studies have been conducted in Europe ($n = 18$), the USA ($n = 4$), Australia ($n = 1$) and China/Taiwan ($n = 2$). A total of 4366 patients (mean age 71 $\pm$ 4 years) were studied with a mean forced expiratory volume in 1 s (FEV1) of 45 $\pm$ 10%; 12 $\pm$ 20% of the patients were on long-term oxygen therapy (LTOT), and all were frequent users of healthcare with a history of relapses and hospitalizations. In the majority of cases, the control groups were on the usual general practitioner (GP) care while the COPD groups were on a second-generation TM platform in 60% of cases and on a third-generation TM platform in 40% of cases for a mean time of 9 $\pm$ 7 months. Reduction in hospitalizations and use of other acute healthcare services, improvement in the quality of life and patient satisfaction were reported in the majority of studies providing chronic home care interventions and patient education at a distance (Table 1).[8–33] These programs were based on a strict adherence to care interventions to enhance symptom self monitoring by patients and their caregivers, through increasing their understanding of drug therapy, monitoring symptoms and treatment, and acting as a liaison between primary care providers and hospital services. This involved the delivery of time-intensive education by nurses and other personnel such as a respiratory therapist.[54–56]

Table 2[34–42] reports RCTs which showed contradictory results (both positive and negative according to the different outcomes). The studies were conducted in Europe ($n = 5$), the USA ($n = 2$) and Australia/New Zealand ($n = 2$). A

Table 1. Summary of RCTs on TM with positive results.

Ref.	Pts, *n*	Inclusion severity	Country	Control group	Experimental group	TM generation	Study time	Outcomes
Bernocchi *et al.*[8]	112	y = 70; FEV1 = 66%; LTOT = 47%; exacerbation history	Italy	Standard care	Nursing and physical therapy program. Call once a week	Third generation	6 months	+ exercise tolerance; + PA; – hospitalizations; + QOL; – dyspnea; – fatigue
Tsai *et al.*[9]	36	y = 74; FEV1 = 64%; LTOT = 0%	Australia	Standard care	Exercise training + videoconferencing three times a week	Third generation	2 months	+ exercise capacity; + QoL; = PA; = physical performance;= health status; + psychological status; + self efficacy
Gellis *et al.*[10]	115	y = 79; FEV1 = NA; LTOT = 0%; 3 or more home visits/week	USA	Standard care (physical therapy, social services, nutrition)	Telehealth nurse reviewed patient data daily. Alerting system	Second generation (daily vital signs to the central station)	12 months	+ general health and social functioning; + depression symptoms; + visits to ER for the control group
Billington *et al.*[11]	73	y = 72; FEV1/FVC <70%; FEV1 = 50%; LTOT = 0%	UK	Self-management plan	Two contacts by a nurse; scheduled phone calls	Second generation (phone calls + data control)	3 months	+ CAT; = exacerbations; = satisfaction
Demeyer *et al.*[12]	343	y = 66; FEV1 = 56%; LTOT = 0%; smoking history of at least 10 p/y	Greece, UK, Switzerland, The Netherlands	Physical activity + medical treatment	Telecoaching (step counter; text message; activities goal review)	Second generation	3 months	+ PA; + functional capacity; = health status
Ho *et al.*[13]	106	y = 80; exacerbation history; FEV1 = 62%; LTOT = 0%	Taiwan	Usual care + a phone line for medical counseling	Phone line + electronic diary of symptoms each day. Alerting system	Second generation (oximeter, temperature, blood pressure) (8 am–8 pm)	2 months	+ time to first readmission for COPD exacerbation; + all-cause readmissions; + COPD-related ER visits
McDowell *et al.*[14]	110	y = 70; FEV1 = 44%; LTOT = 26%; exacerbation/ hosp./ER/urgent GP history	Ireland	Respiratory team and GP + home visits. Alerting system to team	Home-based program + home telehealth system	Second generation (daily transmission of data to a nurse)	6 months	+ SGRQ-C; – HADS; – exacerbations and ER visits; + satisfaction
Segrelles Calvo *et al.*[15]	59	y = 73; FEV1 = 37%; LTOT = yes	Spain	Two visits at home + monthly telephone calls	PROMETE telehealth program. Alerting system to nurse and pulmonologist	Second generation (blood pressure, oxygen saturation, HR on a daily basis and PEF three times/week)	7 months	– ER visits; – hospital length of stay; – hospitalizations; – need of NIV

(Continued)

Table 1. (Continued)

Ref.	Pts, *n*	Inclusion severity	Country	Control group	Experimental group	TM generation	Study time	Outcomes
Bourbeau *et al.*[16]	191	y = 70; FEV1 = 1l; LTOT = 0%; hosp. history	Canada	Usual care with GP	Usual care with GP + disease-specific management program	Third generation (education, supervised training + weekly telephone calls)	12 months	– hospital admissions; – ER visits; – unscheduled physician visits; + QoL
Pedone *et al.*[17]	99	y = 74; FEV1 = 53%; LTOT = 0%	Italy	Standard care	Data evaluated every day by a physician. Alerting system	Second generation (pulse oximeter + telephone)	9 months	– relapses; – hospital admissions
Puig-Junoy *et al.*[18]	180	y = 70; FEV1 = 41%; LTOT = 0%	Spain	Conventional care without nurse's support	Nurse home visits + free patient calls	Third generation (patents' calls were unlimited)	2 months	– health costs; = clinical outcomes
Paré *et al.*[19]	29	y = 71; FEV1 = NA; LTOT = 46%; frequent home visits	Canada	Regular home care	Daily transmission clinical data. Alerting system to nurse and physician	Second generation	6 months	– home visits of nurse; – hospitalizations; = calls; – average hospital stay
Lewis *et al.*[20]	40	y = 71; FEV1 = 39%; LTOT = 0%	UK	Standard care	Standard care + handheld telemonitor. Alerting system to the team	Second generation (questions each day, clinical data to a server)	12 months	+ SGRQ; – hospital anxiety; = hospital depression; = QoL
Chau *et al.*[21]	40	y = 73; FEV1 = 38%; LTOT = 0%; hospitalization history	China	Standard care (home visits + education on self care)	Daily transmission to nurse of clinical data to an online network platform	Second generation (clinical parameters three times/day)	4 months	+ satisfaction; = QoL; = pulmonary function and hospital readmissions
Jódar-Sánchez *et al.*[22]	45	y = 72; FEV1 = 37%; LTOT = 50%; hospitalization history	Spain	Conventional medical care	Each day vital signs sent to a hub and received by the team	Second generation (system generated an alarm)	6 months	– ER visits; = hospital admissions; = QoL; = EQ-5D
Trappenburg *et al.*[23]	115	y = 69; FEV1 = 41%; LTOT = 0%; exacerbation history	The Netherlands	Usual care	Daily questions immediate feedback from service. A nurse reviewed answers	Second generation	6 months	– hospital admissions; – exacerbations; – days in hospital; – medical visits; = QoL

Table 1. (Continued)

Ref.	Pts, *n*	Inclusion severity	Country	Control group	Experimental group	TM generation	Study time	Outcomes
Vitacca *et al.*[24]	220	y = 69; FEV1 = 36%; LTOT = 69%; HMV = 40%; hosp./ exacerbation history	Italy	Outpatient visits every 3 months	Clinical score, pulse oximeter Telenursing and doctor on demand	Third generation (40 h/week, real-time teleconsultation + free calls 24/24 h)	12 months	– hospitalizations; – urgent GP calls; – acute exacerbations; – costs
Steventon *et al.*[25]	315	y = 69; FEV1 = NA; LTOT = 0%	UK	NA	NA	NA	12 months	– mortality; – ER visits; – length of hospital stay; = costs
Abak *et al.*[26]	24	y = 63; FEV1 = 43%; LTOT = 0%; exacerbation/ hosp. history	The Netherlands	Usual care + physiotherapy sessions	Teleconsultation, web-based exercising, self management, activity coach	Second generation	9 months	+ satisfaction
Au *et al.*[27]	123	y = 74; FEV1 = NA; LTOT = 0%	USA	Usual care	Healthy buddy device	Second generation	36 months	– hospital admissions; – exacerbations
Hernandez *et al.*[28]	222	y = 71; FEV1 = 42%; LTOT = 16%	Spain	Standard care	Five nurses access + nonlimited phone calls	Third generation	12 months	– hospitalizations; – ER admissions; + HRQoL; + patient satisfaction; + knowledge of the disease
Casas *et al.*[29]	155	y = 71; FEV1 = 42%; LTOT = 18.5%; hospital stay >48 h	Spain + Belgium	GP visits scheduled every 6 months	Self management specialized nurse weekly phone calls	Third generation	12 months	– readmissions; less % of patients without admissions; = no. of deaths
Farrero *et al.*[30]	122	y = 69; FEV1 = 27.5%; LTOT = 11.5%	Spain	Conventional care	Monthly phone call, home visits every 3 months, home/ hospital visits on demand	Third generation	12 months	– ER visits; – hospital admissions
Wang *et al.*[31]	120	y = 70; FEV1 = 35.5%; LTOT = NA	China	Routine care	Nurses' calls every 2 weeks, home follow-up visits at 1, 3, 6, 12 months	Third generation (web-based coaching program)	12 months	+ lung function; + SGRQ; + 6MWT
Witt Udsen *et al.*[32]	1225	y = 75; FEV1 = NA; LTOT = NA; MRC >3; CAT >10; exacerbation history	Denmark	Usual practice	Daily vital signs sent to the team. Alerting system	Second generation (blood pressure; pulse oximeter)	12 months	+ cost effectiveness; – hospital admissions; – primary care costs

(Continued)

Table 1. (Continued)

Ref.	Pts, *n*	Inclusion severity	Country	Control group	Experimental group	TM generation	Study time	Outcomes
Vasilopoulou *et al.*[33]	147	y = 65.8; FEV1 = 50%; LTOT = 25%; exacerbation history	Greece	Usual care education	2 months of PR + home telerehabilitation; access to call center 5 days/week, 10 h/day; psychological support; dietary and self management; telephone or videoconference	Third generation	12 months	– exacerbations; – hospitalizations; + ER visits; + functional capacity; + HRQoL; + daily physical activity

CAT, COPD assessment test; COPD, chronic obstructive pulmonary disease; EQ-5D, Euro QOL five Dimensions Questionnaire; ER, emergency room; FEV1, forced expiratory volume in 1 s; FVC, forced vital capacity; GP, general practitioner; HADS, Hospital Anxiety and Depression Score; HMV, home mechanical ventilation; HR, heart rate; HRQoL, health-related quality of life; LTOT, long-term oxygen therapy; MRC, Medical Research Council; 6MWT, 6-min walk test; NA, not applicable; NIV, noninvasive ventilation; PA, physical activity; PR, Physical Rehabilitation; PEF, peak expiratory flow; Pt, patient; p/y, pack years; QoL, quality of life; RCT, randomized controlled trial; SGRQ-C, St George Respiratory Questionnaire; TM, telemedicine.

Table 2. Summary of RCTs on TM with positive and negative results.

Ref.	Pts, *n*	Inclusion severity	Country	Control group	Experimental group	TM generation	Study time	Outcomes
Ringbæk *et al.*[34]	281	y = 69; FEV1 = 34%; LTOT = 37.5%; hospitalisation and exacerbation history	Denmark	Respiratory nurses at home or in outpatient clinic	Symptom control by a call center; video consultation. Alerting system, second opinion specialist	Second generation (symptoms, saturation, spirometry)	6 months	= hospital admissions; experimental group had more moderate exacerbations
Kenealy *et al.*[35]	171	y = 65; FEV1 = 27.5%; LTOT = 11.5%	New Zealand	Usual care	Health hub, telephone	Second generation	3–6 months	– anxiety and depression; = QoL, self efficacy and disease-specific measures; = hospital admissions and outpatient visits
Vianello *et al.*[36]	334	y = 76; FEV1 = 41%; LTOT = 40%	Italy	Transmitted parameters daily + alerting system to GP and specialist	Transmitted parameters daily + alerting system to TM team (8–18 Monday–Friday) with specialist	Second–third generation (HR and SpO2)	12 months	= HRQoL; = HADS; = no. and duration of hospitalizations; + readmissions; + specialist visits; + visits to ER; + deaths
Chatwin *et al.*[37]	72	y = 61.8; FEV1 = 0.9 liter; LTOT = 38; hospitalization history	UK	Standard care + contact number with medical team + access to respiratory care nurse	Daily data to healthcare team. Alerting system with staff action	Second generation (HR, SpO2, blood pressure) symptoms	12 months	= time to first admission for an acute exacerbation; – hospital admissions; = GP consultations; + home visits by nurse; + QoL; – HADS
Cordova *et al.*[38]	67	y = 63.5; FEV1 = 31.5%; LTOT = 68%; hosp./ exacerbation history	USA	GP care plan	Phone calls if alerting to nurse or GP. Visits at 6–12–18–24 months	Second generation	24 months	= hospitalizations and mortality; + fewer and more moderate symptoms; + lower symptom index score; = QoL; = dyspnea
De San Miguel *et al.*[39]	71	y = 71.5; FEV1 = NA; LTOT = NA	Australia	Usual educational book	Educational book + telemonitoring alerting to nurses	Second generation (vital signs and health status)	6 months	= hospital admissions; = ER visits; = length of stay; = costs

(Continued)

Table 2. (Continued)

Ref.	Pts, *n*	Inclusion severity	Country	Control group	Experimental group	TM generation	Study time	Outcomes
Koff *et al.*[40]	40	y = 66; FEV1 = 32%; LTOT = 95%	USA	Usual care	Education + self management + remote home monitoring	Second generation (Mon. to Fri. 9 am to 5 pm)	3 months	= QoL; = healthcare costs; = exacerbations; = satisfaction
Jakobsen *et al.*[41]	57	y = 70; FEV1 = 0.7 l; LTOT = 5%	Denmark	Usual care	Daily ward rounds (touch screen for nurse visit)	Third generation (unscheduled calls 24/24 h 7/7 days)	6 months	= hospital readmissions; + need of NIV; + hospitalizations for >5 days; = lung function; = QoL; + satisfaction; + nurses' satisfaction
Farmer *et al.*[42]	166	y = 69.8; FEV1 = 48.5%; LTOT = NA	UK	Usual care + education + EDGE system platform	EDGE system platform + education + video education + tablet + daily monitoring of symptoms, mood, biological signs + red flags	Second generation (twice/week vision of vital signs and health status)	12 months	= specific QoL; = hospital admissions; = GP visits; + generic QoL; fewer nurse visits

ER, emergency room; FEV1, forced expiratory volume in 1 s; FVC, forced vital capacity; GP, general practitioner; HADS, Hospital Anxiety and Depression Score; HR, heart rate; HRQoL, health-related quality of life; LTOT, long-term oxygen therapy; NA, not applicable; NIV, noninvasive ventilation; QoL, quality of life; Pt, patient; RCT, randomized controlled trial; SpO2, pulsed oxygen saturation; TM, telemedicine.

total of 1259 patients (mean age 68 ± 5 years) were studied with a mean FEV1 of 36 ± 8% and 42 ± 31% of cases were on LTOT; similarly to the positive studies, all patients with COPD were frequent users of healthcare and had a history of relapses and hospitalizations. Also in these studies, the control groups were mainly based on usual GP and home nurse care (sometimes with structured educational programs) while the studied groups were on second-generation TM platforms in 78% of cases and on third-generation TM platforms in 22% of cases for a mean time of 9 ± 7 months.

Table 3[43–53] shows RCTs with negative results for TM use. These studies were conducted in Europe (n = 8), the USA (n = 2) and Australia (n = 1). A total of 5699 patients (mean age 69 ± 5 years) were studied with a mean FEV1 of 41 ± 4%, in 3 ± 8% of cases on LTOT, all frequent users of healthcare with a history of relapses and hospitalizations. The control groups were in the majority of cases based on usual GP care with stronger home care support (home visits, nurse availability, social services) compared with the positive studies. The experimental groups were on second-generation TM platforms in 73% of cases and on third-generation TM platforms in 27% of cases for a mean time of 8 ± 3 months.

The literature has shown that the best telemonitoring outcomes are expected in programs dedicated to aged and very sick patients with severe symptoms, frequent exacerbations, multimorbidity, on LTOT and with limited community support; long-term interventions; programs using third-generation telemonitoring systems providing constant analytical and decisionmaking support with monitoring centers led by a physician, staffed by specialist nurses, and have full therapeutic authority 24 h/day, 7 days/week; countries where home care is not widely available (if an extensive home care package with strong community links exists, telemonitoring may add little additional benefit); and zones where ICT and rehabilitation can be delivered directly to the patient's location, regardless of physical proximity to a rehabilitation center. Whilst only a few pulmonary rehabilitation programs worldwide are currently offering telerehabilitation,[57] this is likely to grow as telehealth applications become increasingly accessible to patients and clinicians.

Legal issues

The legal problems associated with teleassistance and TM are still controversial. Given that many processes of teleconsultation are patient specific and unique, the legal principles applying to conventional, face-to-face, doctor–patient relationships may be equally as valid in the context of the practice of medicine at a distance.[58,59] Important system precautions need to be used by e-health users:[60,61]

(1) **Data security and confidentiality**. Suppliers and users must ensure the confidentiality, the authenticity of the data and their reporting, the authorized certification of procedures with digital signature, the protection of confidentiality, the security and privacy of the assisted persons, and the storage and transfer of sensitive data in real time between one unit and the other without manipulation.
(2) **Responsibilities and potential obligations of health professionals**. Three key aspects need to be specified: the responsibility of the physician (teleconsultant) and the patient at distance (teleconsulted); the relationship and coresponsibility between specialist consultant and the requesting physician; the responsibility and the relationship between the applicant, consultant and service supplier or suppliers.
(3) **Interoperability.** Mutual exchange of ICT-enabled solutions and of data are necessary for better coordination and integration across the entire chain of healthcare delivery to offer personalized solutions.

How will TM change clinical practice?

In the near future it is expected that TM will produce changes in work practices, cultural attitudes and organization, which need to be 'negotiated' among all the professional levels involved in the provision of care. Table 4 summarizes the possible change of scenarios in COPD care using TM. Table 5 summarizes barriers and difficulties to TM development in terms of work organization, cultural and technical concerns.[62–64]

Discussion

A 'one glove fits all' approach in offering telemonitoring for COPD appears too simplistic for a heterogeneous population such as these patients.

Table 3. Summary of RCTs on TM with negative results.

Ref	Pts, *n*	Inclusion severity	Country	Control group	Experimental group	TM generation	Study time	Outcomes
Schou *et al.*[43]	44	y = 71.5; FEV1 = 42%; LTOT = 0	Denmark	Usual medical treatment	Daily ward rounds videoconference	Third generation (pulse oximeter + spirometer + thermometer)	3 months	= HRQoL; = daily activity; = anxiety and depression; = self-assessed cognitive decline
Lilholt *et al.*[44]	1225	y = 70; FEV1 = 48%; LTOT = 0; MRC >3; CAT >10; >2 exacerbations	Denmark	Usual practice	Daily vital signs sent to healthcare personnel. Alerting system	Second generation (blood pressure monitor, pulse oximeter)	12 months	= QoL
Berkhof *et al.*[45]	101	y = 68; FEV1 = 40%; LTOT = 7.5%	The Netherlands	Outpatient visit T0, T6 by a pulmonologist + visit at T2 and T4 with a pulmonary nurse practitioner	Every 2 weeks phone call by nurse. Alerting system for pulmonologist	Second generation	6 months	– QoL; + visits to the pulmonologist
Pinnock *et al.*[46]	256	y = 69; exacerbation history; FEV1 = 42%; LTOT = 0	Scotland	Clinical care	Clinical care + telemonitoring	Second generation (daily symptoms saturation)	12 months	= no. of exacerbations; = time to hospital admission; = no. and duration of admissions; = QoL; = anxiety and depression; = self efficacy; = knowledge; = adherence to treatment
Moy *et al.*[47]	238	y = 66.8; FEV1 = NA; LTOT = 28%	USA	Pedometer without plan goals	Pedometer every day, upload daily step counts and access to a website	Second generation	12 months	= QoL; = daily steps count
Antoniades *et al.*[48]	44	y = 69; FEV1 = 0.8 liter; LTOT = 0; hospitalization history	Australia	Patients could call the nurse if they felt unwell	Daily clinical data. A nurse reviewed 5 days weekly. Alerting system for the GP	Second generation. Unscheduled calls	12 months	= hospital admissions; = inpatient bed days; = QoL
Dinesen *et al.*[49]	105	y = 68 FEV1 = 0.91 liter; LTOT = 0	Denmark	Physical activity by themselves	Physical activity and clinical parameters monitored by GP and nurses	Second generation (clinical values, no. of steps) web-based portal GP or nurses could assess data video meeting	10 months	+ rate of admissions

Table 3. (Continued)

Ref	Pts, *n*	Inclusion severity	Country	Control group	Experimental group	TM generation	Study time	Outcomes
Coultas *et al.*[50]	151	y = 69; FEV1 = NA; LTOT = 0; exacerbation history	USA	Educational booklets	Nurses reviewed symptoms, medications, intervention + 1/month call	Second generation	6 months	= health status; = self-reported healthcare utilization
Sorknaes *et al.*[51]	266	y = 71.5; FEV1 = 35%; LTOT = 0	Denmark	Conventional treatment; nurse outpatient consultation (spirometry, oximetry)	Conventional treatment + teleconsultation by video 7 days a week starting within 24 h of discharge	Third generation	6.5 months	= hospital readmissions; = mortality; = time to readmission; = mean no. of readmission days with AECOPD
Cartwright *et al.*[52]	3225	y = 70; FEV1 = NA; LTOT = NA	UK	Usual healthcare and social services + whole system redesign (WSR)	WSR+ synchronous data transfer and automated algorithms interpreted data. Alerting system	Second generation	12 months	= QOL; = psychological outcomes
Schou *et al.*[53]	44	y = 71; exacerbation history; FEV1 = 42%; LTOT = NA	Denmark	Hospitalization until discharge criteria were fulfilled	Education plan to familiarize themselves with the videoconferencing system. Daily ward rounds of patients' parameters were performed by the physician. Patient could connect with the call center 24/24 h 7/7 days	Third generation	1.5 months	= cognitive performance

AECOPD, acute exacerbation of COPD; CAT, COPD assessment test; COPD, chronic obstructive pulmonary disease; FEV1, forced expiratory volume in 1 s; GP, general practitioner; HRQoL, health-related quality of life; LTOT, long-term oxygen therapy; MRC, Medical Research Council; NA, not applicable; Pt, patient; QoL, quality of life; RCT, randomized controlled trial; TM, telemedicine.

Table 4. Changes and impact in scenarios for chronic obstructive pulmonary disease under telemedicine.

Work organization	Cultural changes required	Organizational changes required
Staff workload	Staff experiences with the application	Need for a stakeholders network
Work distribution	Positive view of the technology	Patient empowerment
Routines and patient pathways	Interactions with patients	Patient self management
Constant interaction	Face-to-face nursing work	Bidirectional message exchange for communications between the home of the patient and the hospital
Number of medical units working together to provide service	Interactions	Reconfiguration of existing practices and relationships
Time spent learning to use the application	Designing and implementation of follow-up plans at home	Access to healthcare
Productivity	Specific clinical practice guidelines for each disease	Regionalization prospective
Organization of primary care and specialist care	Structure (norms, rules, values, and resources)	Linkages between rural district hospitals and the main national hospitals
Greater responsibility to nurses	Skills required	Training and education for healthcare professionals in rural areas
Renegotiation of professional roles	Citizens consensus	Implementation of national health policies
Reconfiguration of work practices (burden or empowerment)	Social influence	New businesses

Factors that will be important for the successful implementation of telemonitoring are an individually tailored approach, flexibility and a service that is locally responsive.

There are a number of possible explanations why the telemonitoring approach may not be superior to standard management carried out at home, which may be synthesized as follows:

(1) Patients with COPD who may benefit most from telemonitoring have not yet been identified. In fact, it is not clear which patients would benefit from specific types of care delivery and, more importantly, what preferences patients have. Although many studies have included patients with severe disease, they vary in terms of the inclusion and exclusion criteria regarding baseline diagnosis, history of exacerbations, previous use of healthcare services such as home visits, hospitalizations, or rehabilitation, as well as requirements for supplemental oxygen or home mechanical ventilation. Patients with severe symptoms, frequent exacerbations, multimorbidity and limited community support might well benefit from telemonitoring.[65] In another study across the range of COPD severity, patients with severe COPD (GOLD 3 [Global Initiative for Chronic Obstructive Lung Disease] classification but not GOLD 4)and patients younger than 60 years are likely to be the most cost-effective group.[66] It is also common experience that, in patients with more severe disease, their clinical condition is such that hospital admissions are often inevitable: in any case, telemonitoring does not have the unique aim to avoid hospitalization *per se* but rather to control the progression of the disease, which sometimes will mean accelerating

Table 5. Barriers and difficulties to telemedicine development.[62–64].

Work organization	Cultural barriers	Technical concerns
Short-term funding	Low level of interest	Preferred outpatient clinic visits
Sustainability	Poor user-friendly technology	Follow-up plan customized to each patient
Integration of new technologies into routine service delivery	Low acceptance	Complexity of the system
Time limitations	Person's illness and health literacy	Many different software, hardware and telecommunication options
Requirements for technical competence	Too much responsibility for patients with chronic disease	Poor specification design for each condition
Poor uniformity for standards	Poor knowledge and culture	Legal/confidentiality problems between subjects involved (poor standard of care; manipulation, poor protection
Lack of interoperability among different solutions	Lack of knowledge of e-health among patients, citizens and healthcare professionals	The network may show difficulty to ascertain responsibilities and potential obligations of health professionals
Limited evidence of cost effectiveness	Skepticism from doctors	High startup costs
		Absence of reimbursements

hospitalization, face-to-face visits or home care visits. Early treatment of home exacerbations at distance is often useful to prevent a catastrophic clinical worsening and subsequent need for intensive care unit admission or mechanical ventilation.

(2) The use of different generations of the telemonitoring and e-health devices and platforms may have determined substantial differences in the findings across studies. Available telemonitoring devices range from basic first-generation systems to the far more complete third-generation systems. The role of the case manager/care manager during telemonitoring use may also vary among different countries depending on the current policy of each country's health system.

(3) Previous results indicated that existing resource patterns of patients and variations in delivery-site practices might have a strong influence on cost effectiveness, possibly stronger than the included health or sociodemographic sources of heterogeneity.[66] To evaluate the real cost effectiveness of new methods such as telemonitoring in this population it is important to understand what is meant by 'standard care' and 'usual care' in the papers published so far. In fact, standard care varies greatly not only among European countries, but also within each country.[67] Some studies have also proposed health economic assessments[24,37,52] but the findings were inconclusive. Unfortunately, this 'standard' care is not a common or mandatory care approach in all European Union (EU) countries. If an extensive home care package with strong community links exists, telemonitoring may add little additional benefit, whereas for trials in which less community support was available telemonitoring seems to show more benefit in terms of team expertise and the patient's (or carer's) self efficacy.

(4) Now, the question to evaluate is if the superiority of telemonitoring to the gold standard is really the goal. Equivalence between telemonitoring and the gold standard may be a more appropriate goal; indeed, an intervention that cost-effectively

improves a suboptimal service bringing it on a par with the gold standard would be a success. Cost effectiveness could be the 'gold standard' for each new health service. It is not important for each health organization to push for a 'unique modality' of continuity of care but to press for the 'most efficient' one respecting shared and standardized clinical and scientific targets for chronic care.

Last but not least, negative or positive results clearly depend on the expected outcomes of the study (e.g. healthcare use, patient-related outcomes, adherence, mechanical ventilation initiation and adaptation, need for palliative care) and corresponding methodological development, which differ from one study to the next.

As shown in Table 5[62–64] major barriers for TM implementation are lack of awareness/confidence in e-health, supposed e-health complexity and time consumption during the working day, necessity for complicated medical licensing, the risk for doctors to reduce the area of influence with a decreased chain of command, more cooperation requested between primary and secondary healthcare, risk of data protection and privacy, lack of structured best practices, solid public or private providers and dedicated call centers, the necessity for infrastructure accreditation with certification and labelling obstacles, and last but not least, regional differences in accessing ICT services.

Future directions

Another important aspect in telemonitoring studies is using advanced analytics or machine learning to optimize the patient's condition, for example by early identification of COPD exacerbations. This is going to be an important future direction and challenge in patients with COPD breathing spontaneously.[68–70]

The ATS/ERS [American Thoracic Society/European Respiratory Society] statement on pulmonary rehabilitation states that 'defining the role of telehealth and other new technologies' is the key to addressing the research priority of 'increasing the accessibility to pulmonary rehabilitation'.[71] Critical future steps towards this will be achieving a consensus on what constitutes 'usual care', such that the additional benefits offered by telehealth can be quantified (standardizing models of telehealth in chronic lung disease for a more uniform implementation, thus allowing meaningful comparison across studies); defining the role of telemonitoring and teleassistance across the spectrum of chronic lung disease, that is determining in which diagnostic groups it is most useful, when it should be offered (including considerations of disease severity and acute *versus* stable disease) and when it should be stopped; and conducting robust cost-effectiveness studies to inform health policy. Telehealth can improve access to care, particularly for those living away from major centers. Simple yet innovative telehealth solutions to improve access and uptake have already been implemented in clinical practice, with good results.[72] Such programs, including simple telerehabilitation models and teleconsulting, should be made more widely available. Where high-quality clinical care is already available it is less clear if telerehabilitation adds significant benefit. Current data do not yet justify the routine implementation of telehealth in such a setting, although individual patients may benefit. For future directions, more attention needs to be focused on how to accommodate the increasing number of patients with COPD in a postdischarge telemonitoring management program with real integration between hospital and primary care professionals according to quality standards. The self-management support must also become more integrated, with standardized decision support and outcome measures plus electronic information so that critical information is shared among the various health professionals involved in the home programs. In addition, more research is required on the organizational implications of introducing telemonitoring so that a new service does not duplicate the traditional system, resulting only in greater inefficiency and more costs. More research is also needed on the security and confidentiality of patient data, on the responsibilities and potential obligations of health professionals and on EU jurisdictional problems regarding e-health systems. Finally, we need to provide a useful benchmarking picture of different models of telemonitoring good practice around Europe as an aid to those who fund telemonitoring services in their decisionmaking regarding personnel investment, reduction of redundancy and duplication of care services, as well as prioritization of services. The 'one glove fits all' approach in offering telemonitoring for COPD seems too simplistic for a heterogeneous population such as these patients. Factors important for the successful implementation of telemonitoring are an

individually tailored approach, flexibility and a service that is locally responsive. Chronic diseases increase the burden on healthcare systems. Primary care needs to be sustained in the face of increasing demands: home care and telemonitoring may help primary care professionals and specialists to reduce the expected burden. Hospitalization of chronically ill patients is a 'failure' for healthcare systems and chronic diseases exemplify the need for the large-scale deployment of follow-up programs. For these reasons, home care programs and telemonitoring may provide an opportunity for health organizations to develop new strategies and clinical procedures. Another important aspect that might limit the effectiveness of telemonitoring studies is patient compliance and acceptance: in general telemonitoring is well accepted[24] and patients are enthusiastic about this service.[73]

Anyway, the patient's perspective is not always the doctor's perspective: in a recent survey[74] about 50% of patients receiving home mechanical ventilation responded that they would refuse telemonitoring because it feels like 'big brother', and expressed concerns about privacy of personal information/data. They also felt it might increase anxiety as a result of fewer visits and fewer opportunities to enjoy personal contact, and finally that their actual home care settings 'feels good and they don't want it adjusted'.

Home telemonitoring and telerehabilitation of chronic diseases seems to be a promising patient management strategy that could produce accurate and reliable data, empower patients, influence their attitudes and behavior, and potentially improve their medical conditions. Remote monitoring alone is not sufficient for successful disease management. A patient-centered design approach (continuous improvement allowed feedback from users) has been used in order to allow the personalization of interventions and encourage the completion of daily self-management tasks resulting in high compliance with self monitoring over a prolonged period of time (12 months).[75]

The overall body of literature on this topic shows that the extent and significance of benefits to patients and economic organizational expectations are not always consistent and sometimes remain inconclusive. The impact on clinical effectiveness outcomes and economic viability likewise remains unclear. At the moment the fundamental prerequisite for the efficacy of telemonitoring in COPD management is to establish common standardized protocols rather than determine how to deliver the care.[76] It is clear that telemonitoring alone is not sufficient in itself to yield a better outcome; telemonitoring could be a key element in the management of COPD, but it is difficult to evaluate its benefit without considering the other services received by patients (GP network, home care, access to hospital, social care). Considering the overall care 'package' received by the patient, telemonitoring may have a place as one of the services offered within the package. But other aspects, quality improvement, integration of programs and services, increase in collaboration and communication across the different care settings, and the development of a shared vision, goals and priorities, are needed to improve the efficiency of the healthcare services provided for patients with chronic disease.[76] The key point in optimizing the use of telemonitoring is to correctly identify who the ideal candidates are, and at what time they should receive it and for how long.[76] The time course of disease for each patient is different and a 'correct window' for personalized TM application could be the answer. Initiating a TM program too early might be useless and inefficient, while only the TM program in very advanced conditions might be insufficient due to the high level of disability and instability which cannot be completely managed and monitored at a distance.

In conclusion, TM will provide a framework for patient engagement and a new model of care delivery utilizing integrated practice units, both of which are needed to navigate the healthcare needs of the 21st century. As clinicians we need to identify the specific challenges we face in delivering care changing our future clinical practice implementing flexible systems that can be customized to individual patients' requirements and adapted to our diverse healthcare contexts.

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