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Home Telehealth for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis

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March 2012

Ontario Health Technology Assessment Series; Vol. 12: No. 11, pp. 1–58, March 2012

Suggested Citation

This report should be cited as follows:

Franek J. Home telehealth for patients with chronic obstructive pulmonary disease (COPD): an evidence-based analysis. Ont Health Technol Assess Ser [Internet]. 2012 Mar; 12(11) 1–58. Available from: www.hqontario.ca/en/mas/tech/pdfs/2012/rev_COPD_Telehealth_March.pdf

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Effective April 5, 2011, the Medical Advisory Secretariat (MAS) became a part of Health Quality Ontario (HQO), an independent body funded by the Ministry of Health and Long-Term Care. The mandate of MAS is to provide evidence-based recommendations on the coordinated uptake of health services and health technologies in Ontario to the Ministry of Health and Long-Term Care and to the health care system. This mandate helps to ensure that residents of Ontario have access to the best available and most appropriate health services and technologies to improve patient outcomes.

To fulfill its mandate, MAS conducts systematic reviews of evidence and consults with experts in the health care services community. The resulting evidence-based analyses are reviewed by the Ontario Health Technology Advisory Committee—to which MAS also provides a secretariat function—and published in the *Ontario Health Technology Assessment Series*.

About the *Ontario Health Technology Assessment Series*

To conduct its comprehensive analyses, MAS systematically reviews the available scientific literature, making every effort to consider all relevant national and international research; collaborates with partners across relevant government branches; consults with clinical and other external experts and developers of new health technologies; and solicits any necessary supplemental information.

In addition, the Secretariat collects and analyzes information about how a new technology fits within current practice and existing treatment alternatives. Details about the technology's diffusion into current health care practices add an important dimension to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist decision-makers in making timely and relevant decisions to optimize patient outcomes.

The public consultation process is available to individuals wishing to comment on an analysis prior to publication. For more information, please visit: http://www.hqontario.ca/en/mas/ohtac_public_engage_overview.html.

Disclaimer

This evidence-based analysis was prepared by MAS for the Ontario Health Technology Advisory Committee and developed from analysis, interpretation, and comparison of scientific research and/or technology assessments conducted by other organizations. It also incorporates, when available, Ontario data and information provided by experts and applicants to MAS to inform the analysis. While every effort has been made to reflect all scientific research available, this document may not fully do so. Additionally, other relevant scientific findings may have been reported since completion of the review. This evidence-based analysis is current to the date of the literature review specified in the methods section. This analysis may be superseded by an updated publication on the same topic. Please check the MAS website for a list of all evidence-based analyses: http://www.hqontario.ca/en/mas/mas_ohtas_mn.html.

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List of Abbreviations

CCT	Controlled clinical trial
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CSES	Chinese Self-Efficacy Scale
ED	Emergency department
ITT	Intention-to-treat analysis
RCT	Randomized controlled trial
SGRQ	St. George's Respiratory Questionnaire

Executive Summary

In July 2010, the Medical Advisory Secretariat (MAS) began work on a Chronic Obstructive Pulmonary Disease (COPD) evidentiary framework, an evidence-based review of the literature surrounding treatment strategies for patients with COPD. This project emerged from a request by the Health System Strategy Division of the Ministry of Health and Long-Term Care that MAS provide them with an evidentiary platform on the effectiveness and cost-effectiveness of COPD interventions.

After an initial review of health technology assessments and systematic reviews of COPD literature, and consultation with experts, MAS identified the following topics for analysis: vaccinations (influenza and pneumococcal), smoking cessation, multidisciplinary care, pulmonary rehabilitation, long-term oxygen therapy, noninvasive positive pressure ventilation for acute and chronic respiratory failure, hospital-at-home for acute exacerbations of COPD, and telehealth (including telemonitoring and telephone support). Evidence-based analyses were prepared for each of these topics. For each technology, an economic analysis was also completed where appropriate. In addition, a review of the qualitative literature on patient, caregiver, and provider perspectives on living and dying with COPD was conducted, as were reviews of the qualitative literature on each of the technologies included in these analyses.

The Chronic Obstructive Pulmonary Disease Mega-Analysis series is made up of the following reports, which can be publicly accessed at the MAS website at: http://www.hqontario.ca/en/mas/mas_ohtas_mn.html.

- Chronic Obstructive Pulmonary Disease (COPD) Evidentiary Framework
- Influenza and Pneumococcal Vaccinations for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Smoking Cessation for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Community-Based Multidisciplinary Care for Patients With Stable Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Pulmonary Rehabilitation for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Long-term Oxygen Therapy for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
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- Noninvasive Positive Pressure Ventilation for Chronic Respiratory Failure Patients With Stable Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Hospital-at-Home Programs for Patients With Acute Exacerbations of Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Home Telehealth for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Cost-Effectiveness of Interventions for Chronic Obstructive Pulmonary Disease Using an Ontario Policy Model
- Experiences of Living and Dying With COPD: A Systematic Review and Synthesis of the Qualitative Empirical Literature

For more information on the qualitative review, please contact Mita Giacomini at: http://fhs.mcmaster.ca/ceb/faculty_member_giacomini.htm.

For more information on the economic analysis, please visit the PATH website: http://www.path-hta.ca/About-Us/Contact-Us.aspx.

The Toronto Health Economics and Technology Assessment (THETA) collaborative has produced an associated report on patient preference for mechanical ventilation. For more information, please visit the THETA website: http://theta.utoronto.ca/static/contact.

Objective

The objective of this analysis was to conduct an evidence-based assessment of home telehealth technologies for patients with chronic obstructive pulmonary disease (COPD) in order to inform recommendations regarding the access and provision of these services in Ontario. This analysis was one of several analyses undertaken to evaluate interventions for COPD. The perspective of this assessment was that of the Ontario Ministry of Health and Long-Term Care, a provincial payer of medically necessary health care services.

Clinical Need: Condition and Target Population

Canada is facing an increase in chronic respiratory diseases due in part to its aging demographic. The projected increase in COPD will put a strain on health care payers and providers. There is therefore an increasing demand for telehealth services that improve access to health care services while maintaining or improving quality and equality of care. Many telehealth technologies however are in the early stages of development or diffusion and thus require study to define their application and potential harms or benefits. The Medical Advisory Secretariat (MAS) therefore sought to evaluate telehealth technologies for COPD.

Technology

Telemedicine (or telehealth) refers to using advanced information and communication technologies and electronic medical devices to support the delivery of clinical care, professional education, and health-related administrative services.

Generally there are 4 broad functions of home telehealth interventions for COPD:

- to monitor vital signs or biological health data (e.g., oxygen saturation),
- to monitor symptoms, medication, or other non-biologic endpoints (e.g., exercise adherence),
- to provide information (education) and/or other support services (such as reminders to exercise or positive reinforcement), and
- to establish a communication link between patient and provider.

These functions often require distinct technologies, although some devices can perform a number of these diverse functions. For the purposes of this review, MAS focused on home telemonitoring and telephone only support technologies.

Telemonitoring (or remote monitoring) refers to the use of medical devices to remotely collect a patient's vital signs and/or other biologic health data and the transmission of those data to a monitoring station for interpretation by a health care provider.

Telephone only support refers to disease/disorder management support provided by a health care provider to a patient who is at home via telephone or videoconferencing technology in the absence of transmission of patient biologic data.

Research Questions

1. What is the effectiveness, cost-effectiveness, and safety of home telemonitoring compared with usual care for patients with COPD?
2. What is the effectiveness, cost-effectiveness, and safety of telephone only support programs compared with usual care for patients with COPD?

Research Methods

Literature Search

Search Strategy

A literature search was performed on November 3, 2010 using OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, the Cumulative Index to Nursing & Allied Health Literature (CINAHL), the Cochrane Library, and the International Agency for Health Technology Assessment (INAHTA) for studies published from January 1, 2000 until November 3, 2010. Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search. Articles with unknown eligibility were reviewed with a second clinical epidemiologist, and then a group of epidemiologists until consensus was established. The quality of evidence was assessed as high, moderate, low, or very low according to GRADE methodology.

Inclusion Criteria – Question #1

- frequent transmission of a patient's physiological data collected at home and without a health care professional physically present to health care professionals for routine monitoring through the use of a communication technology;
- monitoring combined with a coordinated management and feedback system based on transmitted data;
- telemonitoring as a key component of the intervention (subjective determination);
- usual care as provided by the usual care provider for the control group;
- randomized controlled trials (RCTs), controlled clinical trials (CCTs), systematic reviews, and/or meta-analyses;
- published between January 1, 2000 and November 3, 2010.

Inclusion Criteria – Question #2

- scheduled or frequent contact between patient and a health care professional via telephone or videoconferencing technology in the absence of transmission of patient physiological data;
- monitoring combined with a coordinated management and feedback system based on transmitted data;
- telephone support as a key component of the intervention (subjective determination);
- usual care as provided by the usual care provider for the control group;
- RCTs, CCTs, systematic reviews, and/or meta-analyses;
- published between January 1, 2000 and November 3, 2010.

Exclusion Criteria

- published in a language other than English;

- intervention group (and not control) receiving some form of home visits by a medical professional, typically a nurse (i.e., telenursing) beyond initial technology set-up and education, to collect physiological data, or to somehow manage or treat the patient;
- not recording patient or health system outcomes (e.g., technical reports testing accuracy, reliability or other development-related outcomes of a device, acceptability/feasibility studies, etc.);
- not using an independent control group that received usual care (e.g., studies employing historical or periodic controls).

Outcomes of Interest

- hospitalizations (*primary outcome*)
- mortality
- emergency department visits
- length of stay
- quality of life
- other [...]

Subgroup Analyses (a priori)

- length of intervention *(primary)*
- severity of COPD *(primary)*

Quality of Evidence

The quality of evidence assigned to individual studies was determined using a modified CONSORT Statement Checklist for Randomized Controlled Trials. (1) The CONSORT Statement was adapted to include 3 additional quality measures: the adequacy of control group description, significant differential loss to follow-up between groups, and greater than or equal to 30% study attrition. Individual study quality was defined based on total scores according to the CONSORT Statement checklist: very low (0 to < 40%), low (≥ 40 to < 60%), moderate (≥ 60 to < 80%), and high (≥ 80 to 100%).

The quality of the body of evidence was assessed as high, moderate, low, or very low according to the GRADE Working Group criteria. The following definitions of quality were used in grading the quality of the evidence:

High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

Summary of Findings

Six publications, representing 5 independent trials, met the eligibility criteria for Research Question #1. Three trials were RCTs reported across 4 publications, whereby patients were randomized to home

telemonitoring or usual care, and 2 trials were CCTs, whereby patients or health care centers were nonrandomly assigned to intervention or usual care.

A total of 310 participants were studied across the 5 included trials. The mean age of study participants in the included trials ranged from 61.2 to 74.5 years for the intervention group and 61.1 to 74.5 years for the usual care group. The percentage of men ranged from 40% to 64% in the intervention group and 46% to 72% in the control group.

All 5 trials were performed in a moderate to severe COPD patient population. Three trials initiated the intervention following discharge from hospital. One trial initiated the intervention following a pulmonary rehabilitation program. The final trial initiated the intervention during management of patients at an outpatient clinic.

Four of the 5 trials included oxygen saturation (i.e., pulse oximetry) as one of the biological patient parameters being monitored. Additional parameters monitored included forced expiratory volume in one second, peak expiratory flow, and temperature.

There was considerable clinical heterogeneity between trials in study design, methods, and intervention/control. In relation to the telemonitoring intervention, 3 of the 5 included studies used an electronic health hub that performed multiple functions beyond the monitoring of biological parameters. One study used only a pulse oximeter device alone with modem capabilities. Finally, in 1 study, patients measured and then forwarded biological data to a nurse during a televideo consultation. Usual care varied considerably between studies.

Only one trial met the eligibility criteria for Research Question #2. The included trial was an RCT that randomized 60 patients to nurse telephone follow-up or usual care (no telephone follow-up). Participants were recruited from the medical department of an acute-care hospital in Hong Kong and began receiving follow-up after discharge from the hospital with a diagnosis of COPD (no severity restriction). The intervention itself consisted of only two 10-to 20-minute telephone calls, once between days 3 to 7 and once between days 14 to 20, involving a structured, individualized educational and supportive programme led by a nurse that focused on 3 components: assessment, management options, and evaluation.

Regarding Research Question #1:

- Low to very low quality evidence (according to GRADE) finds non-significant effects or conflicting effects (of significant or non-significant benefit) for all outcomes examined when comparing home telemonitoring to usual care.
- There is a trend towards significant increase in time free of hospitalization and use of other health care services with home telemonitoring, but these findings need to be confirmed further in randomized trials of high quality.
- There is severe clinical heterogeneity between studies that limits summary conclusions.
- The economic impact of home telemonitoring is uncertain and requires further study.
- Home telemonitoring is largely dependent on local information technologies, infrastructure, and personnel, and thus the generalizability of external findings may be low. Jurisdictions wishing to replicate home telemonitoring interventions should likely test those interventions within their jurisdictional framework before adoption, or should focus on home-grown interventions that are subjected to appropriate evaluation and proven effective.

Regarding Research Question #2:

- Low quality evidence finds significant benefit in favour of telephone-only support for self-efficacy and emergency department visits when compared to usual care, but non-significant results for hospitalizations and hospital length of stay.
- There are very serious issues with the generalizability of the evidence and thus additional research is required.

Background

In July 2010, the Medical Advisory Secretariat (MAS) began work on a Chronic Obstructive Pulmonary Disease (COPD) evidentiary framework, an evidence-based review of the literature surrounding treatment strategies for patients with COPD. This project emerged from a request by the Health System Strategy Division of the Ministry of Health and Long-Term Care that MAS provide them with an evidentiary platform on the effectiveness and cost-effectiveness of COPD interventions.

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Objective of Analysis

The objective of this analysis was to conduct an evidence-based assessment of home telehealth technologies for patients with COPD in order to inform recommendations regarding the access and provision of these services in Ontario. This analysis was one of several analyses undertaken to evaluate interventions for COPD. The perspective of this assessment was that of the Ministry of Health and Long-Term Care, a provincial payer of medically necessary health care services.

Clinical Need and Target Population

Canada is facing an increase in chronic respiratory diseases due in part to its aging demographic. The projected increase in COPD will put a strain on health care payers and providers. There is therefore an increasing demand for telehealth services that improve access to health care services while maintaining or improving quality and equality of care. Many telehealth technologies however are in the early stages of development or diffusion and thus require study to define their application and potential harms or benefits. The Medical Advisory Secretariat therefore sought to evaluate telehealth technologies for COPD.

Technology

Definitions

Definitions for telehealth tend to be diverse and varied. The definitions used for the purposes of this review are described below.

Telemedicine (or telehealth) refers to using advanced information and communication technologies and electronic medical devices to support the delivery of clinical care, professional education, and health-related administrative services.

While telemedicine is often associated with direct patient clinical services, *telehealth* is often associated with a broader definition of remote health care and is perceived to be more focused on other health-related services.

Telemonitoring (or remote monitoring) refers to the use of medical devices to remotely collect a patient's vital signs and/or other biologic health data and the transmission of those data to a monitoring station for interpretation by a health care provider. Generally, there are 2 types of telemonitoring devices: i) *upload devices* which are wireless or modem-compatible devices that can measure biologic information and directly upload the data either automatically or through patient assistance via landline or wireless transmission, and ii) *entry devices* which are devices (either landline-based or wireless) or websites through which patients enter biological health data that was measured by a distinct measurement device. The monitoring of patient data by a health-care practitioner can occur either in real-time (i.e., *real-time monitoring* or *synchronous monitoring*) or can be stored and viewed at a later time (i.e., *store-and-forward monitoring* or *asynchronous monitoring*).

Telephone only support refers to disease/disorder management support provided by a health care provider to a patient who is at home via telephone or videoconferencing technology in the absence of transmission of patient biologic data.

Telenursing generally refers to the in-person visit of a health care provider, typically a nurse, to a patient's home or residence, regularly, in order to provide clinical care or professional education. Because

of the resource requirements, telenursing is generally not feasible from a population perspective and is therefore not discussed further in this review.

Because of the chronic nature of COPD and the subsequent need for continuous patient management, home telehealth technologies are being increasingly used to help outpatients maintain their independence and continue living in their own homes while ensuring their symptoms, vital signs, medication, education, and other management-related factors are monitored and/or managed and/or improved.

Functions

Generally there are 4 broad functions of home telehealth interventions for COPD:

- to monitor vital signs or biological health data (e.g., oxygen saturation),
- to monitor symptoms, medication, or other non-biologic endpoints (e.g., exercise adherence),
- to provide information (education) and/or other support services (such as reminders to exercise or positive reinforcement), and
- to establish a communication link between patient and provider.

These functions often require distinct technologies, although some devices can perform a number of these diverse functions.

Evidence-Based Analysis

Research Question(s)

1. What is the effectiveness, cost-effectiveness, and safety of home telemonitoring compared with usual care for patients with COPD?
2. What is the effectiveness, cost-effectiveness, and safety of telephone only support compared with usual care for patients with COPD?

Research Methods

Literature Search

Search Strategy

A literature search was performed on November 3, 2010 using OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, the Cumulative Index to Nursing & Allied Health Literature (CINAHL), the Cochrane Library, and the International Agency for Health Technology Assessment (INAHTA) for studies published from January 1, 2000 until November 3, 2010. Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search. Articles with unknown eligibility were reviewed with a second clinical epidemiologist, and then a group of epidemiologists at the Medical Advisory Secretariat until consensus was established. The quality of evidence was assessed as high, moderate, low, or very low according to GRADE methodology. A methodological quality checklist was used to help guide the grading of the Methodological Quality domain of GRADE.

Inclusion Criteria – Question #1

- frequent transmission of a patient's physiological data collected at home and without a health care professional physically present to health care professionals for routine monitoring through the use of a communication technology;
- monitoring combined with a coordinated management and feedback system based on transmitted data;
- telemonitoring as a key component of the intervention (subjective determination);
- usual care as provided by the usual care provider in the control group;
- randomized controlled trials (RCTs), controlled clinical trials (CCTs), systematic reviews, and/or meta-analyses;
- published between January 1, 2000 and November 3, 2010.

Inclusion Criteria – Question #2

- scheduled or frequent contact between patient and a health care professional via telephone or videoconferencing technology in the absence of transmission of patient physiological data;
- monitoring combined with a coordinated management and feedback system based on transmitted data;
- telephone support as a key component of the intervention (subjective determination);
- usual care as provided by the usual care provider in the control group;
- RCTs, CCTs, systematic reviews, and/or meta-analyses;
- published between January 1, 2000 and November 3, 2010.

Exclusion Criteria

- published in a language other than English;
- intervention group (and not control) receiving some form of home visits by a medical professional, typically a nurse (i.e., telenursing), beyond initial technology set-up and education, to collect physiological data or somehow manage or treat the patient;
- not recording patient or health system outcomes (e.g., technical reports testing accuracy, reliability, or other development-related outcomes of a device, acceptability/feasibility studies, etc.);
- not using an independent control group that received usual care (e.g., studies employing historical or periodic controls such as before-after studies).

Outcomes of Interest

- hospitalizations (*primary outcome*)
- mortality
- emergeny department (ED) visits
- length of stay
- quality of life
- primary care visits
- specialist visits
- home care visits
- other [...]

Subgroup Analyses

- length of intervention *(primary)*
- severity of COPD *(primary)*
- length of follow-up
- jurisdiction
- interventional
  - modality of transmission for telemonitoring (real time or store and forward [synchronous or asynchronous])
  - service availability (with or without 24-hour/day emergency support)
  - frequency of telephone support contact
- age

Statistical Analysis

Due to excessive clinical heterogeneity in the intervention, control, study population, study methods, and outcomes, no statistical pooling was performed.

Quality of Evidence

The quality of evidence assigned to individual studies was determined using a modified CONSORT Statement Checklist for Randomized Controlled Trials. (1) The CONSORT Statement was adapted to include 3 additional quality measures: the adequacy of control group description, significant differential loss to follow-up between groups, and greater than or equal to 30% study attrition. Individual study

quality was defined based on total scores according to the CONSORT Statement checklist: very low (0 to < 40%), low (≥ 40 to < 60%), moderate (≥ 60 to < 80%), and high (≥ 80 to 100%).

The quality of the body of evidence was assessed as high, moderate, low, or very low according to the GRADE Working Group criteria (1) as presented below:

- Quality refers to the criteria such as the adequacy of allocation concealment, blinding, and follow-up.
- Consistency refers to the similarity of estimates of effect across studies. If there are important and unexplained inconsistencies in the results, our confidence in the estimate of effect for that outcome decreases. Differences in the direction of effect, the magnitude of the difference in effect, and the significance of the differences guide the decision about whether important inconsistency exists.
- Directness refers to the extent to which the interventions and outcome measures are similar to those of interest.

As stated by the GRADE Working Group, the following definitions of quality were used in grading the quality of the evidence:

High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

Results of Evidence-Based Analysis

The literature search returned 759 publications, published between January 1, 2000 and November 3, 2010. Of these 759 publications, 94 full texts were reviewed and 9 publications met the eligibility criteria. (2-10) Table 1 illustrates the body of evidence according to study design.

Table 1: Body of Evidence Examined According to Study Design*

Study Design	Number of Eligible Studies
Randomized Controlled Trials	
Systematic review of RCTs	2†
Large RCT	2
Small RCT	5
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with contemporaneous controls	
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	
Database, registry, or cross-sectional study	
Case series	
Retrospective review, modelling	
Studies presented at an international conference or other sources of grey literature	
Expert opinion	
Total	9

*Abbreviation: RCT, randomized controlled trial.

†The systematic reviews combined randomized controlled trials and observational studies.

Two publications referenced the same systematic review conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH). (9;10) This review included RCTs, CCTs, and observational trials. While the review recognized substantial clinical heterogeneity between trials, summary conclusions were generalized to all of telehealth, stating that telehealth is generally clinically effective for COPD and that more research was needed.

Methodological issues were however noted with this systematic review, pertaining primarily to its eligibility criteria, quality evaluation, and interpretation of results. The Medical Advisory Secretariat therefore sought to conduct an original systematic review to answer the above research questions.

Results are presented by Research Question.

Research Question #1 – Home Telemonitoring

Six publications, representing 5 independent trials, met the eligibility criteria for Research Question #1. (2-7)

Three trials were RCTs reported across 4 publications, (2-4;7) whereby patients were randomized to home telemonitoring or usual care, and 2 trials were CCTs, (5;6) whereby patients or centers were nonrandomly assigned to intervention or usual care. Five relevant observational trials (11-15) were identified in the literature search but were excluded because of study design, and one relevant RCT (16) was excluded because it did not include the monitoring of biological patient data (these exclusions are reported for completeness only).

Patient and study characteristics of included studies are detailed in Appendix 2. A checklist of methodological quality is provided in Appendix 3. Finally, GRADE assessments were carried out for the body of evidence pertaining to each individual outcome (as required by GRADE). Individual GRADE tables by outcome are available in Appendix 4.

A total of 310 participants were studied across the 5 included trials. The mean age of study participants in the included trials ranged from 61.2 to 74.5 years for the intervention group and 61.1 to 74.5 years for the usual care group. The percentage of men ranged from 40% to 64% in the intervention group and 46% to 72% in the usual care group. (2-7)

All 5 trials were performed in a moderate to severe COPD patient population. (2-7) Three trials initiated the intervention following discharge from hospital. (5-7) One trial initiated the intervention following a pulmonary rehabilitation program. (3;4) The final trial initiated the intervention during management of patients at an outpatient clinic. (2)

Four of the 5 trials included oxygen saturation (i.e., pulse oximetry) as one of the biological patient parameters being monitored. (2-4;6;7) Additional parameters monitored included forced expiratory volume in one second, peak expiratory flow, and temperature.

There was considerable clinical heterogeneity between trials in terms of the study design, methodological quality, the technology being used, the additional biological patient parameters being monitored, the timing of the intervention in the clinical course of disease, the number and type of co-interventions, the length of intervention/follow-up, the intensity of the intervention (i.e., the number of data transmissions or communications per day), and the number and specialties of health care practitioners involved in carrying out the intervention.

In relation to the telemonitoring technology itself, 3 of the 5 included studies used an electronic health hub (i.e., entry device) that performed numerous functions beyond the monitoring of biological parameters. (2-5) One study used only a pulse oximeter with modem capabilities (i.e., upload device). (7) Finally, in one study, patients measured and forwarded biological data to a nurse during a televideo consultation (for the purposes of this review, this was considered real-time telemonitoring using an entry device). (6) Usual care varied considerably between studies (see Appendix 2, Table A1).

Results are summarized by outcome.

Hospitalizations

All 5 trials evaluated the effect of home telemonitoring on patient hospitalizations; however, the outcome was defined differently across trials (see Table 2). (2-7) Included studies reported conflicting results, either finding non-significant benefit (i.e., a reduction in hospitalizations) in favour of home telemonitoring compared with usual care, or a significant benefit in favour of home telemonitoring. Two of the studies were powered for the outcome of hospitalizations (i.e., primary outcome), yet both found no significant difference between the groups. (3;6) The quality of the body of evidence for this outcome was very low according to GRADE (see Appendices 3 and 4). All hospitalizations were assumed to be all-cause hospitalizations unless otherwise reported.

Table 2: The Effect of Home Telemonitoring on Hospitalizations When Compared to Usual Care Across Included Studies*†

Author, Year	n	Design	Outcome	Telemonitoring	Usual Care	*P* value
Mean number of hospitalizations per patient over 6 months of follow-up						
Lewis et al, 2010 (3)	40	RCT	COPD-related	0.20	0.35	0.16
Pare et al, 2006 (5)	**29**	**CCT**	**All-cause**	**0.10**	**0.60**	**< 0.05**
Mean hospitalizations per patient-month of follow-up (mean ± SD)						
Vitacca et al, 2006 (7)	**101**	**RCT**	**All-cause**	**0.17 ± 0.23**	**0.30 ± 0.30**	**< 0.019**
Proportion of patients with at least one hospitalization during follow-up						
Koff et al, 2008 (2)	40	RCT	All-cause	1/19 (5.3)	3/19 (15.8)	> 0.05
Pare et al, 2006 (5)	29	CCT	All-cause	1/19 (5.3)	4/10 (40.0)	> 0.05
Sorknaes et al, 2010 (6)	100	CCT	All-cause	8/50 (16.0)	15/50 (30.0)	> 0.05

*Abbreviations: CCT, controlled clinical trial (non-randomized); n, sample size; RCT, randomized controlled trial.
†Bolding denotes significance at *P* value < 0.05.

Time Free of Hospitalization

Two trials evaluated the effect of home telemonitoring on time free of hospitalization as a secondary outcome in a population with severe COPD. (6;7) In an RCT by Vitacca et al, (7) Kaplan-Meier survival analysis adjusting for the use of home mechanical ventilation found that patients in the home telemonitoring group were more likely to have a longer time until first hospitalization than those in the usual care group ($P < 0.0012$). In a CCT by Sorknaes et al, (6) multivariate Cox regression model adjusting for a number of different factors (including age and current smoking status) found that home telemonitoring was protective of early hospitalization (hazard ratio [HR], 0.25; 95% confidence interval [CI], 0.09–0.60; $P < 0.05$). The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Mortality

Only 1 trial evaluated the effect of home telemonitoring on mortality (undefined) as a secondary outcome. (7) The RCT, by Vitacca et al, reported no significant difference in the mortality rate between the home telemonitoring group and the usual care group ($P = 0.148$), but no data were provided. The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Quality of Life

Two trials evaluated the effect of home telemonitoring on quality of life (see Table 3). (2;4) In an RCT by Koff et al, (2) the home telemonitoring group showed a significant improvement in the mean change from baseline in the St. George's Respiratory Questionnaire (SGRQ) score when compared with the usual care group (see Table 3). This study was powered for this specific outcome (i.e., this was the primary outcome). The home telemonitoring group also showed improvement in the individual domains of the SGRQ, although the benefit did not reach statistical significance. In an RCT by Lewis et al, there was no significant difference noted between study groups across 3 different measures: change in SGRQ, hospital anxiety score, and EuroQol 5-D (EQ-5D). (4) This study however was not powered for these outcomes (i.e., these were secondary outcomes). The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Table 3: The Effect of Home Telemonitoring on Quality of Life When Compared to Usual Care Across Included Studies*†

Author, Year	n	Design	Measurement	Telemonitoring	Usual Care	*P*
Mean number of hospitalizations per patient over 6 months follow-up						
Koff et al, 2008 (2)	40	RCT	**∆SGRQ score mean (95% CI)**	**-10.3 (-17.1,-3.1)**	**-0.6 (-6.5, 5.3)**	**.018**
			Symptoms	-12.8 (-24.4, -1.1)	-3.3 (-14.0, 7.4)	.27
			Activity	-8.8 (-18.8, 1.1)	-0.5 (-8.9, 7.9)	.16
			Impact	-6.6 (-15.3, 2.2)	-0.6 (-7.2, 6.0)	.20
Lewis et al, 2010 (4)	40	RCT	∆SGRQ score	NR	NR	.83
			Hospital depression			.70
			Hospital anxiety			.83
			EQ-5D			.64

*Abbreviations: CI, confidence interval; EQ-5D, EuroQol-5D; n, sample size; RCT, randomized controlled trial, SGRQ, St. George's Respiratory Questionnaire.

†Bolding denotes significance at *P* value < 0.05.

Length of Stay

Two trials evaluated the effect of home telemonitoring on hospital length of stay as a secondary outcome. (3;5) No significant differences between arms were identified in an RCT by Lewis et al ($P = 0.66$) (3) or in a CCT by Pare et al ($P > 0.05$) (5) when comparing median days in hospital between study groups. The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Exacerbations

One trial evaluated the effect of home telemonitoring on exacerbations as a secondary outcome. (6) In a CCT by Sorknaes et al, (6) there was no significant difference in the number of exacerbations ($P > 0.05$) between study groups. The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Emergency Department Visits

Two trials evaluated the effect of home telemonitoring on emergency department (ED) visits as a secondary outcome. (2;3) There was no significant difference between study groups in an RCT by Lewis et al (3) that evaluated median ED visits per patient during the study period ($P = 0.24$), and similarly, there appeared to be no significant difference in an RCT by Koff et al (2) that evaluated total ED visits over the study period (*P* value not reported). The quality of the body of evidence for this outcome was very low according to GRADE (see Appendices 3 and 4).

Patient Satisfaction

Patient satisfaction was evaluated across 4 trials. (2;3;5;6) Study participants generally felt safer or more secure when using home telemonitoring, (5;6) participants perceived that the intervention was beneficial, (3;5;6) and lastly, participants reported being satisfied with the equipment. (2)

Time Free of Other Health Care Services

In an RCT by Vitacca et al, (7) Kaplan-Meier survival analysis adjusting for the use of home mechanical ventilation found that patients in the home telemonitoring group were more likely to have a longer time until first ED visit ($P = 0.0003$), first exacerbation ($P < 0.001$), and first urgent generalized practitioner call ($P = 0.013$). The quality of the body of evidence for these outcomes was low according to GRADE (see Appendices 3 and 4).

Safety
No trials reported safety-related outcomes (i.e., adverse events caused by home telemonitoring).

Research Question #2 – Telephone Only Support

Only 1 trial met the eligibility criteria for Research Question #2. (8)

Four relevant RCTs (17-20) were excluded because the intervention included home visits by a nurse, 1 relevant RCT (21) was excluded because there was no coordinated feedback/patient management based on the telephone communication (i.e., the telephone calls provided encouragement only), 2 relevant RCTs (22;23) were excluded because telephone support was not a focus of the intervention, and lastly, 2 relevant observational trials (24;25) were excluded because of study design (these exclusions are reported for completeness only).

Patient and study characteristics of the included study are detailed in Appendix 2. A checklist of methodological quality is provided in Appendix 3. Finally, GRADE assessments were carried out for the body of evidence pertaining to each individual outcome (as required by GRADE). Individual GRADE tables by outcome are available in Appendix 4.

The included trial, by Wong et al, (8) was an RCT that randomized 60 patients to nurse telephone follow-up or usual care (no telephone follow-up). Participants were recruited from the medical department of an acute-care hospital in Hong Kong and began receiving follow-up after discharge from hospital with a diagnosis of COPD (no severity restriction). The intervention itself consisted of only two 10-to 20-minute telephone calls, once between days 3 to 7 and once between days 14 to 20, involving a structured, individualized educational and supportive programme led by a nurse that focused on 3 components: assessment, management options, and evaluation. The trial originally aimed for 196 participants but managed to only recruit 72 (60 of which participated in the trial). The primary outcome of the trial was the change in score on the Chinese Self Efficacy Scale (CSES).

Quality of Life
Participants in the telephone follow-up group significantly improved in the change in CSES (see Table 4). Of the 5 domains of the CSES, significant improvements were also noted in Physical Exertion and in Weather or Environment in favour of the telephone follow-up group. In a multiple regression model, telephone follow-up (β = 0.33; 95% CI, 0.19–0.48; P = 0 .001), having attended a pulmonary rehabilitation programme (β = 0.44; 95% CI, 0.6–0.72; P = 0 .003), smoking (β = 0.34; 95% CI, 0.09–0.57; P = 0.009), and health care use (β = 0.27; 95% CI, 0.47 to -0.07; P = 0.008) were significant factors in predicting patient self-efficacy. (8) The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Table 4: The Effect of Telephone Only Support on Quality of Life When Compared to Usual Care in a Study by Wong et al*†

Author, Year	n	Design	Measurement	Telemonitoring	Usual Care	*P value*
Wong et al, 2005 (8)	60	RCT	**ΔCSES score median (IQR)**	**0.5 (0.7)**	**0.3 (0.6)**	**0.009**
			Negative Affect	0.4 (0.7)	0.3 (0.6)	0.260
			Emotional Arousal	0.5 (0.9)	0.1 (0.6)	0.342
			Physical Exertion	**0.6 (1.0)**	**-0.2 (1.1)**	**0.001**
			Weather or Environment	**0.5 (0.8)**	**0.0 (0.9)**	**0.009**
			Behavioural Risk Factors	0.0 (0.5)	0.0 (1.1)	0.901

*Abbreviations: CSES, Chinese Self-Efficacy Scale; IQR, interquartile range; n, sample size; RCT, randomized controlled trial.

†Bolding denotes significance at P value < 0.05.

Hospitalization
There was no significant difference between study groups when comparing mean hospitalizations per patient during the study and follow-up period ($P = 0.182$). (8) The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Length of Stay
There was no significant difference between study groups when comparing mean days of readmission during the study and follow-up period ($P = 0.354$). (8) The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Emergency Department Visits
The telephone follow-up group had significantly ($P = 0.034$) fewer ED visits (mean 0.1 ± 0.3) compared with the usual care group (mean 0.4 ± 0.7). (8) The quality of the body of evidence for this outcome was low according to GRADE (see Appendices 3 and 4).

Safety
No trials reported safety-related outcomes (i.e., adverse events caused by home telemonitoring).

Quality of the Evidence

GRADE evaluations were performed to summarize the quality of the body of evidence pertaining to each individual outcome (see Appendix 4). A methodological checklist (see Appendix 3) was used to help inform the Methodological Quality component of GRADE (see Appendix 4). The quality of evidence according to GRADE was low to very low quality across all outcomes. Serious to very serious limitations were noted in the methodological quality of studies owing to a lack of blinding, lack of randomization (with the inclusion of controlled clinical trials), significant differences in baseline comparisons (see Appendix 3, Table A3), a lack of baseline comparison, lack of power due to small sample sizes, unplanned subgroup analysis, and a lack of intention-to-treat analysis. Inconsistencies in the magnitude of effect and statistical significance were also noted and contributed to downgrading. Lastly, issues of generalizability, primarily in the intervention, were noted throughout but did not always contribute to downgrading (unless serious issues were noted). Serious issues with generalizability were noted in the telephone only study by Wong et al; (8) specifically, there were issues with the population (Chinese population with limited comorbidities) and with the outcome/intervention (an adapted CSES was used both as a tool to measure self efficacy (i.e., quality of life) and to help guide the intervention).

Economic Analysis

The results of the economic analysis are summarized in issue 12 of the COPD series entitled *Cost-Effectiveness of Interventions for Chronic Obstructive Pulmonary Disease Using an Ontario Policy Model*. This report can be accessed at: www.hqontario.ca/en/mas/tech/pdfs/2012/rev_COPD_Economic_March.pdf.

The results from the systematic review of the clinical evidence for home telemonitoring and telephone only support for COPD were not included in the economic model because of the low to very low quality of evidence and the lack of significant findings for the model inputs.

Conclusions

Regarding Research Question #1:

- Low to very low quality evidence (according to GRADE) shows non-significant effects or conflicting effects (of significant or non-significant benefit) for all outcomes examined when comparing home telemonitoring to usual care.
- There is a trend towards a significant increase in time free of hospitalization and use of other health care services with home telemonitoring, but these findings need to be confirmed further in randomized trials of high quality.
- There is severe clinical heterogeneity between studies that limits summary conclusions.
- The economic impact of home telemonitoring is uncertain and requires further study.
- Home telemonitoring is largely dependent on local information technologies, infrastructure, and personnel, and thus the generalizability of external findings may be low. Jurisdictions wishing to replicate home telemonitoring interventions should likely test those interventions within their jurisdictional framework before adoption, or should focus on home-grown interventions that are subjected to appropriate evaluation and proven effective.

Regarding Research Question #2:

- Low quality evidence shows significant benefit in favour of telephone only support for self-efficacy and ED visits when compared to usual care, but non-significant results for hospitalizations and hospital length of stay.
- There are very serious issues with the generalizability of this evidence and thus additional study is required.

Glossary

6 Minute Walking Test (6MWT)	A measure of exercise capacity which measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes. A widely used outcome measure in respiratory rehabilitation of patients with COPD.
Acute exacerbations of chronic obstructive pulmonary disease (AECOPD)	A change in baseline symptoms that is beyond day-to-day variation, particularly increased breathlessness, cough, and/or sputum, which has an abrupt onset.
Admission avoidance hospital-at-home program	Treatment program for patients experiencing acute exacerbations of COPD which allows patients to receive treatment in their home and avoid admission to hospital. After patients are assessed in the emergency department for an acute exacerbation, they are prescribed the necessary medications and additional care needed (e.g., oxygen therapy) and then sent home where they receive regular visits from a medical professional until the exacerbation has resolved.
Ambulatory oxygen therapy	Provision of oxygen therapy during exercise and activities of daily living for individuals who demonstrate exertional desaturation.
Bilevel positive airway pressure (BiPAP)	A continuous positive airway pressure mode used during noninvasive positive pressure ventilation (see definition below) that delivers preset levels of inspiratory and expiratory positive airway pressure. The pressure is higher when inhaling and falls when exhaling, making it easier to breathe.
Cost-effectiveness acceptability curve (CEAC)	A method for summarizing uncertainty in estimates of cost-effectiveness.
Cor pulmonale	Right heart failure, as a result of the effects of respiratory failure on the heart.
Dyspnea	Difficulty breathing or breathlessness.
Early discharge hospital-at-home program	Treatment program for patients experiencing acute exacerbations of COPD which allows patients to receive treatment in their home and decrease their length of stay in hospital. After being assessed in the emergency department for acute exacerbations, patients are admitted to the hospital where they receive the initial phase of their treatment. These patients are discharged early into a hospital-at-home program where they receive regular visits from a medical professional until the exacerbation has resolved.
Forced expiratory volume in 1 second (FEV_1)	A measure of lung function used for COPD severity staging; the amount of air that can be forcibly exhaled from the lungs in the first second of a forced exhalation.
Forced vital capacity (FVC)	The amount of air that can be forcibly exhaled from the lungs after taking the deepest breath possible.
Fraction of inspired oxygen (FiO_2)	The percentage of oxygen participating in gas exchange.

Hypercapnia	Occurs when there is too much carbon dioxide in the blood (arterial blood carbon dioxide > 45 to 60 mm Hg).
Hypopnea	Slow or shallow breathing.
Hypoxemia	Low arterial blood oxygen levels while breathing air at rest. May be severe ($PaO_2 \leq 55$ mm Hg), moderate (56 mm Hg $\leq PaO_2 <$ 65 mm Hg), or mild-to-moderate (66 mm Hg $< PaO_2 \leq$ 74 mm Hg).[1]
Incremental cost-effectiveness ratio (ICER)	Ratio of the change in costs of a therapeutic intervention to the change in effects of the intervention compared to the alternative (often usual care).
Intention-to-treat analysis (ITT)	An analysis based on the initial treatment the participant was assigned to, not on the treatment eventually administered.
Invasive mechanical ventilation (IMV)	Mechanical ventilation via an artificial airway (endotracheal tube or tracheostomy tube).
Long-term oxygen therapy (LTOT)	Continuous oxygen use for about 15 hours per day. Use is typically restricted to patients fulfilling specific criteria.
Multidisciplinary care	Defined as care provided by a team (compared to a single provider). Typically involves professionals from a range of disciplines working together to deliver comprehensive care that addresses as many of the patient's health care and psychosocial needs as possible.
Nicotine replacement therapy (NRT)	The administration of nicotine to the body by means other than tobacco, usually as part of smoking cessation.
Noninvasive positive pressure ventilation (NPPV)	Noninvasive method of delivering ventilator support (without the use of an endotracheal tube) using positive pressure. Provides ventilatory support through a facial or nasal mask and reduces inspiratory work.
Partial pressure of carbon dioxide ($PaCO_2$)	The pressure of carbon dioxide dissolved in arterial blood. This measures how well carbon dioxide is able to move out of the body.
Partial pressure of oxygen (PaO_2)	The pressure of oxygen dissolved in arterial blood. This measures how well oxygen is able to move from the airspace of the lungs into the blood.
Palliative oxygen therapy	Use of oxygen for mildly hypoxemic or nonhypoxemic individuals to relieve symptoms of breathlessness. Used short term. This therapy is "palliative" in that treatment is not curative of the underlying disease.
Pulmonary rehabilitation	Multidisciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and autonomy. Exercise training is the cornerstone of pulmonary rehabilitation programs.
Pulse oximetry	A noninvasive sensor, which is attached to the finger, toe, or ear to detect oxygen saturation of arterial blood.

[1] The mild-to-moderate classification was created for the purposes of the report.

Quality-adjusted life-years (QALYs)	A measure of disease burden that includes both the quantity and the quality of the life lived that is used to help assess the value for money of a medical intervention.
Respiratory failure	Respiratory failure occurs when the respiratory system cannot oxygenate the blood and/or remove carbon dioxide from the blood. It can be either acute (acute respiratory failure, ARF) or chronic, and is classified as either hypoxemic (type I) or hypercapnic (type II) respiratory failure. Acute hypercapnic respiratory failure frequently occurs in COPD patients experiencing acute exacerbations of COPD.
Short-burst oxygen therapy	Short-duration, intermittent, supplemental oxygen administered either before or after exercise to relieve breathlessness with exercise.
Sleep apnea	Interruption of breathing during sleep due to obstruction of the airway or alterations in the brain. Associated with excessive daytime sleepiness.
Smoking cessation	The process of discontinuing the practice of inhaling a smoked substance.
Spirometry	The gold standard test for diagnosing COPD. Patients breathe into a mouthpiece attached to a spirometer which measures airflow limitation.
SpO_2	Oxygen saturation of arterial blood as measured by a pulse oximeter.
Stable COPD	The profile of COPD patients which predominates when patients are not experiencing an acute exacerbation.
Supplemental oxygen therapy	Oxygen use during periods of exercise or exertion to relieve hypoxemia.
Telemedicine (or telehealth)	Refers to using advanced information and communication technologies and electronic medical devices to support the delivery of clinical care, professional education, and health-related administrative services.
Telemonitoring (or remote monitoring)	Refers to the use of medical devices to remotely collect a patient's vital signs and/or other biologic health data and the transmission of those data to a monitoring station for interpretation by a health care provider.
Telephone only support	Refers to disease/disorder management support provided by a health care provider to a patient who is at home via telephone or videoconferencing technology in the absence of transmission of patient biologic data.
Ventilator-associated pneumonia (VAP)	Pneumonia that occurs in patients undergoing mechanical ventilation while in a hospital.

Acknowledgements

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The role of the expert panel was to provide direction on the scope of the project and the relevant outcomes measures of effectiveness, to review the evidence-based analyses and to identify any societal or systemic issues that are relevant to intervention effectiveness. However, the statements, conclusions and views expressed in this report do not necessarily represent the views of the expert panel members.

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Appendices

Appendix 1: Literature Search Strategies

Search date: November 3, 2010
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, Wiley Cochrane, CINAHL, Centre for Reviews and Dissemination/International Agency for Health Technology Assessment

Database: Ovid MEDLINE(R) <1950 to October Week 3 2010>
Search Strategy:
---
1 exp Pulmonary Disease, Chronic Obstructive/ (14736)
2 (chronic obstructive adj2 (lung* or pulmonary or airway* or airflow or respiratory) adj (disease* or disorder*)).ti,ab. (21651)
3 (copd or coad).ti,ab. (16560)
4 chronic airflow obstruction.ti,ab. (492)
5 exp Emphysema/ (7011)
6 ((chronic adj2 bronchitis) or emphysema).ti,ab. (22852)
7 or/1-6 (54191)
8 exp telecommunications/ (41357)
9 exp Computer Communication Networks/ (46975)
10 (tele* or ehealth or e-health or mhealth or m-health).mp. [mP = title, original title, abstract, name of substance word, subject heading word, unique identifier] (105201)
11 ((remote or wireless or mobile) adj2 (monitor* or consult*)).mp. [mP = title, original title, abstract, name of substance word, subject heading word, unique identifier] (3661)
12 (Aerotel Medical or Aivea or AMD Global Telemedicine or American TeleCare or AvidCare or Carematix or Care2Wear or CareVoyant or Centura or Cifra or Clinidata or CyberCare or Cybernet or DexCom or ExceliCare or FireLogic or FONEMED or Health Buddy or Health Hero or HealthEngage or Health@nywhere or HomMed or Homecare Homebase or iCare Desktop or IEM GmbHOR or iMetrikus or InforMedix or INRange or Intelsis or Lifewatch or Lifelink or March Networks or McKesson or MDHome or Medic4All or MediCompass or MedNovations or MedShare or Morepress or Neptec or NewIt or Patient Care Technologies or PERS Buddy or Pharos or RemoteAccess or RemoteNurse or Senior Health Advantage Network or Spirotel or TCARE or Teledoctor or Telehealth Solutions or TeleMedic or Telescale or TouchPointCare or (Tunstall adj3 Genesis) or ViTel Net or VitalNet or Viterion or Well@home or WiPaM).mp. [mP = title, original title, abstract, name of substance word, subject heading word, unique identifier] (188)
13 or/8-12 (156487)
14 7 and 13 (348)
15 limit 14 to (english language and humans and yr="2000 -Current") (251)

****

Database: EMBASE <1980 to 2010 Week 43>
Search Strategy:
---
1 exp chronic obstructive lung disease/ (48442)
2 (chronic obstructive adj2 (lung* or pulmonary or airway* or airflow or respiratory) adj (disease* or disorder*)).ti,ab. (26232)
3 (copd or coad).ti,ab. (21514)
4 chronic airflow obstruction.ti,ab. (549)
5 exp emphysema/ (25645)
6 exp chronic bronchitis/ (6583)
7 ((chronic adj2 bronchitis) or emphysema).ti,ab. (25526)
8 or/1-7 (88664)
9 exp telecommunication/ (22728)
10 exp mass communication/ (274378)
11 (tele* or ehealth or e-health or mhealth or m-health).mp. [mP = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer] (121632)
12 ((remote or wireless or mobile) adj2 (monitor* or consult*)).mp. [mP = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer] (1182)
13 (Aerotel Medical or Aivea or AMD Global Telemedicine or American TeleCare or AvidCare or Carematix or Care2Wear or CareVoyant or Centura or Cifra or Clinidata or CyberCare or Cybernet or DexCom or ExceliCare or FireLogic or FONEMED or Health Buddy or Health Hero or HealthEngage or Health@nywhere or HomMed or Homecare Homebase or iCare Desktop or IEM GmbHOR or iMetrikus or InforMedix or INRange or Intelsis or Lifewatch or Lifelink or March Networks or McKesson or MDHome or Medic4All or MediCompass or MedNovations or MedShare or Morepress or Neptec or NewIt or Patient Care Technologies or PERS Buddy or Pharos or RemoteAccess or RemoteNurse or Senior Health Advantage Network or Spirotel or TCARE or Teledoctor or Telehealth Solutions or TeleMedic or Telescale or TouchPointCare or (Tunstall adj3 Genesis) or ViTel Net or VitalNet or Viterion or Well@home or WiPaM).mp. [mP = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer] (381)
14 or/9-13 (345125)
15 8 and 14 (954)
16 limit 15 to (human and english language and yr="2000 -Current") (584)

Appendix 2: Study Design and Participant Characteristics

Table A1: Design and Participant Characteristics of Included Studies of Home Telemonitoring*

Author, Year	Country	Outcomes	Recruit. Period/ Study Period	Length of Intervention/ Follow-up (months)	Patient Eligibility Criteria	Arms (n)	Intervention/Control
Randomized Controlled Trials (N = 3)							
Vitacca et al, 2009 (7)	Italy	• hospitalizations • time free of hospitalization • time free of exacerbation • time free of urgent GP call • time free of ED visit • mortality • cost	*Study period:* April 2004 – March 2007	12-month intervention with no additional follow-up	*Eligible participants:* All CRF patients discharged from a single hospital *Inclusion criteria*: 1) need for HMV, and/or need for LTOT and 2) ≥ 1 hospitalization for respiratory illness *Exclusion criteria*: 1) illiteracy, no home telephone, 2) nursing home resident, 3) no caregiver to facilitate telephone, or 4) refusal	Total (240) ---------- Total COPD (101) Intervention (57) Usual care (44)	Intervention *Timing:* Post discharge *Technology:* • pulse oximeter (Nonin 9500) • oximeter; Nonin, Plymouth, MN, USA) • pulse oximeter (Nonin 2500 oximeter; Nonin) plus modem (30 EM model Medical Botticelli web; Digicom, Cardano al Campo, Italy) *Components:* 1) No usual care 2) Home telemonitoring of oximetry data • real-time • nurse 3) Telephone support • scheduled • symptoms assessment • outcomes assessment • nurse 4) Telephone support • unscheduled • symptoms assessment • outcomes assessment • additional needs/questions • specialized physician 5) Coordinated feedback/management

Author, Year	Country	Outcomes	Recruit. Period/ Study Period	Length of Intervention/ Follow-up (months)	Patient Eligibility Criteria	Arms (n)	Intervention/Control
							• via telephone/email/visits • nurse • specialized physician • external contacts: GP <u>Usual care</u> Follow-up outpatient visits were scheduled every 3 months to assess compliance, HMV, and/or LTOT
Lewis et al, 2010a/b (3;4)	United Kingdom.	*Primary*: • hospitalizations *Secondary*: • COPD admissions • ED attendances • GP visits • length of stay • usage • SGRQ • hospital anxiety • hospital depression • EQ-5D • communication	NR	6-month intervention with additional 6 months of observational follow-up during which interventional arm received usual care	*Eligible participants:* Identified from a PR database *Inclusion*: 1) a primary diagnosis of moderate to severe COPD <u>and</u> 2) prescribed optimal medication <u>and</u> 3) at least 12 of 18 sessions in researcher's pulmonary rehabilitation program *Exclusion:* 1) chronic asthma and ILD, 2) no longer living at home, <u>or</u> 3) attended <12 PR sessions	Total (40) Intervention (20) Control (20)	<u>Intervention:</u> *Timing:* Median of 8 months after completion of PR *Technology*: • landline-connected care management system (doc@HOME Docobo Ltd, Bookham, UK) • handheld telemonitor (Docobo Health Hub, Docobo Ltd, Bookham, UK) • manual thermometer (model FT04-1, Beurer, Ulm, Germany) • pulse oximeter (Nonin Inc, Minnesota, USA) *Components:* 1) Usual care, plus: 2) Home telemonitoring of oximetry and temperature data • store-and-forward • chronic disease management team

Author, Year	Country	Outcomes	Recruit. Period/ Study Period	Length of Intervention/ Follow-up (months)	Patient Eligibility Criteria	Arms (n)	Intervention/Control
							3) Home monitoring • store-and-forward • symptoms assessment • medication assessment 4) Coordinated feedback/management • via telephone/visits • chronic disease management team: – specialized nurse – nurse case manager – respiratory physiotherapist <u>Usual care:</u> Continued chronic disease management by the chronic disease management team and hospital/primary care support at the discretion of the team
Koff et al, 2008 (2)	United States	*Primary:* • SGRQ *Secondary:* • Hospitalizations • ED visits • costs • satisfaction • communication	*Recruitment period:* November 2004 – June 2005	3-month intervention with no additional follow-up	*Eligible participants:* Recruited from 2 outpatient clinics at a single hospital *Inclusion*: 1) GOLD stage 3 or 4 COPD <u>and</u> 2) home telephone landline *Exclusion*: 1) active treatment for lung cancer, 2) illiteracy, 3) non-English speaking, or 4) inability to complete a 6-min walking test	Total (40) Intervention (20) Control (20)	<u>Intervention:</u> *Timing*: During management at an outpatient clinic *Technology:* • landline-connected care management system (Health Buddy System HealthHero Network, Palo Alto, CA, USA) • pulse oximeter (Tuffsat, GE Healthcare, Chalfont St Giles, UK) • FEV1 monitor (Microlife PF100, iCare Health Monitoring, Golden, CO, USA) • pedometer (Omron, Omron

Author, Year	Country	Outcomes	Recruit. Period/ Study Period	Length of Intervention/ Follow-up (months)	Patient Eligibility Criteria	Arms (n)	Intervention/Control
							Healthcare Inc., Bannockburn, IL, USA) *Components:* 1) No usual care 2) Self-management education • at enrolment by case manager (respiratory therapist) • reinforced through the landline-connected care management system 2) Disease-specific education • at enrolment by case manager 3) Home telemonitoring of oximetry, FEV1, and 6MWD • store-and-forward • case manager 4) Home monitoring • store-and-forward • symptoms assessment • medications assessment • case manager 5) Telephone support • unscheduled • additional needs/questions • case manager 6) Coordinated feedback/management • case manager • external contacts: GP <u>Usual care:</u> Continued on treatment regimen prescribed by their healthcare provider. The care coordinator made no attempt to change any aspect of the patient's treatment regimen at enrolment.

Author, Year	Country	Outcomes	Recruit. Period/ Study Period	Length of Intervention/ Follow-up (months)	Patient Eligibility Criteria	Arms (n)	Intervention/Control
Controlled Clinical Trials (N = 2)							
Pare et al, 2006 (5)	Canada	*Primary:* • costs *Secondary:* • hospitalizations • home visits • communication	*Recruitment period*: December 2003 – June 2004	6-month intervention with no additional follow-up	*Eligible participants*: Newly admitted patients with severe COPD at a single hospital *Inclusion*: 1) newly admitted, and 2) severe COPD, and 3) required frequent home visits *Exclusion*: 1) psychological or psychiatric disorders, 2) cognitive deficiency that prevented self-treatment, or 3) visual or motor deficiency that prevented use of telemonitoring technology (unless caregiver was able to help)	Total (29) Intervention (19) Control (10)	Intervention: *Timing:* Post-discharge *Technology:* Landline-connected care management system (New IT Technologies Inc., Montreal, Quebec) *Components:* 1) No usual care 2) Home telemonitoring of peak flow • store-and-forward • real-time alerts • nurse 3) Home monitoring • store-and-forward • real-time alerts • symptoms assessment • medications assessment • nurse 4) Coordinated feedback/management • via telephone • nurse • external contacts: GP Usual care: Traditional system of home visits
Sorknaes et al, 2011 (6)	Denmark	Primary: • hospitalizations Secondary: • length of Stay • hospitalizations	*Recruitment period:* June 2007 – March 2008 & August 2008 – January	1-month intervention with no additional follow-up	*Eligible participants:* All patients admitted due to acute exacerbation from COPD to a single hospital	Total (100) Intervention (50) Control (50)	Intervention *Timing:* Within 24 hours after patient discharge *Technology:* Computer with web camera, microphone, physiological measurement

Author, Year	Country	Outcomes	Recruit. Period/ Study Period	Length of Intervention/ Follow-up (months)	Patient Eligibility Criteria	Arms (n)	Intervention/Control
		due to exacerbation • time free from hospitalization	2009		*Inclusion criteria*: 1) COPD, and 2) acute exacerbation, and 3) ≥ 40 years of age, and 4) ≥ 10 pack years, and 5) able to use a phone *Exclusion criteria*: 1) communication problems, 2) previous participation in scientific study, 3) systolic blood pressure < 100 mmHg, 4) pH < 7.35 or pO_2 < 7.3 or saturation < 90%, 5) X-ray with lobar pneumonia or tumour or no X-ray taken, 6) other serious diseases, 7) cancer or severe heart failure (EF < 30%), 8) refused to participate, 9) nurse strike, holiday, not possible to get a suitcase, or 10) death before discharge		equipment, nurse call button and alarm button *Components:* 1) Home telemonitoring of pulse oximetry and lung function • real-time • video consultation • nurse 2) Home monitoring • real-time • symptoms assessment 3) Disease-specific education • by nurse during video monitoring sessions Usual care*:* NR

*Abbreviations: COPD, chronic obstructive pulmonary disease; CRF, chronic respiratory failure; ED, emergency department; EF, ejection fraction; EQ-5D, EuroQol-5D; FEV1, forced expiratory volume in 1 second; h, hour(s); GOLD, the Global Initiative for Chronic Obstructive Lung Disease; GP, general practitioner; HMV, home mechanical ventilation; ILD, interstitial lung disease; LTOT, long-term oxygen therapy; n, sample size; NR, not reported; Recruit., recruitment; SGRQ, St. George's Respiratory Questionnaire.

Table A2: Design and Participant Characteristics of Included Studies of Telephone Only Support*

Author, Year	Outcomes	Recruit. Period / Study Period	Length of Intervention / Follow-up (months)	Patient Eligibility Criteria	Arms (n)	Intervention/Control
Randomized Controlled Trials (N = 1)						
Wong et al, 2005 (8)	Primary: • CSES Secondary: • hospitalizations • length of stay • ED visits	NR	18-day intervention with additional 15- day follow-up	*Eligible participants:* All patients discharged from a single hospital *Inclusion criteria:* 1) diagnosis of COPD, and 2) no ischaemic heart disease, musculoskeletal disorders, or other diseases that might limit rehabilitation, and 3) able to speak Cantonese, and 4) alert and oriented, and 5) contactable by phone/mobile phone *Exclusion criteria:* 1) discharged to an old-age home, 2) serious abuse of alcohol or drugs, or suffering from a psychiatric disease, or 3) dying and/or unable to provide informed consent	Total (60) Intervention (30) Control (30)	Intervention: *Timing:* Post-discharge *Components:* Nurse-led post-discharge telephone support *Description:* A structured, individualized educational and supportive programme, which consisted of 2 telephone contacts on days 3–7 and days 14–20, lasting 10–20 minutes. The protocol consisted of 3 parts: assessment, management options, and evaluation. Usual care: Routine care without follow-up

*Abbreviations: COPD, chronic obstructive pulmonary disease; CSES, Chinese Self-Efficacy Scale; ED, emergency department; n, sample size; NR, not reported; Recruit., recruitment.

Appendix 3: Quality Characteristics

Table A3: Methodological Quality Characteristics of Included Trials of Home Telemonitoring*

Author, Year	n	Adequate Randomization	Adequate Allocation Concealment	Blinding	Baseline Measures Comparable	Sample Size/Power Calculation	Met Sample Size	Lost to Follow-Up	ITT
Vitacca et al, 2009 (7)	101	✓	?	X	X†	X*	?	?	X
Lewis et al, 2010a/b (3;4)	40	✓	✓	Single (some treating physicians and nurses and outcome assessors)	X‡	X	?	Intervention 2/20 (10%) Control 0/20 (0%)	?
Koff et al, 2008 (2)	40	✓	?	X	✓	✓	✓	Intervention 1/20 (5%) Control 1/20 (5%)	X
Pare et al, 2006 (5)	29	X	X	X	✓	X	X	0	✓
Sorknaes et al, 2011 (6)	100	X	X	X	X§	✓	✓	Intervention 2/50 (4%) Control 1/50 (2%)	✓

*Abbreviations: ITT, intention-to-treat analysis; n, sample size.

† Sample size/power calculation and baseline comparisons were estimated for full patient population (N = 240) and not for the unplanned COPD-only subgroup (n = 101).

‡ Intervention and control significantly differed in Body Mass Index (BMI), months since finishing pulmonary rehabilitation, and the Medical Research Council (MRC) dyspnoea score.

§ Intervention and control significantly differed in current smoking status.

Table A4: Methodological Quality Characteristics of Included Trials of Telephone Only Support*

Study	n	Adequate Randomization	Adequate Allocation Concealment	Blinding	Baseline Measures Comparable	Sample Size/Power Calculation	Met Sample Size	Lost to Follow-Up	ITT
Wong et al, 2005 (8)	60	✓	?	Single (outcome assessors only)	✓	✓	X	Intervention 2/30 (7%) Control 2/30 (7%)	✓

*Abbreviations: ITT, intention-to-treat analysis; n, sample size.

Appendix 4: GRADE evaluation

Table A5: GRADE Assessment of Quality of Evidence for Home Telemonitoring for the Outcome of Hospitalizations*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Lewis et al, 2010 (3;4) Pare et al, 2006 (5) Vitacca et al, 2006 (7) Koff et al, 2008 (2) Sorknaes et al, 2010 (6)	RCTs / CCTs	Very serious limitations • included non-randomized trials • lack of blinding • unplanned subgroup analysis • important baseline variables differed significantly in some trials • potential power concerns • other issues	Inconsistency	Potential issues with generalizability of intervention	No serious limitations	N/A	
	HIGH	-2 (LOW)	-1 (VERY LOW)	VERY LOW	VERY LOW	VERY LOW	**VERY LOW**

*Abbreviations: CCT, controlled clinical trial; N/A, not applicable; RCT, randomized controlled trial.

Table A6: GRADE Assessment of Quality of Evidence for Home Telemonitoring for the Outcome of Time Free of Hospitalization*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Vitacca et al, 2006 (7) Sorknaes et al, 2010 (6)	RCTs / CCTs	Very serious limitations • included non-randomized trials • unplanned subgroup analysis • lack of blinding • important baseline variables differed significantly or no comparison of baseline variables	No serious limitations	Potential issues with generalizability of intervention	No serious limitations	N/A	
	HIGH	-2 (LOW)	LOW	LOW	LOW	LOW	**LOW**

*Abbreviations: CCT, controlled clinical trial; N/A, not applicable; RCT, randomized controlled trial.

Table A7: GRADE Assessment of Quality of Evidence for Home Telemonitoring for the Outcome of Mortality*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Vitacca et al, 2006 (7)	RCTs HIGH	Very serious limitations • unplanned COPD subgroup analysis • lack of blinding • no comparison of baseline values for COPD subgroup • sample size and power calculations targeted to whole population not COPD subgroup • no ITT -2 (LOW)	No inconsistency LOW	Potential issues with generalizability of intervention LOW	No serious limitations LOW	N/A LOW	**LOW**

*Abbreviations: COPD, chronic obstructive pulmonary disease; ITT, intention-to-treat analysis; N/A, not applicable; RCT, randomized controlled trial.

Table A8: GRADE Assessment of Quality of Evidence for Home Telemonitoring for the Outcome of Quality of Life*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Koff et al, 2008 (2) Lewis et al, 2010 (3;4)	RCTs	Serious limitations • important differences in baseline variables • no ITT	Inconsistency	Potential issues with generalizability of intervention	No serious limitations	N/A	
	HIGH	-1 (MODERATE)	-1 (LOW)	LOW	LOW	LOW	**LOW**

*Abbreviations: ITT, intention-to-treat analysis; N/A, not applicable; RCT, randomized controlled trial.

Table A9: GRADE Assessment of Quality of Evidence for Home Telemonitoring for the Outcome of Length of Stay*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Lewis et al, 2010 (3;4) Pare et al, 2006 (5)	RCT / CCT	Very serious limitations • included non-randomized study • important differences in baseline variables • potential lack of power	No serious limitations	Potential issues with generalizability of intervention	No serious limitations	N/A	
	HIGH	-2 (LOW)	LOW	LOW	LOW	LOW	**LOW**

*Abbreviations: CCT, controlled clinical trial; N/A, not applicable; RCT, randomized controlled trial.

Table A10: GRADE Assessment of Quality of Evidence for Home Telemonitoring for the Outcome of Exacerbation*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Sorknaes et al, 2010 (6)	CCT HIGH	Very serious limitations • non-randomized • lack of blinding • intervention and usual care differed in current smoker status at baseline -2 (LOW)	No serious limitations LOW	Potential issues with generalizability of intervention LOW	No serious limitations LOW	N/A LOW	**LOW**

*Abbreviations: CCT, controlled clinical trial; N/A, not applicable.

Table A11: GRADE Assessment of Quality of Evidence for Home Telemonitoring for the Outcome of Emergency Department Visits*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Koff et al, 2008 (2) Lewis et al, 2010 (3;4)	RCTs / CCTs	Very serious limitations • included non-randomized trials • lack of blinding • important baseline variables differed significantly • no ITT	Inconsistency	Potential issues with generalizability of intervention	No serious limitations	N/A	
	HIGH	-2 (LOW)	(-1) VERY LOW	VERY LOW	VERY LOW	VERY LOW	**VERY LOW**

*Abbreviations: CCT, controlled clinical trial; ITT, intention-to-treat analysis; N/A, not applicable; RCT, randomized controlled trial.

Table A12: GRADE Assessment of Quality of Evidence for Home Telemonitoring for Time to Other Health Care Services*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Vitacca et al, 2006 (7)	RCTs HIGH	Very serious limitations • unplanned COPD subgroup analysis • lack of blinding • no comparison of baseline values for COPD subgroup • sample size and power calculations targeted to whole population not COPD subgroup • no ITT -2 (LOW)	No inconsistency LOW	Potential issues with generalizability of intervention LOW	No serious limitations LOW	N/A LOW	**LOW**

*Abbreviations: COPD, chronic obstructive pulmonary disease; ITT, intention-to-treat analysis; N/A, not applicable; RCT, randomized controlled trial.

Table A13: GRADE Assessment of Quality of Evidence for Telephone Only Support for the Outcome of Hospitalization*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Wong et al, 2005 (8)	RCT HIGH	No serious limitations HIGH	N/A HIGH	Very serious issues with generalizability • Chinese population • no comorbidities that may have limited pulmonary rehabilitation • intervention (adapted Chinese Self Efficacy Scale used to guide telephone follow-up) -2 (LOW)	No serious limitations LOW	N/A LOW	**LOW**

*Abbreviations: N/A, not applicable; RCT, randomized controlled trial.

Table A14: GRADE Assessment of Quality of Evidence for Telephone Only Support for the Outcome of Quality of Life*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Wong et al, 2005 (8)	RCT	No serious limitations	N/A	Very serious issues with generalizability • Chinese population • no comorbidities that may have limited pulmonary rehabilitation • intervention (adapted Chinese Self-Efficacy Scale used to guide telephone follow-up)	No serious limitations	N/A	
	HIGH	HIGH	HIGH	-2 (LOW)	LOW	LOW	**LOW**

*Abbreviations: N/A, not applicable; RCT, randomized controlled trial.

Table A15: GRADE Assessment of Quality of Evidence for Telephone Only Support for the Outcome of Length of Stay*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Wong et al, 2005 (8)	RCT	No serious limitations	N/A	Very serious issues with generalizability • Chinese population • no comorbidities that may have limited pulmonary rehabilitation • intervention (adapted Chinese Self Efficacy Scale used to guide telephone follow-up)	No serious limitations	N/A	
	HIGH	HIGH	HIGH	-2 (LOW)	LOW	LOW	**LOW**

*Abbreviations: N/A, not applicable; RCT, randomized controlled trial.

Table A16: GRADE Assessment of Quality of Evidence for Telephone Only Support for the Outcome of Emergency Department Visits*

Studies	Quality Assessment					Summary of Findings	
	Design	Quality	Consistency	Directness	Other Modifying Factors	Effect Size	Overall Quality
Wong et al, 2005 (8)	RCT	No serious limitations	N/A	Very serious issues with generalizability • Chinese population • no comorbidities that may have limited pulmonary rehabilitation • intervention (adapted Chinese Self Efficacy Scale used to guide telephone follow-up)	No serious limitations	N/A	
	HIGH	HIGH	HIGH	-2 (LOW)	LOW	LOW	**LOW**

*Abbreviations: N/A, not applicable; RCT, randomized controlled trial.

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ISSN 1915-7398 (online)
ISBN 978-1-4435-7017-6 (PDF)