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Action Plans for Individuals with Chronic Obstructive Pulmonary Disease (COPD): A Rapid Review

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Rapid Review Methodology

Clinical questions are developed by the Division of Evidence Development and Standards at Health Quality Ontario in consultation with experts, end-users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses; if none are located, the search is expanded to include randomized controlled trials (RCTs), and guidelines. Systematic reviews are evaluated using a rating scale developed for this purpose. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies included in the systematic review are retrieved and a maximum of two outcomes are graded. If no well-conducted systematic reviews are available, RCTs and/or guidelines are evaluated. Because rapid reviews are completed in very short timeframes, other publication types are not included. All rapid reviews are developed and finalized in consultation with experts.

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Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. Health Quality Ontario works with clinical experts, scientific collaborators, and field evaluation partners to develop and publish research that evaluates the effectiveness and cost-effectiveness of health technologies and services in Ontario.

Based on the research conducted by Health Quality Ontario and its partners, the Ontario Health Technology Advisory Committee (OHTAC)—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy makers.

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Table of Contents

List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
COPD	Chronic obstructive pulmonary disease
CI	Confidence interval(s)
ED	Emergency department
GP	General practitioner
HQO	Health Quality Ontario
HRQOL	Health-related quality of life
MD	Mean difference
n	Sample size
OR	Odds ratio
RCT	Randomized controlled trial

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Funding (QBF) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

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Objective of Analysis

The objective of this rapid review is to determine the effectiveness of action plans for individuals with chronic obstructive pulmonary disease (COPD). This review focuses on action plans themselves and excludes broader, more comprehensive self-management programs.

Clinical Need and Target Population

Acute Exacerbations of Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease is a disease state that is characterized by a limitation in airflow that is not fully reversible. This airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases. (1) The natural history of COPD involves periods of worsening symptoms known as acute exacerbations. There is some debate about the best definition for 'exacerbations.' A consensus definition developed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines an acute exacerbation as "an event in the natural course of the disease characterized by a change in the patient's baseline dyspnea, cough, and/or sputum that is beyond normal day-to-day variations, is acute in onset, and may warrant a change in regular medication." (2) Patients may also experience a variety of other symptoms such as worsening exercise tolerance, fatigue, malaise, and decreased oxygen saturation. (3)

Two-thirds of COPD exacerbations are caused by an infection of the tracheobronchial tree or by air pollution. The cause is unknown in the remaining cases. (2;4) Risk factors for exacerbations include disease severity, winter months, and a previous exacerbation over the past 8 weeks. (3;5) The frequency of exacerbations seems to vary with disease severity. Using data from the Inhaled Steroids in Obstructive Lung Disease Study (ISOLDE Study), the European Respiratory Society Study on COPD, and the Copenhagen City Lung Study, Donaldson et al (3) found that patients with severe disease (GOLD category III) experienced an average of 3.43 exacerbations per year, whereas patients with moderate disease (GOLD category II) experienced an average of 2.68 exacerbations per year. (3)

Exacerbations have an important impact on patients and on the health care system. For patients, exacerbations result in decreased quality of life, potential permanent loss in lung function, and increased risk of mortality. For patients with severe exacerbations that require hospitalization, estimates of inpatient mortality range from 4% to 30%. Higher hospital mortality rates are observed for patients admitted with

respiratory failure. Mortality following discharge is also high. Data from the United Kingdom show a 14% mortality rate within 3 months of readmission, and data from the United States show a 43% mortality rate after 12 months. (3;5) In addition, exacerbations of COPD are a leading cause of ED visits and hospitalizations, particularly in winter. The health care burden associated with exacerbations is high—inpatient costs have been estimated to account for 70% of total health care costs for COPD treatment. (6;7)

Ontario Context

In collaboration with the Family Physician Airways Group of Canada and Living Well with COPD, the Canadian Thoracic Society has developed a standardized action plan for individuals with COPD. It is available online at http://www.respiratoryguidelines.ca/COPD-actionplan.

Action Plans

Action plans are written instructions to help an individual with COPD identify an acute exacerbation and understand the steps that should be taken to treat it (e.g., changing medication, initiating antibiotics, or visiting a health care provider). (8;9) Action plans were developed to help patients initiate treatment quickly, since prompt treatment of acute exacerbations of COPD has been shown to result in faster recovery and a better quality of life compared to those individuals who neglect treatment for their exacerbations. (8) Action plans have been shown to be effective in the treatment of asthma. (8)

Action plans are one of many tools that can be used to promote self management in COPD. A 2009 systematic review by the Cochrane Collaboration defined self management as "educational programs aimed at teaching skills needed to carry out medical regimens specific to the disease, guide behaviour change, and provide emotional support for patients to control their disease and live functional lives." (10)

Rapid Review

Research Questions

What is the effectiveness of action plans for individuals with chronic obstructive pulmonary disease (COPD)?

Research Methods

Literature Search

A literature search was performed on September 15, 2012, using OVID MEDLINE, OVID MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, the Wiley Cochrane Library, and the Centre for Reviews and Dissemination database, for studies published from January 1, 2008, until September 15, 2012. Titles and 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.

Inclusion Criteria

- English language full-reports
- published between January 1, 2008, and September 15, 2012
- systematic reviews, meta-analyses, and health technology assessments
- analyses in which action plans are the primary intervention evaluated in the included studies

Exclusion Criteria

- analyses in which discrete results on COPD cannot be abstracted
- analyses that include studies evaluating comprehensive self-management programs in which the action plan component is not isolated

Outcomes of Interest

Clinical Outcomes

- Use of medications (steroids and antibiotics)
- Health-related quality of life (HRQOL)
- Mortality
- Lung function
- Functional capacity
- Symptoms

Health System Outcomes

- Emergency department (ED) visits
- Family physician or clinic visits

- Hospital admissions
- Hospital length of stay

Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodological quality of systematic reviews. (11)

Within the systematic review, the quality of the body of evidence for each outcome was examined according to the GRADE Working Group criteria. (12) The overall quality was determined to be very low, low, moderate, or high using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that may raise the quality of evidence were considered: large magnitude of effect, dose response gradient, and accounting for all residual confounding factors. (12) For more detailed information, please refer to the latest series of GRADE articles. (12)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	Very confident that the true effect lies close to the estimate of the effect
Moderate	Moderately confident in the effect estimate—the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Confidence in the effect estimate is limited—the true effect may be substantially different from the estimate of the effect
Very Low	Very little confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Results of Literature Search

The database search yielded 50 citations published between January 1, 2008, and September 15, 2012 (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment. Figure 1 shows the breakdown of when and for what reason citations were excluded in the analysis.

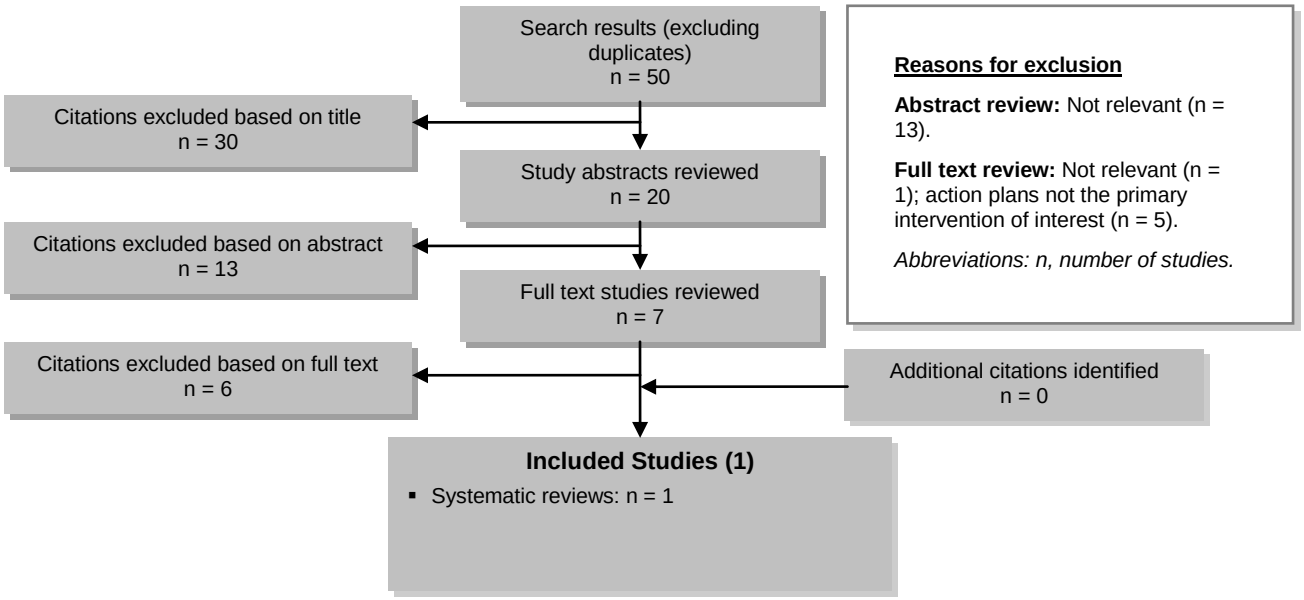

Figure 1: Citation Flow Chart

One study, a Cochrane Collaboration systematic review conducted by Walters et al, (8) met the inclusion criteria. Walters et al (8) defined action plans as "guidelines detailing self-initiated interventions (such as changing medication regime or visiting a [general practitioner] or hospital) which were undertaken in response to alternations in the state of the patients' COPD (e.g., increase in breathlessness, increased amount or purulence of sputum), i.e., changes that would suggest the commencement of an exacerbation." In addition to the action plan, the study's intervention could include a short education component (≤ 1 hour in length). Studies that examined comprehensive self-management programs in which the action plan component could not be isolated were excluded.

Walters et al (8) included 5 randomized controlled trials (RCTs) with 574 individuals with COPD who were followed for 6 to 12 months. The interventions varied: 2 studies used individualized action plans, 2 studies used standardized action plans, and 1 study provided individuals with instructions on what to do in an exacerbation. (8) The action plans were supplemented with prescriptions for antibiotics and corticosteroids in 4 of the studies, although not all patients received the prescriptions in 2 of the 4 studies. (8) Four of the studies provided individuals in the intervention group with additional education, including informational booklets (including information on smoking cessation, controlling breathlessness, nutrition, medications, etc.) and up to 1 hour of specific educational instruction. In the usual care groups, the individuals did not receive action plans. However, individuals did receive some education in 2 of the studies. (8)

Using the AMSTAR measurement tool to assess the methodological quality of the systematic review, Walters et al (8) had an overall score of 7 out of 11 (refer to Table A1 in Appendix 2 for more details). Walters et al (8) used GRADE to evaluate the overall body of evidence for several of the primary outcomes. The GRADE scores are discussed below.

Primary Outcomes

Health Care Utilization

For the majority of health care utilization outcomes examined, no statistically significant differences were observed in the action plan group compared with the usual care group. A summary of the pooled results are shown in Table 1 for hospital admissions, ED visits, and GP visits/phone calls.

Table 1: Meta-Analysis Results for Health Care Utilization Outcomes

Outcome	No. of Studies	No. of Participants	Mean Difference (95% CI)	GRADE Quality of Evidence
Hospital admission (12 m)	2	205	0.23 (−0.03 to 0.49)[a]	Moderate[b]
ED visits for COPD (12 m)	2	201	0.37 (−0.50 to 1.24)[c]	Moderate[b]
COPD-related GP visits / phone calls	3	256	0.53 (−0.45 to 1.50)[a]	Moderate[a]
Non-COPD GP visits / phone calls	2	200	1.25 (−1.54 to 4.03)[a]	NR

Abbreviations: CI, confidence intervals; ED, emergency department; GP, general practitioner; m, months; No, number; IV, inverse-variance; Not reported.

[a]Fixed effects model

[b]GRADE score was not downgraded due to important concerns regarding the potential risk of bias in the studies.

[c]Random effects model

Source: Walters JAE, Turnock AC, Walters EH, Wood-Baker R. Action plans with limited patient education only for exacerbations of chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2010, Issue 5. Art. No.: CD005074. DOI: 10.1002/14561858.CD005074.pub3.

In the systematic review, the assessment of the quality of the evidence for hospital admissions, COPD-related ED visits, and COPD-related GP visits/phone calls was downgraded to moderate quality of evidence because the estimate of effect includes both benefit and harm associated with action plans (imprecision/sparse evidence). (8) The authors did not downgrade the studies based on risk of bias; however, the review identifies a number of important concerns regarding the methodological quality of the studies included in these outcomes. For example, there was inadequate information in the published report of 1 of the 2 studies used in the pooled results for hospital admission and ED visits for COPD on randomization methods, allocation concealment, blinding of participants, outcome assessors, and personnel recruiting participants, how incomplete quality of life data were addressed, and whether the study is free of selective reporting and other biases. The second study also did not report adequate information on randomization methods and blinding of participants and outcome assessors. (8) Given that these are important methodological considerations, the GRADE scores could be downgraded to low quality. Therefore, the moderate GRADE level may overestimate the certainty in the estimate of effect.

One study (sample size [n], 89) did show a significant increase in the total number of ambulance calls in the action plan group compared with the usual care group (mean difference [MD], 1.70; 95% confidence interval [CI], 0.17–3.23). (8)

Use of Medications

Four studies reported information on the use of corticosteroids during the follow-up period. Although the study did not present the raw data, 1 study found that individuals in the action plan group were statistically significantly more likely to be treated with oral corticosteroids for an acute exacerbation over 12-months follow-up ($P < 0.001$). (8) Two studies showed a statistically significant increase in the number of courses of oral corticosteroids over 12 months of follow-up (n, 200; MD, 0.74; 95% CI, 0.12–1.35) (GRADE = moderate); however, the other 2 studies showed no statistically significant difference in the odds of being treated with at least 1 course of oral corticosteroids for an acute exacerbation (n, 200; odds ratio [OR], 2.60; 95% CI, 0.98–6.90) (GRADE = not reported). (8) Of note, as discussed above, the GRADE score does not take into consideration potentially important concerns regarding the

methodological quality of the studies. Therefore, the moderate GRADE level may overestimate the certainty in the estimate of effect.

In contrast, the pooled odds of being treated with at least 1 course of antibiotics for an acute exacerbation of COPD were statistically significantly higher (n, 349; OR, 2.02; 95% CI, 1.29–3.17), but there was no statistically significant difference in the number of courses of antibiotics (n, 200; MD, 0.78[1]; 95% CI, −0.24 to 1.79). (8) A statistically significant increase in the number of days on antibiotics was observed for the action plan group in 1 study (n, 56; MD, 6.00; 95% CI, 1.40 to 10.60). (8) While a similar trend in increased days on corticosteroids in the action plan group was also observed, this difference was not statistically significant (n, 56; MD, 6.00; 95% CI, −5.53 to 17.53). (8)

Secondary Outcomes

COPD Self-Management Knowledge and Actions

One study (n, 154) evaluated COPD self-management knowledge and actions using a validated standardized COPD self-management questionnaire. Overall, the study found that individuals in the action plan group had statistically significant higher scores for knowledge outcomes and for actions that participants would take when experiencing an acute exacerbation compared with the usual care group. The knowledge outcomes examined were recognition of respiratory health stability (MD, 1.10; 95% CI, 0.46–1.74), recognition of an early exacerbation (MD, 1.80; 95% CI, 0.75–2.85), and recognition of a severe exacerbation (MD, 2.50; 95% CI, 1.04–3.96). (8) Individuals in the action plan group also had statistically significantly higher scores for actions taken in an early exacerbation (MD, 2.30; 95% CI, 0.96–3.64) and actions in a severe exacerbation (MD, 1.50; 95% CI, 0.62–2.38) compared with the control group. (8)

A second study (n, 111) also evaluated COPD knowledge and found no significant differences between the action plan and control groups for knowledge or actions to be taken for an acute exacerbation. However, the questionnaire used to assess these outcomes is not validated. (8)

Other Outcomes

No statistically significant differences were observed for the other reported secondary outcomes of anxiety, depression, mortality, symptoms, functional capacity, or lung function. (8)

Walters et al (8) found that adverse effects were not well reported in the included studies, but references other literature which highlights potential concerns associated with increased adverse drug reactions due to increased oral corticosteroid use because of the use of action plans.

Summary of the Evidence

Overall, Walters et al (8) concluded that "the practice of giving patients an action plan and limited self management education for the management of COPD exacerbations, without a multi-faceted self management program or ongoing case management, cannot be recommended as the standard of care in COPD." This conclusion is based on evidence from other systematic reviews that have looked at more comprehensive self-management programs—in which action plans may be 1 component of the intervention—that have shown benefits for individuals with COPD. For example, a 2009 Cochrane Collaboration systematic review that evaluated COPD self-management education programs concluded that self-management education is associated with a reduction in hospital admissions. (10) Similarly, a systematic review by Peytremann-Bridevaux et al (13) concluded that COPD-disease management programs improved exercise capacity, health-related quality of life, and hospital admissions.

[1] The text of the review reports the mean differences as 0.79, but the forest plot and summary data table (Comparison 1. action plan versus usual care) report the mean difference as 0.78. (8)

Conclusions

Based on 1 systematic review that evaluated the effectiveness of action plans with or without limited education (education sessions up to 1 hour in length) compared with usual care, the following conclusions were reached:

- Action plans significantly increase antibiotic and corticosteroid use during an acute exacerbation.
- Action plans significantly increase patient knowledge about COPD and what actions to take during an exacerbation.
- Action plans do not impact health care utilization or other clinical outcomes including health-related quality of life, mortality, lung function, functional capacity, symptoms, anxiety, or depression.

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Appendices

Appendix 1: Literature Search Strategies

Search date: September 15, 2012
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE; Cochrane Library; CRD

Q: COPD action plans
Limits: 2008-current; English
Filters: health technology assessments, systematic reviews, and meta-analyses

Database: Ovid MEDLINE(R) <1946 to September Week 1 2012>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <September 14, 2012>, Embase <1980 to 2012 Week 37>
Search Strategy:

#	Searches	Results
1	exp Pulmonary Disease, Chronic Obstructive/ use mesz	19095
2	Chronic Obstructive Lung Disease/ use emez	60772
3	Chronic Bronchitis/ use emez	7298
4	(chronic adj2 obstructive adj2 (lung* or pulmonary or airway* or airflow or respiratory) adj (disease* or disorder*)).ti,ab.	61114
5	(copd or coad).ti,ab.	52753
6	chronic airflow obstruction.ti,ab.	1094
7	exp Emphysema/	39763
8	((chronic adj2 bronchitis) or emphysema).ti,ab.	53761
9	or/1-8	173230
10	Self Care/	46311
11	Patient Care Planning/	57345
12	Health Plan Implementation/ use mesz	3252
13	Health Care Planning/ use emez	71752
14	Treatment Planning/ use emez	85608
15	(action adj2 plan*).mp.	10482
16	((self adj (care or manag* or treat*)) or self-care or self-manag* or self-treat*).ti.	11431
17	((care or disease) adj manag*).ti.	8602
18	((care or disease or health or patient*) adj2 plan*).ti.	18638
19	Patient Care/	176297
20	*Patients/ use mesz	9149
21	*Patient/ use emez	133261
22	*Chronic Patient/ use emez	426
23	or/19-22	317588

24	Health Planning/ use mesz	20354
25	Planning/ use emez	15783
26	or/24-25	36137
27	23 and 26	1634
28	or/10-18,27	294968
29	Meta Analysis.pt.	36232
30	Meta Analysis/ use emez	65756
31	Systematic Review/ use emez	52961
32	exp Technology Assessment, Biomedical/ use mesz	8833
33	Biomedical Technology Assessment/ use emez	11371
34	(meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab.	288884
35	((health technolog* or biomedical technolog*) adj2 assess*).ti,ab.	3611
36	or/29-35	348468
37	9 and 28 and 36	112
38	limit 37 to english language	101
39	limit 38 to yr="2008 -Current"	51
40	remove duplicates from 39	42

Cochrane Library

MeSH descriptor: [Pulmonary Disease, Chronic Obstructive] explode all trees 1838
chronic near/2 obstructive near/2 (lung* or pulmonary or airway* or airflow or respiratory) next (disease* or disorder*):ti,ab,kw OR copd or coad:ti,ab,kw OR chronic airflow obstruction:ti,ab,kw 7234
MeSH descriptor: [Emphysema] explode all trees 92
(chronic near/2 bronchitis) or emphysema:ti,ab,kw 1932
#1 or #2 or #3 or #4 8822
MeSH descriptor: [Self Care] this term only 2158
MeSH descriptor: [Patient Care Planning] this term only 386
MeSH descriptor: [Health Plan Implementation] this term only 63
action near/2 plan* or (self next (care or manag* or treat*)) or self-care or self-manag* or self-treat*:ti or (care or disease) next manag*:ti or (care or disease or health or patient*) near/2 plan*:ti 1854
#6 or #7 or #8 or #9 3759
MeSH descriptor: [Patient Care] this term only 91
MeSH descriptor: [Patients] this term only 219
#11 or #12 310
MeSH descriptor: [Health Planning] this term only 58
#13 and #14 0
#5 and #10 76

CDSR=8
DARE=2
HTA=1

CRD

Line	Search	Hits
1	MeSH DESCRIPTOR Pulmonary Disease, Chronic Obstructive EXPLODE ALL TREES	298
2	(chronic adj2 obstructive adj2 (lung* OR pulmonary OR airway* OR airflow OR respiratory) adj (disease* OR disorder*)):TI OR (copd OR coad):TI OR (chronic airflow obstruction):TI	236
3	MeSH DESCRIPTOR Emphysema EXPLODE ALL TREES	19
4	((chronic adj2 bronchitis) OR emphysema):TI	50
5	#1 OR #2 OR #3 OR #4	372
6	MeSH DESCRIPTOR Self Care	282
7	MeSH DESCRIPTOR Patient Care Planning	62
8	MeSH DESCRIPTOR Health Plan Implementation	13
9	(action ADJ2 plan*) OR ((self ADJ (care OR manag* OR treat*)) OR self-care OR self-manag* OR self-treat*):TI OR ((care OR disease) ADJ manag*):TI OR ((care OR disease OR health OR patient*) ADJ2 plan*):TI	325
10	#6 OR #7 OR #8 OR #9	574
11	MeSH DESCRIPTOR Patient Care	26
12	MeSH DESCRIPTOR Patients	22
13	MeSH DESCRIPTOR Health Planning	32
14	#11 OR #12	48
15	#13 AND #14	0
16	#5 AND #10	25

Appendix 2: AMSTAR Checklist

Table A1: Results of Assessment of Systematic Review Quality Using AMSTAR

Question	Score and Details
1. Was an a priori design provided?	1 (yes): research question and inclusion criteria were clearly stated
2. Was there duplicate study selection and data extraction?	1 (yes): duplicate study selection and data extraction was used and there was a process in place to deal with disagreements
3. Was a comprehensive literature search performed?	1 (yes): > 2 electronic databases were searched, key words and MESH terms were stated
4. Was the status of publication (i.e., grey literature) used as an inclusion criteria?	0 (can't answer): this information was not provided in the review
5. Was a list of the studies (included and excluded) provided?	1 (yes): both included and excluded studies were listed
6. Were the characteristics of the included studies provided?	1 (yes): data from the original studies including characteristics of the participants, interventions, and outcomes were provided
7. Was the scientific quality of the included studies assessed and documented?	1 (yes): the Cochrane Collaboration risk of bias tool was used to assess the quality of the studies, and the overall quality of the evidence was assessed using GRADE
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	0 (no): while the quality of the studies was assessed and discussed, the quality of the evidence was not explicitly stated in the recommendations or in the conclusions
9. Were the methods used to combine the findings of the studies appropriate?	0 (no): for some outcomes (COPD GP visits/phone calls, non-COPD GP visits/phone calls, at least 1 course of antibiotics, at least 1 course of corticosteroids) there was substantial heterogeneity (I^2 > 50%), but the fixed effects model was still used
10. Was the likelihood of publication bias assessed?	1 (yes): the methods state that funnel plots were used to assess publication bias; however, the results of the funnel plot are not reported
11. Was the conflict of interest stated?	0 (no): while sources of support were listed for the systematic review authors, sources of support for the authors of the included studies were not reported
TOTAL SCORE	**7 out of 11**

Abbreviations: COPD, chronic obstructive pulmonary disease; GP, general practitioner; MESH, medical subject headings.

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