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ORIGINAL RESEARCH

# Quality indicators for in-hospital management of exacerbation of chronic obstructive pulmonary disease: results of an international Delphi study

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## Abstract

**Aim.** To report a Delphi study that was conducted to select process and outcome indicators that are relevant to study quality of care and impact of care pathways for patients hospitalized with exacerbation of chronic obstructive pulmonary disease.

**Background.** Management of patients hospitalized with exacerbation of chronic obstructive pulmonary disease is suboptimal and outcomes are poor. To evaluate the impact of care pathways properly, relevant indicators need to be selected.

**Design.** Delphi study.

**Methods.** The study was conducted over 4 months in 2008, with 35 experts out of 15 countries, including 19 medical doctors, 8 nurses and 8 physiotherapists. Participants were asked to rate, for 72 process and 21 outcome indicators, the relevance for follow-up in care pathways for in-hospital management of exacerbation of chronic obstructive pulmonary disease. Consensus (agreement by at least 75% of the participants) that an indicator is relevant for follow-up was sought in two rounds.

**Results.** Consensus was reached for 26 of 72 process indicators (36·1%) and 10 of 21 outcome indicators (47·6%). Highest consensus levels were found for the process indicators regarding oxygen therapy (100%), pulmonary rehabilitation (100%) and patient education (94·5–88·6%) and for the outcome indicators concerning understanding of therapy (91·4–85·7%) and self-management (88·6–88·2%).

**Conclusion.** The selected indicators appear to be sensitive for improvement. Therefore, researchers and clinicians that want to study and improve the care for patients hospitalized with exacerbation of chronic obstructive pulmonary disease should primarily focus on these indicators.

**Keywords:** care pathway, chronic obstructive pulmonary disease, Delphi technique, disease exacerbation, hospitalization, nursing, quality indicator

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## Introduction

Chronic obstructive pulmonary disease (COPD) is a disease state characterized by airflow limitation that is not fully reversible [Global Initiative for Chronic Obstructive Lung Disease (GOLD) (2009)]. Worldwide, the disease affects 9·8% of men and 5·6% of women (Halbert *et al.* 2006) and is a leading cause of morbidity and mortality (Mannino & Buist 2007).

Patients with COPD experience frequent exacerbations of symptoms, varying from 0·5–3·5 a year (Izquierdo *et al.* 2009, Seemungal *et al.* 2009, Chenna & Mannino 2010). COPD exacerbations are characterized by a change in baseline dyspnoea, cough and/or sputum that is beyond normal day-to-day variations; is acute in onset; and may warrant additional treatment in a patient with underlying COPD (Burge & Wedzicha 2003). COPD exacerbations contribute tremendously to the disease burden. They are a leading cause of hospital admission worldwide, with 35% of COPD patients having at least one admission a year and up to 40% of admitted patients having two or more readmissions a year (Garcia-Aymerich *et al.* 2003, Cao *et al.* 2006, Izquierdo *et al.* 2009).

Studies about in-hospital management of COPD exacerbations have shown suboptimal performance of care activities recommended by worldwide accepted guidelines, especially for arterial blood gas measurement, administration of corticosteroids, smoking cessation, patient education and referral to pulmonary rehabilitation (Decramer *et al.* 2003, Hosker *et al.* 2007, Lodewijckx *et al.* 2009). Similarly, studies about outcomes in patients hospitalized due to a COPD exacerbation have demonstrated poor and varying outcomes, especially for 6-month readmission (30–43%) (Groenewegen *et al.* 2003, Bratzler *et al.* 2004, Almagro *et al.* 2006); 30-day mortality (5·2–17·2%) (Agabiti *et al.* 2010); and 1-year mortality (23–37%) (Groenewegen *et al.* 2003, Bratzler *et al.* 2004).

## Background

A possible strategy to optimize care processes and to improve outcomes is the implementation of a care pathway, also known as critical pathway or clinical pathway (Pearson *et al.* 1995, Campbell *et al.* 1998, Panella *et al.* 2003, Vanhaecht *et al.* 2009). Care pathways are 'complex interventions for the multidisciplinary decision-making and organization of predictable care for a well-defined group of patients during a well-defined period, with the aim to enhance the quality of care across the continuum by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction and optimizing the use of resources' (Vanhaecht *et al.* 2007).

Although care pathways are used worldwide (Van Herck *et al.* 2004, Sermeus *et al.* 2005, Vanhaecht *et al.* 2006, Rotter *et al.* 2010), the effectiveness of care pathways for in-hospital management of COPD exacerbation is not known. A recent literature review on care pathways for COPD exacerbation revealed only four studies (Lodewijckx *et al.* 2011). Three studies used a pre-post test design; the fourth study was a non-randomized controlled trial comparing an experimental group where patients were treated according to a care pathway with a control group where usual care was provided. The studies described few positive effects of the care pathways on diagnostic processes and on clinical outcomes. Although, due to follow-up of very few and diverse indicators, limited statistical analysis and weak design of the studies, the internal validity of results is limited and so reliable conclusions could not be drawn (Lodewijckx *et al.* 2011). Therefore, appropriately designed research like a cluster randomized controlled trial is needed to evaluate the impact of COPD care pathways on performance of care processes and clinical outcomes (Campbell *et al.* 2007, Craig *et al.* 2008). To study quality of care and impact of care pathways for patients hospitalized with COPD exacerbation appropriately, a valid and feasible set of process and outcome indicators needs to be defined (Rubin *et al.* 2001, Campbell *et al.* 2003, Mainz 2003).

## The study

### Aim

The aim of this Delphi study was to select process and outcome indicators that are relevant to study quality of care and impact of care pathways for patients hospitalized with COPD exacerbation.

### Design

To select relevant process and outcome indicators, the Delphi consensus method was used. This method, which rigorously solicits and synthesizes expert opinion, is recommended in areas of knowledge where methodologically rigorous research evidence is limited and experts disagree on its interpretation. The Delphi method is a group facilitation technique designed to transform individual opinions into group consensus and includes two or more postal rounds of questionnaires. With this technique, a large group of experts can be consulted from a geographically dispersed population (Hasson *et al.* 2000, Campbell *et al.* 2003, Keeney *et al.* 2006). In this Delphi survey, consensus on relevance of indicators for follow-up in care pathways for COPD exacerbation was sought in two rounds of questionnaires (Figure 1).

### Participants

The objective was to generate an international and multidisciplinary Delphi panel of medical doctors, nurses and physiotherapists (Hasson *et al.* 2000, Keeney *et al.* 2006). Selection of the participants occurred by purpose sampling and was performed by a medical doctor, a clinical nurse specialist and a physiotherapist with internationally recognized experience and networking in COPD care.

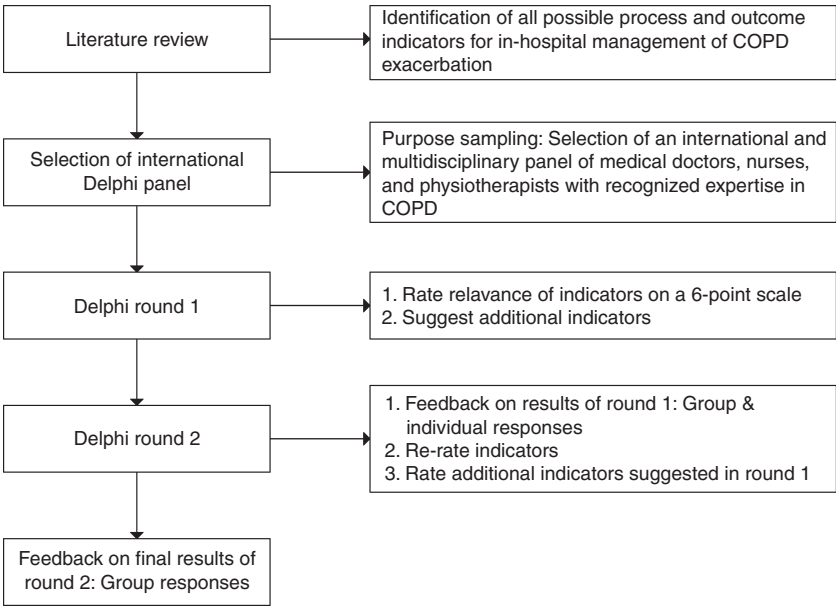


**Figure 1** The Delphi Survey.

For the selection of the medical doctors, members of the committee of the Global Initiative for Chronic Obstructive Lung Disease and the authors who contributed to the European Respiratory Monograph booklet regarding management of COPD were contacted (Siafkas & Wedzicha 2006, GOLD 2009). The nursing group and the physiotherapists were selected by contacting the allied respiratory professionals, assembly representatives of respective nurses and physiotherapists of the European Respiratory Society (http://www.ersnet.org). Finally, the first authors of the trials included in the reviews about 'adherence to international guidelines' (Lodewijckx *et al.* 2009) and about 'Impact of COPD care pathways' (Lodewijckx *et al.* 2011) were contacted.

To avoid major influence of organizational factors such as professional culture and clinical practice in organizations, we included for each of the three disciplines the criterion that experts from the same country had to be affiliated with different organizations. Also, the authors of this articlewere not part of the expert panel.

## Data collection

### *Delphi questionnaire and rating*

To develop a Delphi questionnaire including all possible process and outcome indicators for in-hospital management of COPD exacerbations, an extensive literature review was conducted by the first author. The following resources were explored: (i) Websites of international respiratory societies: American Thoracic Society (ATS), British Thoracic Society (BTS), European Respiratory Society (ERS), Global Strategy for Diagnosis, Management and Prevention of COPD (GOLD), National Institute for Health and Clinical Excellence (NICE) and (ii) Electronic databases: Medline, EMBASE, Cochrane library, CINAHL. The following search terms were used: COPD, disease exacerbation, management, patient care management, practice guideline and outcomes. Applied limits included: published between 2003–2008; written in English, French, German, Italian or Dutch; and (iii) Map of Medicine (http://www.mapofmedicine.com). A two-level screening of the publications was applied. Firstly, publications were assessed on relevance based on review of the title and abstract. Subsequently, the full text of the selected guidelines, reviews or process flows were reviewed. Following inclusion criteria were applied: (i) description of management or outcomes of patients hospitalized with COPD exacerbation; (ii) process indicators: evidence was reported in terms of guidelines, reviews or process flows; (iii) published between 2003–2008; (iv) published in English, French, German; Italian or Dutch; and (v) possible to assess strength of recommendations and the quality of the evidence.

As a result, five clinical practice guidelines (Celli & Macnee 2004, NICE 2004, Siafkas & Wedzicha 2006, Rodriguez-Roisin 2006, GOLD 2009); two process flows (Map of Medicine 2008a, 2008b); and 12 outcome studies were included (Seemungal *et al.* 1998, 2009, Garcia-Aymerich *et al.* 2003, Groenewegen *et al.* 2003, Roberts *et al.* 2003, Gudmundsson *et al.* 2005, Wang & Bourbeau 2005, Yohannes *et al.* 2005, Cao *et al.* 2006, Izquierdo *et al.* 2009, Agabiti *et al.* 2010, Chenna & Mannino 2010). Based on the selected literature, 72 process and 21 outcome indicators were identified.

The Delphi questionnaire, based on the literature search, included three main parts: 72 process indicators; 21 outcome indicators; and 9 demographic questions (city, country, name and type of organization, number of beds, professional group, years of experience, age and gender) (see supporting information Data S1 in the online version of the article in Wiley Online Library). The provisional Delphi questionnaire was pretested by a medical doctor, a nurse and a physiotherapist. These experts did not participate in the expert panel. Based on their feedback, the questionnaire was adapted where needed and a final version was constructed for surveying the expert panel.

For the first part with the 72 process indicators, experts were asked to rate, on a 6-point scale, what impact they believe that the listed processes have on clinical outcomes and therefore how relevant they believe that these process indicators are for follow-up in studies investigating quality of in-hospital management of COPD exacerbation. Score '1' meant 'low impact on outcomes and thus not relevant,' and score '6' meant 'high impact on outcomes and thus highly relevant.' For the second part with the 21 outcome indicators, experts were asked to rate, on a 6-point scale, how sensitive to change they believe the listed outcome indicators would be when implementing a COPD care pathway and therefore how relevant they believe that these outcome indicators are for follow-up in studies investigating quality of in-hospital management of COPD exacerbations. Score '1' meant 'low sensitive to change and thus not relevant,' and score '6' meant 'high sensitive to change and so highly relevant.' A 6-point rating scale was used to avoid a tendency to score 'in the middle' (Polit & Beck 2006). Panellists were also offered the opportunity to suggest additional process and outcome indicators, or other remarks concerning the Delphi questionnaire.

### *Content validity index and consensus*

The content validity index (CVI) refers to the proportion of experts who are in agreement about content validity and thus

 

relevance of a specific item (Wynd *et al.* 2003). In this study, CVI for a specific indicator refers to that proportion of experts that scored 5 or 6 for that indicator. A CVI of 75% or higher in round 2 was considered to be consensus by the panel that an indicator is relevant for follow-up in COPD exacerbation care pathways (Hasson *et al.* 2000). This cut-off point was defined at the outset of the study.

*Delphi survey*

The Delphi survey was conducted by electronic mail between September 2008–December 2008 (Hasson *et al.* 2000). At the outset of the study, it was decided that the Delphi survey would include two rounds of responses (Figure 1) (Hasson *et al.* 2000, Keeney *et al.* 2006). Invitation for participation in the Delphi study, together with explanation about the aim of the study and the Delphi procedure was included in the mailing of round 1 (Hasson *et al.* 2000). Also, as background information, the GOLD guidelines were included. These are evidence-based guidelines for COPD diagnosis, management and prevention, developed by GOLD (2009). For each mailing round, panellists were asked to return the completed datasheets in 2 weeks. Confidentially was guaranteed in this way that respondents will be known to the researcher and even to one another, but their judgments and opinions remain strictly confidential (McKenna 1994).

For the first round, according to each discipline, the panellists were contacted by three recognized leaders of the European Respiratory Society (ERS) (http://www.ersnet.org), namely the vice president (MD), the secretary of the ERS assembly group 'Physiotherapists' and the chair of the ERS assembly group 'Nurses'. We believed this mailing strategy would increase the response rate (Hasson *et al.* 2000, Keeney *et al.* 2006). The mailing for round 2 was sent by the main researcher (CL). A reminder was sent 1 month after the initial mailing (Hasson *et al.* 2000).

In the first round, the panellists were asked to rate the relevance of each process and outcome indicator and to provide the demographic information. In round 2, feedback on the round 1 responses was provided to all panellists, presented by following summary statistics: number of respondents who answered the questionnaire; number of respondents who rated 1 or 2, 3 or 4 and 5 or 6 (percentage); central tendencies (median, mode); and the respondent's own responses (Hasson *et al.* 2000, Keeney *et al.* 2006). Using this information, respondents were asked to re-rate the indicators in case they wanted to change their previous answer. Experts were also asked to rate the process and outcome indicators suggested by the respondents in round 1. The results of round 2 were considered as the final results of the Delphi survey. If participants of round 1 did not respond in round 2, their answers of round 1 were considered as final answers.

In a final and third mailing, feedback on the final group results was provided. This included a final list of all process and outcome indicators for which consensus (CVI ≥ 75%) was obtained, or in other words, all the indicators that were rated 5 or 6 by at least 75% of the panellists in round 2. Also an overview of the involved experts was provided.

### Ethical considerations

The research protocol was approved by the research ethics committee at Leuven University (identifier: ML5617). Consent to participation was considered to be present when the participant returned the questionnaire. To inform potential participants in a proper manner, we provided one sheet with explanation and aim of the study, their involvement in it, how the Delphi works and what was expected of them. Finally, to respect privacy of each participant, it was guaranteed to the panellists that their judgments and opinions would remain strictly confidential (McKenna 1994).

### Data analysis

Results were analysed and presented in two ways: results obtained by the overall panel and results obtained per discipline. Descriptive statistics were used to report the expert panel responses. To assess the differences in CVIs between the three disciplines, *P* values from the Kruskal–Wallis exact test were calculated. Two-tailed tests were used and *P* values were considered statistically significant if $P < 0{\cdot}05$. If important differences were found, a post hoc Mann–Whitney *U*-test was performed to assess which pairs of groups had important differences. Finally, to adjust for multiple testing, the Bonferroni correction was used; consequently *P* values were considered statistically significant if $P < 0{\cdot}017$. Data were analysed using the statistical software program SPSS version 16.0 [IBM SPSS Statistics 19 International Business Machines Corporation (IBM)., Armonk, NY, USA].

## Results

### Participant characteristics

In round 1, 35 of 50 contacted experts returned the questionnaire (response rate: 70·0%). The panel included representatives from three continents (Table 1) and 15 countries: Australia ($n = 1$), Belgium ($n = 4$), France ($n = 2$), Germany ($n = 2$), Greece ($n = 1$), Ireland ($n = 1$), Italy ($n = 1$), Poland

**Table 1** Characteristics of the Delphi panel ($n$ = 35).

| Characteristics | $n$ (%) |
|---|---|
| Gender | |
| Male | 22 (62·9) |
| Female | 13 (37·1) |
| Age* (years) | |
| 30–49 | 14 (40·0) |
| 50–69 | 19 (54·3) |
| ≥70 | 1 (2·9) |
| Discipline | |
| Medical doctor | 19 (54·3) |
| Nurse | 8 (22·9) |
| Physiotherapist | 8 (22·9) |
| Years of experience in respiratory care* | |
| 5–14 | 7 (20·0) |
| 15–24 | 11 (31·4) |
| 25–34 | 11 (31·4) |
| ≥40 | 5 (14·3) |
| Type of institution | |
| Academic hospital | 25 (71·4) |
| Community teaching hospital | 4 (11·4) |
| Respiratory physiotherapy centre | 2 (5·7) |
| Primary care trust | 2 (5·7) |
| Research centre for medical studies | 2 (5·7) |
| Number of beds, $n$ (%)† | |
| <200 | 9 (31·0) |
| 200–399 | 5 (17·2) |
| 400–599 | 6 (20·7) |
| 600–799 | 5 (17·2) |
| ≥800 | 8 (27·6) |
| Continent, $n$ (%) | |
| Australia | 1 (2·9) |
| Europe | 30 (85·7) |
| North America | 4 (11·4) |

*$n$ = 34 (missing: $n$ = 1; 2·9%).
†$n$ = 29 hospitals.

($n$ = 1), Portugal ($n$ = 1), Spain ($n$ = 2), Sweden ($n$ = 1), the Netherlands ($n$ = 2), Turkey ($n$ = 1), UK ($n$ = 11) and USA ($n$ = 4). The respondents included 19 medical doctors (54·3%), 8 nurses (22·9%) and 8 physiotherapists (22·9%). All respondents had at least 5 years of experience in respiratory care, with 77·1% of the experts reporting 15 years or more of experience. Twenty-five panellists (71·4%) were affiliated with academic hospitals and 4 (11·4%) with community teaching hospitals. Other affiliated organizations were respiratory physiotherapy centres ($n$ = 2), primary care trusts ($n$ = 2) and research centres for medical studies ($n$ = 2). The number of beds in the 29 hospitals varied from less than 200 beds (31·0%) to 800 beds and more (27·6%). In round 2, 31 of 35 panellists who participated in round 1 returned the completed questionnaire (response rate: 88·6%), including 17 of 19 medical doctors (89·5%), 6 of 8 nurses (75·0%) and all 8 physiotherapists (100%).

### Results of the overall panel: process indicators

Experts reached consensus (CVI ≥75%) for 26 of 72 process indicators (36·1%). Table 2 lists the indicators in descending order of the CVIs. A CVI of 100% was reached for three process indicators: 'controlled oxygen therapy', 'initiation of long-term oxygen therapy (LTOT)', and 'referral to pulmonary rehabilitation'. Also, a CVI of more than 90% was reached for five other process indicators: 'education about recognition and treatment of exacerbations' (97·1%), 'identification for pulmonary rehabilitation' (94·3%), 'education about inhaler therapy' (94·3%), 'smoking cessation advice when active smoker' (91·4%) and 'treatment of comorbid conditions' (91·4%).

Table 2 also displays the CVIs obtained after round 1. Ten indicators shifted from CVI <75% in round 1 to consensus (CVI ≥75%) in round 2 (Table 2, nos. 9, 11, 15, 19, 20, 22, 23, 24, 25, 26). Furthermore, for all other indicators, except for 'arterial blood gas measurement at admission' (Table 2, no. 21), CVIs increased with 5–10% in round 2.

Four other process indicators were suggested by participants in round 1: 'glucose control', 'assessment and management of anxiety and depression', 'patient education about coping strategies for possible depression and self-management' and 'monitoring following discharge for at least 2 weeks'. In the second round no consensus was reached for these additional indicators.

### Results of the overall panel: outcome indicators

Consensus (CVI ≥75%) was reached by the overall panel for 10 of 21 outcome indicators (47·6%). Table 2 also lists the outcome indicators in descending order of the CVIs. A CVI of 91·4% was obtained for the indicator 'correct use of inhaler therapy'. Six indicators reached a CVI between 85–89%: 'successful management at home' (88·6%), 'able to cope in usual environment' (88·2%), 'correct use of oral therapy' (85·7%), 'correct use of oxygen therapy (85·7%), 'interval before next admission' (85·7%) and 'health-related quality of life' (85·7%).

Outcome indicators for which consensus (CVI ≥75%) was obtained in round 1 were the same in round 2; however, CVIs of 8 of the 10 outcome indicators (80%) increased in round 2 (Table 2). Six additional indicators were suggested by the panellists: 'fat-free mass index (FMI)', 'fatigue', 'functional status', 'type of social support', 'type of follow-up' and 'unplanned use of healthcare

 

system'. No consensus was reached for these extra indicators in the second round.

### Results per discipline: process indicators

Medical doctors reached consensus (CVI ≥75%) for 22 of 72 process indicators (30·6%) and nurses and physiotherapists each for 40 of 72 indicators (55·6%). Table 3 lists all process and outcome indicators for which consensus was reached in each professional group. The indicators are presented in descending order of the CVIs of the medical doctors, because this discipline was mostly represented in the panel (Table 1) and because 39 of 72 scored indicators (54·2%) included strict medical indicators.

The Kruskal–Wallis test, performed for all 72 scored process indicators, revealed 12 important differences in CVIs

**Table 2** Content validity indexes of the process indicators for which consensus was reached by the overall panel*.

| | Content validity index* Round 1 | Content validity index* Round 2 |
|---|---|---|
| | *n*/*n* (%) | *n*/*n* (%) |
| Process indicators | | |
| 1. Controlled oxygen therapy in hypoxemic patients | 31/35 (88·6) | 35/35 (100) |
| 2. Initiation of long-term oxygen therapy (LTOT) if the patient remains hypoxemic | 30/35 (85·7) | 35/35 (100) |
| 3. Referral to pulmonary rehabilitation | 34/35 (97·1) | 35/35 (100) |
| 4. Patient education: Information about recognition and treatment of exacerbations | 32/35 (91·4) | 34/35 (97·1) |
| 5. Identification for pulmonary rehabilitation | 31/35 (88·6) | 33/35 (94·3) |
| 6. Patient education: Instruction on how to use inhalers and other treatments | 31/35 (88·6) | 33/35 (94·3) |
| 7. Smoking cessation advice when active smoker | 30/35 (85·7) | 32/35 (91·4) |
| 8. Treatment of comorbid conditions | 31/35 (88·6) | 32/35 (91·4) |
| 9. Medical history before exacerbation: Number of previous exacerbations in the previous year | 25/35 (71·4) | 31/35 (88·6) |
| 10. Medical history before exacerbation: pre-existing comorbidities | 27/35 (79·4) | 31/35 (88·6) |
| 11. Pulse oximetry: prior to discharge in patients hypoxemic during a COPD exacerbation | 26/35 (74·3) | 31/35 (88·6) |
| 12. Appropriate prescription of long-acting bronchodilatators (B-agonists and/or anticholinergics) | 28/35 (80·0) | 31/35 (88·6) |
| 13. Antibiotics in patients if indicated | 29/35 (82·9) | 31/35 (88·6) |
| 14. Patient education: Information about oxygen treatment | 27/35 (77·1) | 31/35 (88·6) |
| 15. Medical history before exacerbation: documentation of possible limitation of daily activities | 26/35 (74·3) | 30/35 (85·7) |
| 16. Appropriate prescription of glucocorticosteroids: oral or intravenous | 25/35 (75·8) | 30/35 (85·7) |
| 17. Physiotherapy: Activities of Daily Life | 28/35 (80·0) | 30/35 (85·7) |
| 18. Assessment of differential diagnosis | 28/35 (80·0) | 30/35 (85·7) |
| 19. Medical history before exacerbation: cardiovascular status | 24/35 (68·6) | 29/35 (82·9) |
| 20. Pulse oximetry at admission | 24/35 (68·6) | 29/35 (82·9) |
| 21. Arterial blood gas measurement at admission | 29/35 (82·9) | 29/35 (82·9) |
| 22. Arterial blood gas measurement: prior to discharge in patients hypoxemic during a COPD exacerbation | 24/35 (70·6) | 29/35 (82·9) |
| 23. Fluid administration in dehydrated patients | 26/35 (74·3) | 29/35 (82·9) |
| 24. Assessment of symptoms | 23/35 (65·7) | 28/35 (80·0) |
| 25. Assessment and management of social situation | 26/35 (74·3) | 28/35 (80·0) |
| 26. Patient education: information about the nature of COPD | 22/35 (62·9) | 28/35 (80·0) |
| Outcome indicators | | |
| 1. Patient and/or home caregiver fully understands correct use of inhaler | 30/35 (85·7) | 32/35 (91·4) |
| 2. Patient, family and physician are confident that the patient can manage successfully at home | 28/35 (80·0) | 31/35 (88·6) |
| 3. Able to cope in usual environment | 26/35 (76·5) | 30/35 (88·2) |
| 4. Patient and/or home caregiver fully understand correct use of oral therapy | 30/35 (85·7) | 30/35 (85·7) |
| 5. Patient and/or home caregiver fully understand correct use of inhaler therapy | 28/35 (80·0) | 30/35 (85·7) |
| 6. Patient and/or home caregiver fully understand correct use of oxygen therapy (LTOT) | 27/35 (77·1) | 30/35 (85·7) |
| 7. Interval before next admission | 26/35 (76·5) | 30/35 (85·7) |
| 8. Health-related quality of life | 24/35 (70·6) | 30/35 (85·7) |
| 9. Patient, if previously ambulatory, is able to cope with basic needs in his/her situation | 27/35 (77·1) | 28/35 (80·0) |
| 10. Mortality within 1 year after exacerbation | 30/35 (85·7) | 28/35 (80·0) |

*Content validity index (CVI): Proportion of experts scoring 5 or 6 for a specific indicator (score of 5 or 6 means that the indicator is scored as highly relevant for follow-up); Consensus: CVI ≥75% obtained in round 2.

**Table 3** Content validity indexes of process and outcome indicators for which consensus was reached by medical doctors, nurses and physiotherapists*.

| | Content validity index* Round 2 | | | |
|---|---|---|---|---|
| | Medical doctors, *n/n* (%) | Nurses, *n/n* (%) | Physio-therapists, *n/n* (%) | *P*§ |
| Process indicators† | | | | |
| 1. Controlled oxygen therapy in hypoxemic patients‡ | 19/19 (100) | 8/8 (100) | 8/8 (100) | 1·000 |
| 2. Initiation of long-term oxygen therapy (LTOT) if the patient remains hypoxemic‡ | 19/19 (100) | 8/8 (100) | 8/8 (100) | 0·336 |
| 3. Referral to pulmonary rehabilitation‡ | 19/19 (100) | 8/8 (100) | 8/8 (100) | 0·065 |
| 4. Treatment of comorbid conditions‡ | 19/19 (100) | 6/8 (75·0) | 7/8 (87·5) | 0·885 |
| 5. Patient education: Information about recognition and treatment of exacerbations‡ | 18/19 (94·7) | 8/8 (100) | 8/8 (100) | 0·048 |
| 6. Medical history before exacerbation: Number of previous exacerbations in the previous year‡ | 18/19 (94·7) | 7/8 (87·5) | 6/8 (75·0) | 0·128 |
| 7. Medical history before exacerbation: Pre-existing comorbidities‡ | 18/19 (94·7) | 7/8 (87·5) | 6/8 (75·0) | 0·803 |
| 8. Identification for pulmonary rehabilitation‡ | 17/19 (89·5) | 8/8 (100) | 8/8 (100) | 0·026 |
| 9. Patient education: Instruction on how to use inhalers and other treatments‡ | 17/19 (89·5) | 8/8 (100) | 8/8 (100) | 0·170 |
| 10. Smoking cessation advice when active smoker‡ | 17/19 (89·5) | 7/8 (87·5) | 8/8 (100) | 0·575 |
| 11. Assessment of differential diagnosis‡ | 17/19 (89·5) | 7/8 (87·5) | 6/8 (75·0) | 0·813 |
| 12. Medical history before exacerbation: Cardiovascular status‡ | 17/19 (89·5) | 6/8 (75·0) | 6/8 (75·0) | 0·462 |
| 13. Appropriate prescription of long-acting bronchodilatators (B-agonists and/or anticholinergics)‡ | 16/19 (84·2) | 8/8 (100) | 7/8 (87·5) | 0·463 |
| 14. Antibiotics in patients if indicated‡ | 16/19 (84·2) | 8/8 (100) | 7/8 (87·5) | 0·046 |
| 15. Patient education: Information about oxygen treatment‡ | 16/19 (84·2) | 8/8 (100) | 7/8 (87·5) | 0·347 |
| 16. Appropriate prescription of glucocorticosteroids: Oral or intravenous‡ | 16/19 (84·2) | 8/8 (100) | 6/8 (75·0) | 0·436 |
| 17. Pulse oximetry: Prior to discharge in patients hypoxemic during a COPD exacerbation‡ | 15/19 (78·9) | 8/8 (100) | 8/8 (100) | 0·137 |
| 18. Arterial blood gas measurement at admission‡ | 15/19 (78·9) | 7/8 (87·5) | 7/8 (87·5) | 0·842 |
| 19. Arterial blood gas measurement: Prior to discharge in patients hypoxemic during a COPD exacerbation‡ | 15/19 (78·9) | 6/8 (75·0) | 8/8 (100) | 0·291 |
| 20. Assessment and management of social situation‡ | 15/19 (78·9) | 6/8 (75·0) | 7/8 (87·5) | 0·391 |
| 21. Pulmonary testing after discharge: Spirometry‡ | 15/19 (78·9) | *4/8 (50·0)* | 6/8 (75·0) | 0·357 |
| 22. Deep venous thrombosis prophylaxis | 15/19 (78·9) | *1/8 (12·5)* | *5/8 (62·5)* | 0·041 |
| 23. Medical history before exacerbation: Documentation of possible limitation of daily activities‡ | *14/19 (73·7)* | 8/8 (100) | 8/8 (100) | 0·070 |
| 24. Physiotherapy: Activities of Daily Life‡ | *14/19 (73·7)* | 8/8 (100) | 8/8 (100) | 0·016 |
| 25. Pulse oximetry at admission‡ | *14/19 (73·7)* | 8/8 (100) | 7/8 (87·5) | 0·395 |
| 26. Fluid administration in dehydrated patients‡ | *14/19 (73·7)* | 7/8 (87·5) | 8/8 (100) | 0·019 |
| 27. Patient education: Information about the nature of COPD‡ | *14/19 (73·7)* | 6/8 (75·0) | 8/8 (100) | 0·571 |
| 28. Assessment and management for anxiety and depression | *11/16 68·8* | 4/5 (80·0) | 5/6 (83·3) | 0·289 |
| 29. Assessment of symptoms‡ | *13/19 (68·4)* | 7/8 (87·5) | 8/8 (100) | 0·143 |
| 30. Smoking status | *13/19 (68·4)* | 7/8 (87·5) | 6/8 (75·0) | 0·203 |
| 31. Pulse oximetry: In the following 3 months in patients hypoxemic during a COPD exacerbation | *13/19 (68·4)* | 7/8 (87·5) | 6/8 (75·0) | 0·836 |
| 32. Assessment of comorbidities | *12/19 (63·2)* | 6/8 (75·0) | *4/8 (50·0)* | 0·503 |
| 33. Physiotherapy: Endurance exercise training | *12/19 (63·2)* | 6/8 (75·0) | 7/8 (87·5) | 0·023 |
| 34. Patient education: self-management plan | *10/16 (62·5)* | 4/5 (80·0) | 5/6 (83·3) | 0·530 |
| 35. Medical history before exacerbation: Present treatment regimen | *11/19 (57·9)* | 7/8 (87·5) | *5/8 (62·5)* | 0·538 |
| 36. Pulse oximetry: After discharge in patients with LTOT | *11/19 (57·9)* | 6/8 (75·0) | 6/8 (75·0) | 0·388 |
| 37. Appropriate prescription of short-acting bronchodilators | *10/19 (52·6)* | 6/8 (75·0) | *5/8 (62·5)* | 0·296 |

**Table 3** (*Continued*)

| | Content validity index* Round 2 | | | |
|---|---|---|---|---|
| | Medical doctors, *n/n* (%) | Nurses, *n/n* (%) | Physio-therapists, *n/n* (%) | $P^{\S}$ |
| 38. Patient education: Strategies for minimizing dyspnoea | *10/19 (52·6)* | 6/8 (75·0) | 8/8 (100) | 0·005 |
| 39. Referral to dietician in patient with obesity or cachexy | *10/19 (52·6)* | 6/8 (75·0) | 7/8 (87·5) | 0·515 |
| 40. Physiotherapy: Resistance training to improve skeletal muscle strength | *9/19 (47·4)* | 6/8 (75·0) | 8/8 (100) | 0·003 |
| 41. Monitoring following discharge for at least 2 weeks | *3/16 (37·5)* | 4/5 (80·0) | 3/6 (50·0) | 0·224 |
| 42. Supplementary nutrition in patients with BMI >20 | *7/19 (36·8)* | 6/8 (75·0) | 8/8 (100) | 0·001 |
| 43. Physiotherapy: Chest physiotherapy | *6/19 (31·6)* | *5/8 (62·5)* | 8/8 (100) | 0·002 |
| Outcome indicators | | | | |
| 1. Able to cope in usual environment | 17/19 (89·5) | 7/8 (87·5) | 7/8 (87·5) | 0·941 |
| 2. Patient and/or home caregiver fully understand correct use of inhaler | 16/19 (84·2) | 8/8 (100) | 8/8 (100) | 0·158 |
| 3. Patient, family and physician are confident that the patient can manage successfully at home | 16/19 (84·2) | 7/8 (87·5) | 8/8 (100) | 0·819 |
| 4. Interval before next admission | 16/19 (84·2) | 7/8 (87·5) | 7/8 (87·5) | 0·553 |
| 5. Patient and/or home carer fully understand correct use of oral therapy | 15/19 (78·9) | 8/8 (100) | 7/8 (87·5) | 0·107 |
| 6. Patient and/or home carer fully understand correct use of inhaler therapy | 15/19 (78·9) | 8/8 (100) | 7/8 (87·5) | 0·248 |
| 7. Patient and/or home carer fully understand correct use of oxygen therapy (LTOT) 095 | 15/19 (78·9) | 8/8 (100) | 7/8 (87·5) | 0·095 |
| 8. Health-related Quality of Life | 15/19 (78·9) | 8/8 (100) | 7/8 (87·5) | 0·683 |
| 9. Unplanned use of the healthcare system | *11/14 (78·6)* | *2/6 (33·3)* | *3/6 (50·0)* | 0·406 |
| 10. Mortality within 1 year after exacerbation | *14/19 (73·7)* | 7/8 (87·5) | 7/8 (87·5) | 0·690 |
| 11. Patient, if previously ambulatory, is able to cope with basic needs in his/her situation | *13/19 (68·4)* | 7/8 (87·5) | 8/8 (100) | 0·263 |
| 12. Patient has been clinically stable for 12–24 hours | *13/19 (68·4)* | 7/8 (87·5) | *5/8 (62·5)* | 0·941 |
| 13. Symptoms at rest and during exercise | *11/18 (61·1)* | *5/8 (62·5)* | 7/8 (87·5) | 0·125 |
| 14. Patient satisfaction with therapy and care | *10/19 (52·6)* | 6/8 (75·0) | 6/8 (75·0) | 0·082 |
| 15. Patient is able to eat and sleep without frequent awakening by dyspnoea | *10/19 (52·6)* | 7/8 (87·5) | 7/8 (87·5) | 0·144 |
| 16. Patient satisfaction with therapy and care | *10/19 (52·6)* | 6/8 (75·0) | 6/8 (75·0) | 0·082 |
| 17. Patient's perception of coordination between hospital and home health care | *9/19 (47·4)* | *4/7 (57·1)* | 6/8 (75·0) | 0·183 |
| 18. Type of social support | *6/14 (42·9)* | 4/5 (80·0) | *2/6 (33·3)* | 0·321 |
| 19. Length of stay (LOS) | *8/19 (42·1)* | *5/8 (62·5)* | 6/8 (75·0) | 0·131 |
| 20. Six-minute walking distance | *7/19 (36·8)* | 4/8 (50·0) | 6/8 (75·0) | 0·130 |

*Content validity index (CVI): Proportion of experts scoring 5 or 6 for a specific indicator (score of 5 or 6 means that the indicator is scored as highly relevant for follow-up); Consensus: CVI ≥75% obtained in round 2; Italic means no consensus (CVI < 75% obtained in round 2).
†Process and outcome indicators are displayed in descending order of CVIs obtained by medical doctors.
‡Indicators for which overall consensus was obtained in round 2 (nos. 1–20; nos. 23–27; no. 29).
§*P* values were considered significant if <0·05.

between disciplines, varying from differences of 5% to 70% (Table 3, nos. 5, 8, 14, 22, 24, 26, 33, 38, 40, 42, 43). One important difference was not displayed in the table, namely 'medical history: documenting frequency and severity of cough,' as no consensus was reached for this indicator by any of the three disciplines. CVIs for this indicator of medical doctors, nurses and physiotherapists were, respectively, 5·3%, 25·0% and 0·0% ($P$ = 0·026).

After Mann–Whitney *U*-tests with Bonferroni correction, eight important differences in CVIs between disciplines were found (Table 4). These included differences in CVIs of 30–60% between medical doctors and physiotherapists about hydration, nutrition, education and physiotherapy (Table 4, nos. 2, 3, 4 and 5) and a difference of more than 60% between medical doctors and nurses concerning deep venous prophylactics (Table 4, no. 7).

### Results per discipline: outcome indicators

Concerning outcome indicators, medical doctors reached consensus for 4 of 20 outcome indicators (20%), nurses for 13 of 20 indicators (60·0%) and physiotherapists for 11 of 20 indicators (55·0%) (Table 3). The outcome indicators are also presented in descending order of the CVIs of

**Table 4** Significant differences in content validity indexes between disciplines after Mann–Whitney test with Bonferroni correction.

| | Content validity index* Round 2 | | | |
|---|---|---|---|---|
| Process indicators | Medical doctors, *n/n* (%) | Nurses, *n/n* (%) | Physio-therapists, *n/n* (%) | $P^{\dagger}$ |
| 1. Identification for pulmonary rehabilitation | 17/19 (89·5) | | 8/8 (100) | 0·016 |
| 2. Fluid administration in dehydrated patients | *14/19 (73·7)* | | 8/8 (100) | 0·011 |
| 3. Supplementary nutrition in patients with BMI >20 | *7/19 (36·8)* | | 8/8 (100) | 0·000 |
| 4. Patient education: Strategies for minimizing dyspnoea | *10/19 (52·6)* | | 8/8 (100) | 0·002 |
| 5. Physiotherapy: Resistance training to improve skeletal muscle strength | *9/19 (47·4)* | | 8/8 (100) | 0·002 |
| 6. Physiotherapy: Chest physiotherapy | 17/19 (89·5) | | 6/8 (75·0) | 0·001 |
| 7. Deep venous thrombosis prophylaxis | 15/19 (78·9) | *1/8 (12·5)* | | 0·010 |
| 8. Physiotherapy: Endurance exercise training | | 6/8 (75·0) | 7/8 (87·5) | 0·001 |

*Content validity index (CVI): Proportion of experts scoring 5 or 6 for a specific indicator (score of 5 or 6 means that the indicator is scored as highly relevant for follow-up); Consensus: CVI ≥75% obtained in round 2. Italic means no consensus (CVI <75% obtained in round 2).

†Bonferroni correction: *P* values are considered significant if <0·017.

the medical doctors in Table 3. The Kruskal–Wallis test showed no important differences in CVIs between disciplines; however, non-significant differences in consensus of 30% or more were found for six outcome indicators (Table 3, nos. 9, 11, 15, 18, 19 and 20).

## Discussion

Consensus that an indicator is relevant for follow-up in studies on quality of in-hospital management of COPD exacerbation was reached by the overall Delphi panel for 26 of 72 process indicators (36·1%) and 10 of 21 outcome indicators (47·6%). Highest consensus levels were reached for the process indicators concerning oxygen therapy (100%), patient education (100%) and pulmonary rehabilitation (100%) and for the outcome indicators regarding understanding of therapy (91·4–85·7%) and self-management (88·6–88·2%) (Table 2).

### Strengths and limitations

Some methodological issues need to be addressed. Firstly, we used the Delphi technique, which is a structured facilitation technique that explores consensus among a group of experts by synthesizing opinions (Hasson *et al.* 2000, Campbell *et al.* 2003). Several other consensus techniques exist, including consensus development conferences, the nominal group technique, the RAND appropriateness method and iterated consensus rating procedures (Campbell *et al.* 2003). The Delphi method was selected because it does not require face-to-face contact and therefore enables the anonymous inclusion of a large number of individuals across diverse locations and expertise (Campbell *et al.* 2003). Moreover, one of the key advantages of Delphi is that persuasive or prestigious experts cannot have undue influence on the opinions of others, as could happen in a face-to-face meeting of experts (Keeney *et al.* 2006).

Secondly, selection procedure and composition of the expert panel need to be discussed. Delphi studies use individuals with known or demonstrable expertise in the subject being investigated (Hasson *et al.* 2000, Keeney *et al.* 2006). Based on this principle, participants cannot be selected randomly. Instead, purposive sampling needs to be used, which implies that individuals are selected by an experienced investigator based on particular characteristics required of the sample members (Trochim 2009). The sampling procedure resulted in 35 international experts from 15 developed countries, with 30 experts from Western Europe, one expert from Australia and finally four experts, respectively, from the United States. While 12 of 15 involved countries had a comparable representation of one participant ($n$ = 8 countries) or two participants ($n$ = 3 countries) in the panel, two countries (Belgium and the US) had four representatives. Finally, the UK was represented in the panel by a considerably higher number of 11 experts (including seven medical doctors, three nurses and one physiotherapist). The unequal representation of the countries and lack of representatives from other developed countries in the Delphi panel could have biased the results because of influence of cultural and economic features. However, since 2000, several worldwide established, rigorous evidence-based clinical practice guidelines (CPGs) have been developed for the assessment and management of patients with COPD (Pierson 2006); for example, the guidelines of the GOLD (2009); the American Thoracic Society (ATS)-European Respiratory Society (ERS) Task Force Celli & Macnee (2004); and the NICE (2004). These CPGs are remarkably consistent and have very few areas of clinically relevant discrepancy. Moreover, these

 

guidelines, intended for worldwide use, are available free via the internet and provide for regular updating. Therefore, it is assumed that COPD experts out of developed countries are more or less familiar with these guidelines and the optimal management strategies addressed in the guidelines. In consequence, it is a reasonable assumption that lack or unequal representation of certain developed countries in the panel, although each with their own socio-demographic influences did not have major impact on Delphi results. Also important, no experts from continents like Africa, Asia and South America were included. However, we believe that non representation of these continents in the Delphi panel would not have affected our results, as our primarily aim was to achieve knowledge for the developed healthcare systems. In conclusion, it is to believe that selected indicators and related management strategies are universal applicable in developed countries (Marchal *et al.* 2003). A third issue is the multidisciplinary character of the Delphi panel. This multidisciplinary approach is unique and favourable for validity and credibility of results, since COPD patients require specific multidisciplinary care, with medical doctors, nurses and physiotherapists being the prime actors in care for patients hospitalized with COPD exacerbation (Kuzma *et al.* 2008). After Mann–Whitney test with Bonferroni correction, eight important differences between the disciplines were found, including differences between medical doctors, on the one hand and physiotherapists and nurses, on the other hand (Table 4). These eight indicators were 'non-medical' interventions like physiotherapy, revalidation, hydration and nutrition. These results confirm the need for inclusion of a multidisciplinary panel to rate multidisciplinary indicators. Also, these findings suggest that it is recommendable to also consider those indicators for which no overall consensus but consensus in one or two disciplines was obtained (Table 3).

We note that twice as many doctors were included in the Delphi panel in comparison to the nurses and physiotherapists (Table 1). On the one hand, this is justifiable as 39 of 72 scored process indicators (54·2%) were strictly medical indicators. On the other hand, this unequal representation could have biased the overall results and the results per discipline. Firstly, as also indicated by the findings of our study (Table 3), it is evident that each panellist tends to rate higher for indicators related to their own discipline. In this study, the higher presentation of medical doctors may have biased the overall results in favour of the strictly medical indicators. In our study, 18 of 26 finally selected process indictors (69·2%) were strictly medical indicators (Table 2). Although, this finding could also be explained by the fact that half of 72 process indicators (54·2%) included in the Delphi questionnaire were indeed strictly medical indicators. Secondly, with regard to the results per discipline, medical doctors reached consensus for half as many process and outcome indicators (20–30%) compared with nurses and physiotherapists (55–60%) We believe that this finding can possibly be explained by the higher representation of medical doctors in the panel, since it is evident that the more persons are included, the fewer the likelihood that consensus will be reached (Polit & Beck 2006).

A fourth methodological issue has to do with the identification of the indicators to build the Delphi questionnaire. It would have been interesting if we also considered the document of the ATS/ERS about outcomes for COPD pharmacological trials, as this provides a systematic overview of possible outcome measures (Cazzola *et al.* 2008). Based on this document, outcomes as functional status, dyspnoea, frequency of exacerbation and topics regarding socioeconomic burden (i.e. use of healthcare resources, productivity losses and economic analysis) could also have been included in the questionnaire. The initial included outcome parameters could have been described in a more standardized way. Finally, response rates could be considered high and so favourable for validity of results, as they varied from 70% in round 1–88·6% in round 2.

### Relevance of the set of process and outcome indicators

Looking to the 26 process indicators for which consensus was reached by the overall Delphi panel, it turned out that these indicators refer to care activities that are suboptimally performed according to the literature regarding COPD management (Decramer *et al.* 2003, Hosker *et al.* 2007, Lodewijckx *et al.* 2009); for example, referral to pulmonary rehabilitation, smoking cessation and patient education. Similarly, the selected outcome indicators refer to clinical outcomes that, according to outcome studies, are poor and show high variability across different hospitals; for example, readmission, mortality and quality of life. The high accordance between Delphi results and the literature suggests that the selected indicators have potential for improvement and therefore are relevant for follow-up when studying the impact of interventions implemented to improve performance on care processes and clinical outcomes concerning in-hospital management of COPD exacerbation (Panella *et al.* 2003).

### The European Quality of care pathways study on COPD exacerbation

The European Pathway Association has launched the European Quality of Care Pathways (EQCP) study, a

## What is already known about this topic

- In-hospital management of exacerbation of chronic obstructive pulmonary disease is suboptimal compared with recommendations of guidelines accepted worldwide and outcomes during and after hospitalization are poor.
- A possible strategy to optimize care processes and to improve outcomes is the implementation of a care pathway, also known as critical pathways or clinical pathways.
- To study the impact of a care pathway for chronic obstructive pulmonary disease exacerbation on performance of care processes and outcomes, relevant indicators need to be defined.

## What this paper adds

- An international Delphi panel identified 26 process and 10 outcome indicators for in-hospital management of exacerbation of chronic obstructive pulmonary disease.
- The selected indicators have potential for improvement and therefore are relevant for research on quality of in-hospital management of exacerbation of chronic obstructive pulmonary disease.
- When different clinical disciplines are represented in the Delphi panel, also results without overall consensus but with consensus in at least one discipline should also be considered.

## Implications for practice and/or policy

- Considering their potential for improvement, researchers and clinicians that want to study and improve the care for patients hospitalized with chronic obstructive pulmonary disease exacerbation should primarily focus on these indicators.
- These indicators should also be embedded in daily clinical practice to encourage continuous quality assessment and improvement of care for patients hospitalized with exacerbation of chronic obstructive pulmonary disease.
- Future randomized controlled trials are needed to address whether the selected indicators are really sensible to change and furthermore to evaluate reliability and feasibility of the indicators

cluster randomized controlled trial, with the aim to measure the impact of care pathways on performance of care processes and clinical outcomes in patients hospitalized with an COPD exacerbation (Vanhaecht *et al.* 2010a). Care pathways aim to standardize care processes and to improve clinical outcomes (Vanhaecht *et al.* 2006, 2009). In the EQCP study, process and outcome indicators will be followed up in organizations where a pathway was implemented compared with organizations where usual care is provided. The selected set of process and outcome indicators will be applied in this study (Vanhaecht *et al.* 2010b).

## Conclusion

By conducting the Delphi survey with 35 experts out of 15 countries, 26 process and 10 outcome indicators were selected as being relevant for follow-up of care provided to patients hospitalized with COPD exacerbation. The selected indicators refer to care activities and outcomes that, according to earlier studies, are poor and show high variability across different hospitals, which indicate that these indicators are sensitive for improvement. Therefore, researchers and clinicians who want to appropriately study quality of care and impact of care pathways for patients hospitalized with COPD exacerbation should primarily focus on these indicators. In addition, indicators should be embedded in daily clinical practice to encourage continuous quality assessment and improvement. Moreover, variance analysis and continuous evaluation of process and outcome indicators is a main characteristic in care pathways (Vanhaecht *et al.* 2007).

Future randomized controlled trials are needed to address whether or not the selected indicators are really sensitive to change and furthermore to evaluate reliability and feasibility of the indicators. Also, when applying these indicators in a clinical practice setting, multidisciplinary decision-making by all stakeholders is recommended to decide which of these indicators should be followed up with regard to feasibility (data collection, time and man power) and interest of the involved stakeholders.

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## Conflict of interest

No conflict of interest has been declared by the authors.

## Author contributions

All authors meet at least one of the following criteria (recommended by the ICMJE: http://www.icmje.org/ethical_1author.html) and have agreed on the final version:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

## Supporting Information

Additional Supporting Information may be found in the online version of this article:

**Data S1.** Questionnaire.

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