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Original Article

Indicators of pulmonary exacerbation in cystic fibrosis: A Delphi survey of patients and health professionals

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Abstract

Background: There is uncertainty about the most important indicators of pulmonary exacerbations in CF.
Methods: Two parallel Delphi surveys in 13 CF centres (UK and Ireland). Delphi 1: 31 adults with CF, ≥ one exacerbation over 12 months. Delphi 2: 38 CF health professionals. Rounds 1 and 2 participants rated their level of agreement with statements relating to indicators of exacerbation; Round 3 participants rated the importance of statements which were subsequently placed in rank order.
Results: Objective measurements were of higher importance to health professionals. Feelings of increased debility were rated most important by adults with CF.
Conclusions: There were clear differences in perspectives between the two groups as to the most important indicators of an exacerbation. This highlights that CF health professionals should take more cognisance of specific signs and symptoms reported by adults with CF, especially since these may be a precursor to an exacerbation.

Keywords: Pulmonary exacerbation; Delphi technique; Cystic fibrosis

1. Introduction

Pulmonary exacerbations (PEXs) in cystic fibrosis (CF) are associated with disease progression, increased morbidity, mortality, and substantial healthcare costs [1–4]. PEXs are experienced by a large proportion of patients with CF. The most recent annual information from the CF Registry of Ireland reported 451 paediatric admissions and 680 adult admissions for a PEX treated with intravenous antibiotics, using data that was available for 881 registered patients [5]. The CF Registry of the UK reported 3732 paediatric lung infections and 5062 adult lung infections using data that was available for 8794 registered patients [6]. Minimising PEXs is critical for the long term health of adults with CF since patients who have more than two PEXs per year have a significantly reduced three year survival compared to those who have one or none [4]. PEXs are associated with a more rapid decline in FEV_1, which results in a further decline in overall wellbeing [7,8]. Health related quality of life (HRQoL) worsens during PEX and more severe exacerbations have a greater negative impact on HRQoL [1,8]. Most people with CF die of respiratory failure which has typically been induced by a PEX [9–11].

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PEXs are also frequently used as an end point in clinical trials and recommended by European Medicines Agency (EMA) and Food and Drug Administration (FDA) as primary efficacy end points [2,12–14]. However, neither agency mandates any definition of a PEX. Consequently definitions used in clinical trials are multiple and are inconsistent with each other [15]. In addition, they often show inconsistencies with criteria routinely used by CF health professionals [16–18].

Previously it was suggested that the Delphi technique is an appropriate methodology to identify which criteria should be included in a definition of a PEX in CF [17]. This technique uses a series of repeated surveys to gain consensus on a given issue [19–22].

This method reduces peer pressure and encourages unbiased responses, as participants remain anonymous to the core members of the research team and to other participants [19,21–23]. The Delphi technique is a practical, efficient, inexpensive and widely used consensus research method in health care research [24,25].

The aim of this study was to identify the important indicators of an exacerbation determined by a group of adults with CF and a group of CF health professionals.

2. Methods

2.1. Design and recruitment

Two parallel Delphi surveys were used to investigate agreement among a group of adults with CF and CF health professionals regarding the important indicators of an exacerbation.

This was a multicentre study across the UK and Ireland. Twenty-seven CF centres were approached to take part aiming to recruit two to three adults with CF and two to three CF health professionals per centre. Participants were identified by a designated key health professional at each CF centre who was responsible for ensuring that all participants met the inclusion criteria for their participant group. The inclusion criteria for adults with CF were: confirmed diagnosis of CF, over 18 years, FEV_1 less than or equal to 80% predicted, experienced at least one exacerbation requiring IV antibiotics in the previous 12 months and computer literate with internet access available for the duration of the study. The inclusion criteria for CF health professionals were: CF health professionals working in adult CF centres in the UK/Ireland, currently involved in assessing if CF patients are having an exacerbation and deciding a treatment plan and computer literate with internet access available for the duration of the study.

The stages of this Delphi survey are summarised in Fig. 1. Ethical approval was obtained from the Office for Research Ethics Committees Northern Ireland. Research governance was sought at participating sites. Data collection took place over a seven month period (Sept 2010–April 2011). In each round non responders were followed up and sent weekly reminders to complete the survey.

2.2. Delphi Round 0: statement generation

The aim of Round 0 was to generate a list of statements for Round 1 of the Delphi survey. The first step in developing the Delphi survey for this study was to conduct a systematic literature search and extract criteria used to identify an exacerbation. This search identified 218 criteria from 86 articles. However, there were many similarities in the terminology used, consequently criteria that were similar in meaning were grouped together to

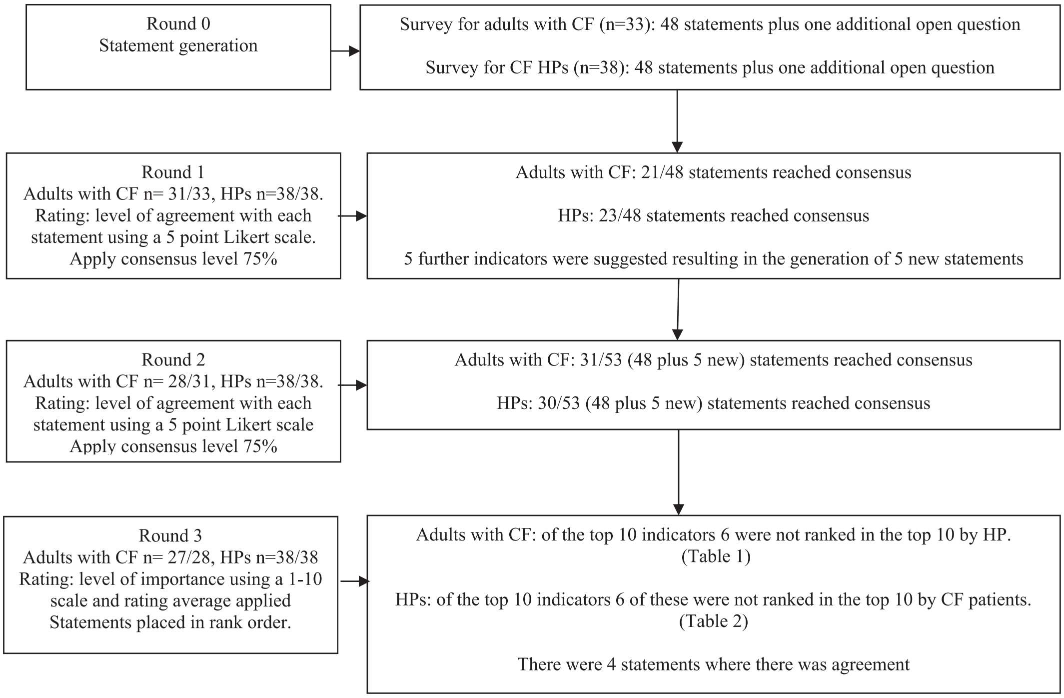

Fig. 1. **Summary of the stages of the Delphi surveys**. Key. Health professionals: HPs, cystic fibrosis: CF.