

Original Article

Cystic fibrosis research in allied health and nursing professions[☆]

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Received 23 September 2011; received in revised form 7 March 2012; accepted 7 March 2012

Available online 17 April 2012

Abstract

This report is the result of the “Allied Health and Nursing Professions Working Group” meeting which took place in Verona, Italy, November 2009, which was organised by the European Cystic Fibrosis Society, and involved 32 experts. The meeting was designed to provide a “roadmap” of high priority research questions that can be addressed by Allied Health Professionals (AHP) and nursing. The other goal was to identify research skills that would be beneficial to AHP and nursing researchers and would ultimately improve the research capacity and capability of these professions. The following tasks were accomplished: 1) a Delphi survey was used to identify high priority research areas and themes, 2) common research designs used in AHP and nursing research were evaluated in terms of their strengths and weaknesses, 3) methods for assessing the clinimetric and psychometric properties, as well as feasibility, of relevant outcome measures were reviewed, and 4) a common skill set for AHPs and nurses undertaking clinical research was agreed on and will guide the planning of future research opportunities. This report has identified important areas and themes for future research which include: adherence; physical activity/exercise; nutritional interventions; interventions for the newborn with CF and evaluation of outcome measures for use in AHP and nursing research. It has highlighted the significant challenges AHPs and nurses experience in conducting clinical research, and proposes strategies to overcome these challenges. It is hoped that this report will encourage research initiatives that assess the efficacy/effectiveness of AHP and nursing interventions in order to improve the evidence base. This should increase the quality of research conducted by these professions, justify services they currently provide, and expand their skills in new areas, with the ultimate goal of improving care for patients with CF.

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Keywords: Allied Health Professions; Nursing; Research areas; Research design; Outcome measures; Key research skills

[☆] Supported by: ECFS International Physiotherapy Group for Cystic Fibrosis, International Nurse Specialists Group (CF), European Cystic Fibrosis Nutrition Group and Psychosocial Special Interest Group. The meeting was sponsored by the following organisations: Belgian CF Association; Chiesi, UK; Gilead; Novartis; Respiration; Transave; University of Ulster.

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1. Introduction

Allied Health Professionals (AHPs) and nurses provide interventions to patients that impact the physical, psychological, social and emotional impact of CF [1]. These interventions contribute greatly to the overall management of patients with CF. However, recent CF guidelines have highlighted the need to improve the quality of AHP and nursing research and thus, a consensus conference was convened to identify both the priority areas for future AHP and nursing research and to identify research skills which can be improved. There are a number of barriers for AHPs and nurses to overcome to increase the quality of their research: limited time because of high clinical workloads; a lack of formal recognition of research responsibilities in AHP/nursing job plans; a lack of research leadership and mentorship; difficulty obtaining funding; and a general lack of knowledge about research design and statistical techniques that are appropriate for answering AHP and nursing questions [2–4].

The European Cystic Fibrosis Society (ECFS) organised a meeting that focused on AHP and Nursing Research in Verona in November 2009. This meeting was designed to identify priority areas for AHP and nursing research in CF and to establish strategies for increasing research capacity and capability. To address these aims, the conference had four objectives:

1. To identify and prioritise key research areas for AHP and nursing research in CF
2. To identify optimal study designs for AHP and nursing research in CF
3. To identify appropriate outcome measures for AHP and nursing studies in CF (a. patient-reported outcomes; b. objective and physiological endpoints)
4. To identify skills needed to conduct AHP and nursing research with paediatric and adult patients

2. Overview of the document

An international group of 32 multidisciplinary experts and one lay member addressed each of the specific aims outlined above. This paper summarises our conclusions and recommendations, and where relevant, makes reference to electronic supplementary information that complements this paper.

3. Objective 1: identification and prioritisation of key research areas for AHP and nursing in CF

A Delphi survey was used to identify priority research areas and themes for AHPs and nurses [5–8]. Priority areas and themes were defined as AHP and nursing questions and topics that could be addressed in clinical research and could potentially attract funding. Results from trials/studies in these areas were deemed important to improve care, could potentially change clinical practice and were likely to have a significant impact on CF care and/or the quality of life of patients with CF.

The Delphi process and subsequent results are summarised in Fig. 1. The results of the Delphi process were discussed,

along with the extensive literature reviews conducted by participants, to confirm these gaps in the literature, and to focus more specifically on key research questions. The following areas were considered high priority for AHP and nursing research:

- Adherence: assessment, exploration of barriers and adherence interventions
- Exercise/physical activity: a. physical activity/exercise versus airway clearance techniques for bronchial hygiene in stable CF patients; b. exercise/physical activity in the well patient with CF; c. exercise tests for children with CF, d. nutritional/exercise interventions to improve body composition
- Airway clearance techniques and interventions for the newborn with CF
- Evaluation of outcome measures for use in AHP and nursing research

The European Working Group did not attempt to prioritise this list further and concluded that all these areas were identified as important areas for further research. It was anticipated that clinicians undertaking research and also grant funding organisations would find this list useful to ensure their research fell “within areas” identified as important at a European level as important for further research.

Table 1 shows the Top 10 Research Themes agreed upon in the Delphi survey. The identification of research themes in the Delphi survey was separate from the “identification of priority areas” and this has resulted in some themes identified in the Delphi survey e.g. “antibiotics, inhaled therapies, infection control” not linking to priority research areas. It is likely that this has occurred as participants were asked to rate the “priority” of research areas—a priority was defined as “AHP and nursing” questions/topics that could be addressed in clinical research and could potentially attract funding. Research on e.g. antibiotics and inhaled therapies whilst very important, requires large multicentre studies often driven by the pharmaceutical industry and therefore not considered high priority for AHP and nursing research.

Although the authors acknowledge limitations in the Delphi methodology used to generate these themes, it is hoped that this information will be valuable to clinicians undertaking research and grant funding organisations to prioritise important areas and themes for research funding in CF. Further information on the results of the Delphi study results is available electronically (Table 2 <http://www.ecfs.eu/projects/ahp-nursing-research/tables>).

4. Objective 2: identification of optimal study designs for AHP and nursing research in CF

Key research designs used in AHP and nursing research, including randomised controlled trials (RCTs), cohort or case control studies, cross sectional surveys, single system studies, case reports, case series and interview methods, were reviewed. The working group agreed that there was not one research design suitable for all AHP and nursing questions and that it was important to choose the correct research design to answer the question of interest. In order to guide these decisions, the

Stage 1. Rationale: To develop a list of areas and themes for consideration as priority for AHP/nursing research	
Methods	Results
<ul style="list-style-type: none"> • 32 multi-disciplinary experts plus 6 patients/carers asked to identify priority research areas • Research areas were grouped into themes and compressed by removing duplicates and areas known to have already been addressed 	89 proposed research areas 23 proposed themes
↓	
Stage 2. Rationale: To gain agreement on priority areas and themes for AHP/nursing research	
Methods	Results
<ul style="list-style-type: none"> • 89 research areas and 23 themes were presented to 32 multi-disciplinary expert participants via SurveyMonkey • Participants asked to rate agreement that research area was a priority using a 5 point Likert Scale (Strongly Agree, Agree, Neither Agree or Disagree, Disagree, Strongly Disagree) • Participants asked to rank top 10 out of 23 themes 	97% (n=31/32) response rate (n=2 partial response; n=29 complete response) 32 areas reached >60% agreement and moved to next stage 12 themes reached >55% agreement and moved to next stage
↓	
Stage 3. Rationale: To gain agreement on priority areas and themes for AHP/nursing research	
Methods	Results
<ul style="list-style-type: none"> • 32 research areas and 12 themes were presented to 32 multi-disciplinary expert participants via SurveyMonkey • Participants were given overall group response and their original response from stage 2 and asked to revise their opinion on agreement that research area was a priority using a 5 point Likert Scale • Participants asked to rank Top 10 themes 	97% response rate (n=31/32) response rate (n=31 complete response) 17 areas reached >70% agreement in either Stage 2 or 3 Top 10 themes identified
↓	
Stage 4. Rationale: To confirm if there was a gap in literature and to focus the research areas.	
Methods	Results
<p>Review of literature to:</p> <ul style="list-style-type: none"> • ascertain if any of 17 research areas had previously been answered • focus the research area 	7 research areas identified as priority for future AHP/nursing research

Fig. 1. Overview of Delphi survey to identify priority research areas and themes.

merits and limitations of common research designs, were reviewed. A number of key texts are available to facilitate design choice [9–12]. Although RCTs are recognised as providing the best evidence, the group acknowledged that there are challenges in conducting RCTs in CF.

Table 1
Top 10 research themes identified by Delphi survey.

Top 10 research themes (1=most important; 10=least important)	
1	Adherence
2	Airway clearance
3	Outcome measures
4	Exercise/physical activity
5	Education
6	Well/very young/new born screening
7	Antibiotics
8	Inhaled therapies
9	Infection control
10	Nutritional support

The working group reached consensus on the most appropriate use of RCTs and their relative merits and limitations (available electronically, Table 3: <http://www.ecfs.eu/projects/ahp-nursing-research/tables>). In addition the working group discussed variations on the traditional parallel RCT (e.g. factorial RCTs, equivalence trials, preference trials, cluster randomised trials) available electronically (Table 4: <http://www.ecfs.eu/projects/ahp-nursing-research/tables>). Significant challenges include the cost of conducting an RCT, the need for multicentre studies to achieve adequate sample size, and difficulties in achieving “blinding” of AHP and nursing interventions in RCT, which although not essential for conducting RCTs, is considered an important quality indicator in RCTs [12]. Many AHP/nursing interventions are focused on managing the physical, psychological, social and emotional aspects of care. As such, an RCT is not always the most appropriate design to answer research questions in these areas [1].

Other research designs (e.g. non-randomised controlled trials, cohort or case control studies, cross sectional surveys,

single system studies, case reports/series) were also reviewed and this is available electronically (Table 4: <http://www.ecfs.eu/projects/ahp-nursing-research/tables>). In addition, a variety of interview techniques (face-to-face, telephone, focus groups, Delphi surveys, structured and semi structured questionnaires) may be useful to support patient-centred AHP and nursing research. AHPs and nurses should consider mixed methodologies, especially in studies designed to evaluate the efficacy/effectiveness of complex interventions.

A number of crucial issues should be considered when carrying out any type of research. These include: 1) the choice of study design, which depends on the question being asked, 2) funding, 3) staffing, 4) available sample size, and 5) inclusion of a statistician or methodology expert at the protocol development phase.

One central issue, sample size estimation, was identified as a relative weakness for AHP and nursing researchers and was considered an important target for future training. Studies may be underpowered (too few participants) or overpowered (too many participants). The importance of obtaining statistical advice at the planning and design stage of a study was emphasised. Useful guidance is also available from published literature [13,14], and many software packages for performing sample size/power calculations are available, such as: Minitab, PS, GPower, Epi-info/StatCalc. Of those, PS (<http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize>) is useful because it covers the most commonly used study designs, is relatively easy to use, and is free to download. Additionally, there are many websites for performing sample size/power calculations, although the study designs covered vary across websites. A good example of this is the Obstetrics and Gynaecology site of the Chinese University of Hong Kong, which covers a range of study designs and is relatively easy to use (<http://department.obg.cuhk.edu.hk/researchsupport/statstestshome.asp>).

For interventional studies, in which a hypothesis is being tested, the key information required for sample size calculation is available electronically (Table 5: <http://www.ecfs.eu/projects/ahp-nursing-research/tables>). Evaluating the implementation of interventions is also important and different approaches can be considered: a process evaluation approach (fidelity, dose delivered, dose received, reach); a RE-AIM approach (reach, effectiveness, adoption, implementation, maintenance); or a MRC framework approach (publication, getting evidence into practice, surveillance/monitoring/long term outcomes) [1,15–17].

5. Objective 3: identification of appropriate outcome measures for AHP and nursing in CF

There is a clear need to provide additional education and training to AHP and nursing researchers on the selection of measurement tools. This should be guided by the specific research question, the clinimetric and psychometric properties of the instruments, and the feasibility of utilising these measures in a particular study. For the purpose of this paper, both terms (clinimetrics and psychometrics) are described; clinimetrics refers to clinical measurements and psychometrics refers to psychological measurements. Both terms include the reliability, validity,

and responsiveness of an outcome measure. Specific definitions for each of these terms and the rationale for their importance were agreed upon by participants. An overview of the statistical analysis procedures involved in the assessment of these properties is available electronically (Table 6: <http://www.ecfs.eu/projects/ahp-nursing-research/tables>).

A number of issues should be considered when deciding which measure to choose. Clinimetric/psychometric properties are population dependant; therefore these properties were examined specifically for CF populations. The feasibility and utility of different measurement tools is also important [18,19]. Evaluation of feasibility should include consideration of the population, quality of data produced, and ease of analysis and interpretation of the data. Utility assessments should include acceptability and relevance to the patient, ability to provide additional or unique information, and contribution to clinical decision-making. Guidance on how to evaluate these components of measurement is available electronically (Table 7: <http://www.ecfs.eu/projects/ahp-nursing-research/tables>).

The ECFS-Clinical Trials Network (CTN) standardisation committee are currently reviewing outcome measures for clinical trials in CF and developing standardised operating procedures. This group is using the template developed by the AHP and nursing group to assess the clinimetric properties of outcome measures. They are focusing on outcomes relevant to clinical trials including: CFTR bioassays; inflammatory markers; respiratory function; microbiological explorations; chest imaging and nutrition.

The current group focused on patient-reported outcomes that are more frequently used by AHPs and nurses, plus a range of objective and physiological endpoints that were not addressed by the ECFS-CTN standardisation committee (quality of life, adherence, exercise testing, physical activity, shortness of breath, mucociliary clearance, rheology and sputum volume/weight). The AHP and nursing group collated some of the key evidence available on the clinimetric/psychometric properties and feasibility of these outcome measures. Due to limitations in journal space, a summary of this evidence is available electronically (<http://www.ecfs.eu/projects/ahp-nursing-research/intro>). Outcome measures relevant to nutritional evaluation (anthropometry, body composition) were assessed as part of the AHP and nursing meeting; however these will be published separately and in collaboration with ECFS-CTN Standardisation Committee.

6. Objective 4: identification of key skills required to conduct AHP and nursing research in CF

AHPs and nurses are active participants in and leaders of many research activities (e.g., preparing grant applications, leading/coordinating research, writing abstracts, presenting results) [2,3]. However, AHPs and nurses encounter a number of barriers in engaging fully in the research process. A lack of resources is often the main reason these professionals are less involved in clinical research, which include high clinical demands, lack of dedicated research time, availability of space, equipment needs (e.g. computers, equipment), and research support and supervision. In addition, many AHPs and nurses

have never received training in study design and research methodology, either at a basic training level or in post-qualification courses or degrees. Language skills may also be a barrier since many national and international meetings are in English. Many AHPs and nurses expressed a lack of confidence in writing scientific reports and giving oral presentations in English.

To assist AHPs and nurses in overcoming these barriers, the experts at the meeting proposed a set of key skills required to undertake research, along with options for obtaining additional training in these skills. They also proposed strategies for how the ECFS could support AHPs and nurses in increasing their involvement in research.

6.1. Skills needed to conduct research

A common skill set is required for all AHPs and nurses to undertake research, regardless of the age of the participants. These skills include the ability to:

- comply with internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting trials (i.e. Good Clinical Practice training)
- turn a high priority question into a research proposal
- design an appropriate study to answer the question
- write a research protocol
- develop case report forms, patient information/consent forms
- complete and submit appropriate regulatory documents (e.g. for institutional review boards/research ethics committees, and research governance)
- identify funding opportunities and write a grant proposal
- carry out study procedures according to a set protocol
- access expert statistical support and perform basic statistical analysis
- disseminate findings (e.g. write abstracts/papers and oral presentation of results)

It was also recognised that specialised skill sets for paediatric researchers should be identified for all levels of practitioner (from novice to expert). The skills needed to conduct research with children with CF [20,21] include: 1) the ability to communicate with young children and teenagers, 2) knowledge of child development and its potential impact on study participation, 3) training in child-focused interventions and outcome measures, 4) understanding the specific ethical issues related to research with children, 5) writing patient information sheets/informed consent in language understandable for children, 6) ability to gain consent/assent from children and parents, 7) use of strategies for recruitment of children, and 8) knowledge of guidelines on confidentiality of children's data.

Although conducting research requires a wide variety of skills, it is not necessary to learn all of these skills at once. Those with less experience should be encouraged to seek opportunities to learn with a mentor and engage in other research training activities to gain the necessary skills over time. Research mentoring programmes exist at some institutions/

universities and identifying a colleague who is willing to serve as a research mentor is an important first step for novice researchers.

6.2. How to support AHPs and nurses to obtain research skills

A number of resources can be accessed to obtain research skills, however these options range widely in terms of cost and time commitment. Unfortunately, few AHPs or nurses opt for formal research education (MSc and PhD) due to costs and time. However, low cost alternatives exist, such as attendance at sponsored meetings (e.g. investigator/initiation meetings), working on an existing research team or with a mentor, online courses (e.g. Good Clinical Practice training), and courses specifically run by specialist interest societies (e.g. ECFS/ERS). The consensus group was eager to encourage AHPs and nurses to explore alternative options for research available in their own areas.

An additional learning opportunity is being sought from the ECFS-CTN. The Training Committee of the CTN is exploring different ways to provide appropriate education to member centres. Thus, representatives of the AHP and nursing group met with representatives of the ECFS-CTN to discuss how to share resources and facilitate access to relevant research education. As a result, information from both groups will be made available electronically (<http://www.ecfs.eu/projects/ahp-nursing-research/intro>).

A European taskforce has been set up to address the learning needs of AHPs and nurses within the ECFS, with the hope that there will be an opportunity to apply for Working Party status in the near future. Support from the ECFS means there will be ongoing research-specific sessions for AHPs and nurses at future ECFS annual conferences — with the inaugural session launched in Valencia in June 2010 and a symposium on research strategies at the ECFS conference in Hamburg in June 2011.

7. Summary

This report has identified the significant challenges faced by AHPs and nurses in conducting clinical research. This report provides strategies for overcoming these challenges by identifying priority areas for research, providing an overview of common research designs suitable to address complex questions relevant to AHPs and nurses, establishing methodologies for determining clinimetric and psychometric properties of outcome measures, and outlining key research skills needed by AHP and nursing researchers to undertake high quality research. It is hoped that this report will encourage the initiation of AHP and nursing research that develops an evidence base for the interventions performed by these professionals with patients with CF. Long-term, we hope to increase the quality of research conducted by AHPs and nurses, raise the profile of their research nationally and internationally, and provide justification for both existing services and expansion of these services into new areas that will ultimately improve the care of CF patients across the disease trajectory.

Supplementary data to this article can be found online at doi:[10.1016/j.jcf.2012.03.004](https://doi.org/10.1016/j.jcf.2012.03.004).

Acknowledgements

Fiona McCourt (University of Ulster), Brenda O'Neill (University of Ulster) and Lauren Green (Belfast Health and Social Care Trust), supported the administration of the Delphi survey.

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