

10 Areas for Future Research

The GDG recognises that there is a large amount of ongoing research activity in many aspects of the management of COPD. The evidence tables also highlight that there is a large volume of research that is already relevant to the COPD guidelines. Nevertheless a large number of studies were rejected because of methodological limitations and as well as identifying specific areas for future research the GDG concluded that there was a need to make some general recommendations about the design of studies on the management of COPD.

10.1 General Points

Many of the papers that were reviewed as part of the guideline process lacked operational definitions for example:

- an adequate and explicit operational definition of stable COPD
- explicit operational definitions of COPD disease severity
- lack of a system for adequately defining COPD exacerbations
- operational definitions vary between countries e.g. differences in what constitutes an Intensive Care Unit (ICU) between countries
- lack of definition regarding packages of care, e.g. differences between hospital-at-home schemes versus assisted or early discharge schemes.

These deficiencies must be overcome in future studies.

Trials that are adequately powered for primary outcomes were often potentially underpowered for the secondary outcomes. The GDG recommends that future trials on the management of COPD are adequately powered (i.e. have a large enough sample size), are of sufficient duration to determine long term efficacy of therapies and include patients with an appropriate range of ages. The study design and analysis should allow for the heterogeneity of the disease and patients should be appropriately characterized to allow sub group analysis of different phenotypes. Account also needs to be taken of the stability of the patients included and in particular whether they have recently had an exacerbation. Patients included in studies should be representative of the spectrum of patients with COPD seen in practice but steps should be taken to avoid the inclusion of patients with asthma.

As well as placebo controlled studies to show efficacy there is a need for studies of the comparative efficacy of management strategies (both pharmacological and non-pharmacological) to try to identify which therapies should be used and when.

Studies should include a range of outcome measures and not concentrate simply on FEV₁. Ideally there should be agreed standardized outcome measures to allow comparison of results across studies and facilitate meta analysis. In addition to this, details regarding the primary and secondary outcomes should be clearly specified. Cost effectiveness analyses should be included in the study design. Results should be reported in a way that allows identification of subgroups which show particularly large or small effects.

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The GDG also noted that there may be practical issues regarding the organization of randomized placebo controlled double blind clinical trials. These include ethical concerns about the withholding of therapies such as oxygen or non-invasive ventilation, and the difficulties in obtaining supplies of medication and matching placebo for studies not sponsored by the pharmaceutical industry. The GDG recommends that the costs of medication and placebo are met by research sponsors and that manufacturers should supply them to studies that have been peer reviewed and are supported by recognised funding agencies. The GDG also concluded that there was a need for studies supported by independent funding agencies as well as those supported by the pharmaceutical industry.

10.2 Specific points

The GDG concluded that there was a particular need for studies in three broad areas.

10.2.1 Pharmacological Management

There is a need for long term studies on the absolute and comparative efficacy of:

- long-acting bronchodilators
- theophylline
- mucolytics (including the development of outcome measures)
- combination therapies
- ambulatory oxygen
- alpha-1 antitrypsin replacement therapy.

10.2.2 Adjunctive therapies

There is a need for further studies on the efficacy of:

- nebulised therapy
- non-invasive ventilation
- oxygen delivery systems
- physiotherapy
- pulmonary rehabilitation (in particular its efficacy compared to pharmacological therapies and its efficacy in patients with mild and severe COPD).

10.2.3 Patient focused strategies

There is a need for further studies on:

- the content and efficacy of educational packages for patients with COPD
- the content and efficacy of self management strategies for exacerbations.



Areas for future research

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