Author's response to reviews

Title: Protocol for a mixed-methods study of supplemental oxygen in pulmonary fibrosis

Authors:

Amanda Belkin (belkina@njhealth.org)
Kaitlin Fier (fierk@njhealth.org)
Karen Albright (karen.albright@ucdenver.edu)
Susan Baird (msbaird49@comcast.net)
Brenda Crowe (croweb@exempla.org)
Linda Eres (leres@comcast.net)
Marjorie Korn (marjkor@yahoo.com)
Leslie Maginn (maginnl@njhealth.org)
Mark McCormick (mccormickm1@comcast.net)
Elisabeth D. Root (Elisabeth.Root@Colorado.EDU)
Thomas Vierzba (tvier@comcast.net)
Frederick S. Wamboldt (wamboldtf@njhealth.org)
Jeffrey J. Swigris (swigrisj@njc.org)

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Author's response to reviews:

Catia Cornacchia PhD
Executive Editor
BMC-series Journals
BioMed Central
236 Gray's Inn Road
London, WC1X 8HB
United Kingdom

Dear Dr. Cornacchia:

We appreciate the opportunity to respond to the Reviewer's comments on our manuscript MS: 9829894831243207 Protocol for a mixed-methods study of supplemental oxygen in pulmonary fibrosis.

Below, you will find our response to each comment. For ease of review, we have labeled comments (e.g., Comment 1 = C1), and we have labeled the Author's reply accordingly (e.g., Author reply to Comment 1 = AR:C1).

We hope you find our responses acceptable and look forward to your reply.

Sincerely,
I. There are no comments to address from Reviewer 2.

II. Comments from Reviewer 3.

(C1) How will the different types of pulmonary fibrosis be defined? Stratification of the different types of pulmonary fibrosis would enhance this research.

AR:C1) We have included text stating that we will perform stratified analyses. Page 12, line 276: “We will conduct certain analyses with the sample stratified on type of pulmonary fibrosis using clinical data acquired from the subjects’ treating physicians.”

(C2) Is there a reference for the sentence on page 3, sentence beginning on line 82. This is worded very strongly with a supporting reference?

AR:C2.1) We have toned down the wording and added two references for the statement (Page 3, line 80).

(C3) On page 4, lines 95-97 - this is another statement that lacks validation. In the US, oxygen cannot be prescribed unless the patient qualifies for it. That would be the sound, quantifiable evidence that explains why it is important.

AR:C2.3) We agree with the Reviewer’s comment: in the U.S., patients can only be prescribed supplemental oxygen if they qualify. However, the point we wished to address is that fact that there are no published data on what supplemental oxygen will do for patients with PF. For example, in certain patients with COPD, we know that supplemental oxygen improves survival. There are no data to say that oxygen has the same benefit in any patients with PF. Similarly, there are no data on whether oxygen improves functioning, symptoms or quality of life in patients with PF. In our study, we aim to generate these data.

(C4) I understand the challenges patients are faced with when prescribed supplemental oxygen, but I am concerned with the use of subjective measures to measure improvement (pg 8-9). Will the activity monitor measure oxygen saturation and will this be available for immediate feedback for the patient? I think this study would be much stronger than it already is, if there was an objective measure also included to monitor improvement/digression. The teaching has always been that desaturation does not equate to dyspnea, and this research would be an important way to add to confirm or disclaim this teaching.

AR:C2.4) The Reviewer brings up an excellent point. Unfortunately, the activity monitor does not measure peripheral saturation. We and other investigators have wrangled with how to assess oxygen adherence and appropriate use. For example, should we have patients wear a pulse oximeter 24/7 and adjust their oxygen flow to maintain a peripheral oxygen saturation > 90% at all times? That
would be my preference (and I suspect the Reviewer’s preference as well)…but, it’s probably not practical.

For study purposes, one would need a continuously recording SpO2 monitor, and she would need to decide how to analyze the data. We agree that assessing the fidelity and appropriateness of oxygen use (i.e., ensuring that SpO2 is > 90%) would strengthen the study, but this would require yet another device for patients to wear (in addition to the activity monitor and GPS unit). We felt this was asking too much of subjects. In the end, we (and our patient informants) examined all the issues—including those brought up by the reviewer—assessed all the possibilities for addressing those issues and tried to balance subject burden and the generation of meaningful data.