Author's response to reviews

Title: A Decision Aid for COPD patients considering inhaled steroid therapy: development and before and after pilot testing

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Author's response to reviews: see over
April 5, 2007

RE: “A Decision Aid for COPD patients considering inhaled steroid therapy: development and pilot testing”

Dear Dr. Saltman,

We appreciate the reviewers’ positive feedback and suggestions. We have addressed their concerns and made the requested changes in the attached revised manuscript. Please find below our point-by-point response.

This manuscript has not been published in another journal and is not under consideration by any other peer-reviewed media. It presents original work in which all the authors listed on the manuscript have contributed sufficiently to the project to be included as authors.

With kind regards,

Elie A. Akl, MD, MPH
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Reviewer 1: Eric Bateman

General

This is interesting innovative work. The paper describes the theory behind, development of a decision aid for patients who are being considered /are considering treatment with inhaled corticosteroids for COPD.

We appreciate the reviewer’s interest.

Result from a small pilot study performed on 8 patients is included. Although largely descriptive, the more interesting and essential work is yet to come. Demonstrating its utility in a pragmatic controlled trial.

We completely agree with the reviewer that the more interesting and essential work is yet to come. As we mention in the discussion section of the manuscript, we are planning to conduct a pragmatic clinical trial evaluating the impact of the decision aid on decision processes and decision quality. We have added the following statement to the discussion section:

“While the pilot testing in 8 patients provided us with important information, it is insufficient for claiming its widespread use”

We have also added the following disclaimer at the end of the manuscript and on the home page of the DA:

“Disclaimer: The Decision Aid for making decisions about using inhaled steroids in COPD (DA) is not a substitute for medical advice, examination, diagnosis treatment or judgment of a physician or health care professional. If you have any concerns about your health, talk to a doctor. Also, do not disregard or delay seeking medical advice because of something you read on the DA. The information found on the DA is to be used solely for informational purposes. Additionally, in spite of our best efforts, the information in the DA may become out of date over time. The DA team accepts no liability for the accuracy or completeness or use of, nor any liability to update, the information or materials provided in the DA. ”

I am more concerned about its uptake than its validity. It seems unlikely that more than a minority of patients with COPD will have the inclination, computer skills (the authors mention this concern, since most COPD patients are elderly, and may be unfamiliar with the use of the web for medical purposes) and patience to make use of the DA. This needs to be examined in some future study. However, as a concept this approach is sound.
We share the reviewer’s concern that the computer-based format might be challenging for older patients and we do raise it as a limitation. However, the proportion of COPD patients who are computer literate should be on the rise. We are also considering partial use of the decision aid in the paper format.

The authors do not provide very convincing motivation for a DA on this topic. One can think of other decisions that are more difficult and a better indication for developing a DA.

There are definitely other healthcare decisions that are more difficult and challenging for patients and that would benefit from a decision support tool. However, as we attempt to argue in two of the four paragraphs of the introduction, COPD is a prevalent disease, is a major cause of morbidity and mortality, and its treatment with inhaled steroids requires balancing benefits and harms. In addition, COPD as a disease is an area of interest to the authors.

Major Compulsory Revisions

The paper is well written, and I have no major problems with what is presented. Its main limitation is descriptive nature.

We appreciate the reviewer’s positive feedback.

Minor Essential Revisions

My criticisms are not of the paper, but of the aid, which I viewed on the web.

Firstly, there are several spelling errors e.g. budesonide (budenoside), iintiating, throat (thorat).

We appreciate the reviewer’s attentiveness and detail. We have proofread the entire text of the decision aid and made the necessary corrections.

Next, there is a picture of an adult with a spacer with facemask, which is not the preferred method. Most adults use and prefer mouthpieces. Perhaps both should be shown with a reason for the differences. This is misleading and is a missed learning opportunity for patients.

We have taken the concerns of the reviewers into consideration. We have replaced the picture of an adult with a spacer and facemask with a picture of an adult with a mouthpiece.

The picture of thrush is extreme. This severity is hardly ever seen, and creates a fearful image for patients that is bound to affect their choice. The same applies to the bruising.
We have now a picture that shows a less severe thrush compared with the one previously shown. Similarly we have now a picture that shows a less severe bruising compared with the one previously shown.

The discussion lacks balance, as in most COPD patients bruises are contributed to by courses of oral corticosteroids and aging itself. Therefore the oversimplification that these are all due to ICS is misleading. The counterpoise involves the possible greater need for courses of OCS and the side-effects of these.

We agree with the reviewer that some of the side effects of ICS are also side effects of OCS and that the concomitant use of these medications can therefore confuse the picture. This is exactly why we were very careful in extracting data on side effects of ICS only from randomized controlled trials comparing ICS to placebo. Thus any change in the incidence of side effects should be attributed to the use of ICS.

Itch is mentioned often, but is a rare complication. See the Gronigen ICS questionnaire and papers using systematic questioning of patients receiving ICS. Itch scores lower than other symptoms.

We thank the reviewer for referring us to the Groningen ICS questionnaire. Indeed, this is a very comprehensive questionnaire inquiring about 57 different symptoms, itching being one of them. The systematic review we used to extract outcome data did not list itching as one of the side effects.

On another web page, in attempting to illustrate risk reduction (of exacerbations), the illustration is of a patient who might have 10 exacerbations over a period of time, having only 7 on ICS. Exacerbation rates per annum are much lower than this (1.1 or 1.2). Using these high numbers, which most COPD patients won’t have in a “life-time” of COPD creates a false perspective of risk and benefit.

We primary way we attempt to illustrate the reduction in the risk of exacerbations is the relative risk reduction:

“Inhaled steroids reduce the number of flare ups in patients with COPD by approximately 30% relatively to patients not using inhaled steroids.”

We also use number of events over a period of time as the IPDAS guidelines recommend the use of multiple methods to view probabilities. We have, based on the reviewer suggestion changed the text to:

“For example, if you suffer 3 flare ups over a certain time period, using inhaled steroids will reduce this number to 2 flare ups during that period.”

It is not clear how each of these methods affects the decision making process. As stated in the discussion section, this decision aid presents an opportunity to study different ways of presenting information and evaluate their effect on the decision making process comparatively.
These examples illustrate to me that although the intentions are good, attempts to educate have to ensure correct portrayal of the facts or the decisions remain ill-informed and no better than the paternalistic model of doctor deciding for the patient and persuading them to take it regardless of their preference.

We believe we have done our best to portray the facts as accurately as possible and have provided responses to the reviewer that in part explain why bruising for instance may be a real problem of ICS (it is a side effect based on RCTs). Unfortunately, we do not know whether this decision aid promotes decisions most consistent with patient values and preferences, but the limited testing that we have done has been positive. The planned pragmatic trial would be the best way to evaluate that.
Reviewer 2: France Legare

The subject of this study is of interest to the research community involved with the development of decision support interventions and most specifically to those interested in chronic management diseases. Overall, the paper has a clear and logical structure. It provides sufficient details about the decision aid itself. Indeed, it was much appreciated that the authors made the computer-based decision aid available on-line for the reviewers to experience. However, I have one main concern regarding the study under review as well as few questions for its authors.

We thank the reviewer for the overall positive feedback.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

What is the nature of the study under review?
The nature of the study under review is not clear. In the discussion section, the authors refer to the strengths and limitations of the decision aid that was developed and not to those of the study itself.

The scientific project described here relates to the development of the decision aid. It is an observational study that includes the use of literature search methods, web design and computer interaction design, as well as pilot testing. Although the manuscript includes pilot testing of the decision aid, its major focus is the development of the aid and the related methods which are important to plan and describe prior to widespread use. We thus discuss the strengths and limitations of the decision aid as the major product of this study, but also refer to the fact that the part involving patients (n = 15) is a relatively small study.

“While the pilot testing in 8 patients provided us with important information, it is insufficient for claiming its widespread use.”

Also, the authors could have presented a better rationale for using the Ottawa Decision Support Framework and provided more details about its main features. The Ottawa Decision Support Framework (ODSF) is the standard framework for developing decision aids and has been used, according to the Ottawa Health Research Institute website, “to guide the development and evaluation of more than 30 patient decision aids, practitioner decision support resources, and tools to evaluate the quality and outcomes of providing decision support.”

We now include in the text more detailed information about the ODSF as follows:

“This framework is an evidence-based, practical, mid-range theory for guiding patients making health or social decisions. Mid-range theories are moderately abstract and inclusive theories that address specific phenomena and are composed of concepts and propositions that are measurable. The framework supports decision making through providing information about the disease, its treatment alternatives and the associated outcomes; through clarifying values; and finally through augmenting skills in decision making.”
Then, the methods used by the authors could have been different. They could have used a qualitative approach to assess the decisional needs of the target audience based on this framework. The authors could have also reviewed the literature on the sources of difficulties experienced by COPD patients when facing decisions about inhaled steroid therapy. Then, either the decisional needs assessment with the target audience or a relevant literature review could have identified sources of difficulties that could have been taken into account in the decision aid. This would have been a study in itself. (for example, see Stacey D, DeGrasse C, Johnston L. Addressing the support needs of women at high risk for breast cancer: evidence-based care by advanced practice nurses. Oncol Nurs Forum. 2002 Jul;29:E77-84.)

Before we started the development of the decision aid, we did review the literature on the topic. We did not identify at that time any study about the difficulties experienced by COPD patients deciding whether to start inhaled steroid therapy. We had noted such difficulties in the course of our clinical practice and when speaking to colleagues. Furthermore, we found that the benefits and downsides did not point towards a decision that was compatible with a strong recommendation or with a situation in which all fully informed patients would make the same decision. This, in the view of guideline developers, makes this topic a candidate for a decision aid (Schunemann H et al. AJRCCM, 2006). We agree with the reviewer that a qualitative study focusing on that issue would have been a study in itself.

We have added the following sentence to the last paragraph of the background section:

“Although we did not identify any study about the difficulties with making such a decision, we had noted difficulties in the course of our clinical practice and when speaking to colleagues.”

My understanding was that in the present study, the researchers used the existing structure of an existing generic decision aid produced with the Ottawa Decision Support Framework but did not fully operationalize the framework itself. As clarified above, the ODSF is a theory for guiding patients making health or social decisions. Although it serves as a framework for developing decision aids, it does not include a generic decision aid. Our decision aid is unique in that it combines a number of features that prior or other decision aids to not include (e.g. the measurement of values and preferences and the decision making suggestion).

In summary, the nature of the study under review needs to be better circumscribed. I have proposed a brief summary as I understood it: a before-and-after pilot-testing of the decision aid with 8 subjects.

We appreciate the reviewer’s suggestion. As we have written the manuscript with the main intent to describe the development of the decision aid, we prefer to keep in “development”. We have accordingly changed the title to:

“A Decision Aid for COPD patients considering inhaled steroid therapy: development and before and after pilot testing”

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Minor Essential Revisions
1- I feel that in Table 2, there is a danger of multiple comparisons and believe that the p value for statistical signification should have been set more conservatively for each one of the 13 items of the evaluation questionnaire. I would advise the editor to seek statistical advice.

We have taken a conservative approach in response to this comment. While the outcome variables are not strictly independent and thus a more lenient correction for multiple testing would have been in order we changed the cutoff for statistical significance to the more conservative value of 0.01. As a result the score for one variable (perceived improvement in knowledge) is not considered anymore statistically significant. We have made the corresponding changes in the text.

2- The authors said they interviewed 7 COPD patients to get feedback on the decision aid. Was the interview audiotaped? Is there a possibility to expand the methods section as well as the results section with this group of participants?

The interviews were not audiotaped, but written notes were kept. These patients reviewed the decision aid in the early stages of development and we used their feedback to make modifications to improve the DA.

3- The authors used the term “Decision making models” for what I understand was the “Preferred role in decision making”. They also refer to a set of four models but in the decision aid, only three were made explicit. Where is the fourth model in the decision aid?

Indeed we used “decision making models” to refer to the four decision making approaches as defined by Amiram Gafni and Kathy Charles: (1) the informed decision making model, (2) the physician as an agent model, (3) the shared decision making model, and (4) the paternalistic model.

On the “Your Participation” page (http://www.preditonline.com/copd/smbs/spm_copd/decision.php), the first arrow from above relates to the 1st model, the second arrow relates to the 2nd model, the third arrow (at the bottom) refers to the 4th model.

In order to apply the 3rd model (shared decision making model) the patient reviews the medical information in the decision aid and goes through the value clarification process first, and then makes the decision together with his health care provider. We have clarified this in the text as follows:

“Under the “shared decision making model” the patient reviews the medical information in the DA and goes through the value clarification process, first, and then and makes the decision together with his health care provider.”

4- The authors have to be congratulated for tackling a decision about using inhaled steroid therapy in the context of COPD. However, their discussion needs to be enriched. For example, it took about 32 minutes to complete the decision aid and 75% of the 8 COPD patients needed assistance. Given the fact that many other decisions need to be made by the COPD patients, do the authors plan to produce more decision aids?

We thank the reviewer for the suggestion. We have expanded on that issue as follows:
“Second, the computer-based format of the decision aid might not be ideal for older patients. However, the proportion of COPD patients who are computer literate should be on the rise”

We are considering producing decision aids for emerging COPD treatments that involve a benefit risk tradeoff (e.g. protease inhibitors). These are decisions for long term treatments that would not be revisited frequently, and the time spent making them (using decision aid or not) is probably worth it.

5- The authors referred to the IPDAS criteria. Can they be more specific? Can they indicate how many of the quality criteria from the IPDAS Collaboration are met in their decision aid?
We have clarified this in the text as follows:

“First, it meets 14 of the 23 quality criteria for “content” and 15 of the 19 quality criteria for “development process” recently proposed by the International Patient Decision Aid Standards (IPDAS) Collaboration”

This collaboration produced its standards after we had completed the development of the decision aid.