Reviewer's report

Title: Community Assessment of COPD Health Care study: a clinical audit on primary care performance variability in COPD care

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Reviewer: Stefan Markun

Reviewer's report:

The authors are to be commended for their relevant work because most of the patients affected by COPD are treated in general practice and consecutively depend on the quality of care delivered in this healthcare setting.

The manuscript describes an audit performed to assess the degree of adherence to guidelines for stable COPD in Spanish general practice.

The manuscripts merit consideration because of the relevant topic but in my view, the following points should be addressed by the authors:

ABSTRACT

- "To the best of our knowledge, there has been no previous audit of primary healthcare interventions for chronic obstructive pulmonary disease (COPD) patients.": Several studies have assessed performance of primary healthcare for COPD (see: Jochmann A et al.: General practitioner's adherence to the COPD GOLD guidelines: baseline data of the Swiss COPD Cohort Study. Swiss Med Wkly 2010; Steurer-Stey C, et al.: Management of chronic obstructive pulmonary disease in Swiss primary care: room for improvement. Qual Prim Care 2012; 20: 365-373.; Kaufmann C et al.: Performance Measures in the Management of Chronic Obstructive Pulmonary Disease in Primary Care - A Retrospective Analysis. PRAXIS 2015; 104: 897-907.; Belletti D et al.: Results of the CAPPS: COPD - Assessment of Practice in Primary Care Study. Curr. Med. Res. Opin. 2013; 29: 957-966.). Even if they are not labelled as "audits" these studies reflect performance of primary care for COPD. In addition a simple google search imputing "audit COPD primary care" identified two more studies on the first search page, one being a very large project from Wales UK
The opening statement thus seems inaccurate and should be amended.

"The Community Assessment of COPD Health Care (COACH) study was an observational, multicenter, nationwide, randomized, non-interventional, clinical audit of primary care in Spain." Please state also whether the audit was performed prospectively (--> with an associated comment in Limitation section concerning awareness of physicians --> risk for over-estimation of true performance [Hawthorne-Effect]) or retrospectively (--> with associated comment in Limitation section concerning unawareness of physicians --> risk of under-estimation of true performance because of lacking documentation about interventions performed in reality i.e. smoking cessation advice performed but not documented [information bias]).

"Diagnosis based on previous exposure plus...": By exposure you mean exposure towards risk-factors? If yes I don't understand because risk-factors are not a requirement for diagnosing COPD (yet they are a case-finding strategy to decrease the number of patients with unidentified COPD and may be used for screening for COPD [but not for diagnosis, especially because COPD rarely also occurs without exposure to risk factors, i.e. alpha-1-antitrypsin deficiency]). In my understanding, diagnosis of COPD should rest on spirometry including reversibility testing.

"Regarding treatment, 33.6% received no maintenance inhaled therapies.": This result is pure description without questioning the appropriateness of the intervention (what I would expect from an audit). Do the guidelines you operationalized not provide recommendations on who to treat with inhaled therapies? Since you state to have reports about exacerbations within previous year it should be feasible to check whether at least those with exacerbations received inhalative treatments. This would enable you to distinguish the under-treated population where improvements are possible. This would make the results meaningful in the context of the manuscript's aim to be an audit.

BACKGROUND

- page 5, line 15: check writing "...are currently have shown..."
- page 5, line 56-59 "However, to the best of our knowledge, there has been no previous audit of primary health care interventions for COPD patients." Please amend according to comment on same statement in Abstract

METHODS
- Spelling error detectable by Microsoft Word (page 7 line 56 "calssified")
- page 8 line 27: were the number of exacerbation the audited measure or was the processes of ASSESSING this number audited (logically I can think only of the second [because assessing the number is recommended by guidelines to enable steering of care / selecting appropriate interventions] but it reads as the first would be the intention of the audit which would reflect just the disease severity in the population but not the quality of care)
- page 8 line 53: as commented before, the previous inhalation exposure is not a diagnostic requirement for COPD. This seems to belong to a different study question, namely whether testing for COPD is appropriate. It would be interesting whether the GPs actually consider COPD in the population with inhalation exposure and the proportion of this population actually identified and forwarded to spirometry. On the other hand, what proportion of patients receives spirometry without risk factors. Together these proportions would estimate the failure to test for COPD (under-use) and unnecessary tests for COPD (over-use) which would be the meaningful audit outcomes. The data, however, just grasps positively identified COPD cases leaving unknown the proportions were diagnostic testing would have been needed but not performed. Therefore, if my understanding of COPD diagnosis is accurate then i would detach the inhalation exposure from the accuracy of diagnosis definition. Otherwise I would welcome an update on my understanding of COPD diagnosis by the authors.
- page 9 line 7. Accepting also spirometries without bronchodilatator is pragmatic and may have moderate false-positive inclusion because of asthma. however, it hardly reflects the guidelines saying which you declare to use as standards of care. Why do you make this trade-off, would it not be very important to report the appropriateness of diagnostic procedures this in your audit?
- I cannot find how cases were identified. Electronical searches or manual searches of consecutive patients? Also: who identified the cases? The doctors in charge or the person conducting the audit?

- Do "cases" translate into "patients" implying that every individual contributes to the dataset only once or is there a risk of single patients being counted/audited multiple times? If yes this should be mentioned in the Limitations section. If no, what precautions were in place, given that the audit form used did not contain personal data as described on page 10 line 43. In summary, the methods lack a description how audited cases were identified, usually a flow-chart is used to further illustrate this process for readers.

- The Methods section should be re-written and I strongly recommend using a reporting guideline in order to address all necessary points of methodology.

RESULTS

- No results from the process of identifying audited cases are visible. This would be very important to understand representiveness of the population starting from the participation rates of physicians. Please include this results from the process of accruing your study population on all levels (ideally in the flow-chart).

- Page 12 line 2: Since you report on variability concerning various patient characteristics and find significant differences i expect in the Discussion section a comment on the implications and relevance of these numerous differences especially with regard to COPD care. If you see no important implications even if you found so many differences, then I would wonder why you have measured and tested for all these differences in the first place.

- Page 12 line 2: Apart from this comment belonging to the Discussion section: apart from gender, age and BMI, FEV1 is one of the few anthropometric measures among the patient characteristics you compare. There is an important risk for diagnostic bias in antropometric measures but even more in the comorbidities you report. I believe it to be very difficult to distinguish actual morbidity of the population from mere performance of healthcare in establishing the diagnoses you report. Therefore I recommend not to over-interpret this variability in patient characteristics which are also hardly an important outcome of your audit on COPD healthcare.
- Page 12 contains many comments on results ("Interestingly..."). These belong to the Discussion section.

- Page 13 line 15: To prescribe ICS in GOLD A and B I understand as clear over-prescribing of ICS. This is a key finding that could be easily targeted by a quality improvement program reducing both adverse outcomes and costs. I would expect this to be pointed out in the discussion section.

- It is a pity that the proportion of available post-bronchodilator spirometry is not presented because this would really reflect accurate diagnosis. I strongly recommend reporting this, especially since you should have this in your dataset.

DISCUSSION

- Page 13 line 22. Again the novelty of the manuscript is emphasized. I believe that novelty is not an important characteristic of a clinical audit. Time passes and medical care changes. Audits don't need to be the first in order to be relevant. Audits should be implemented regularly and inform quality improvement interventions (e.g. in pre- post-designs). Besides from being inaccurate the novelty is not important and stating this in the summary of the findings (designated first paragraph in discussion) seems inappropriate to me.

- Page 13 line 26: As different auditors have performed the audit, how can we be sure that variability did not originate from auditors? Have you made any interventions or measurements to guarantee the auditors uniformity in extracting the information from the medical charts? If no, this must be stated in the limitation section (information bias).

- Page 13 line 35 to 45: This whole section does not discuss the results of the study (but replicates a section from the Background).

- Page 13 line 47: Strength and limitations should be discussed at the end of the discussion section

- Page 14 line 43 to 47: In my understanding GOLD 2017 groups (A to D) are most certainly NOT based on pre-specified therapies as the authors state. GOLD groups are specified according to 1-years exacerbations (with or without hospital stay) and impact of disease (CAT or MMRC). The recommendations for pharmacological therapies then apply to the GOLD groups (not the other way).
- Page 15 line 22-46: In GOLD A a bronchodilatator therapy is suggested but not strictly recommended by the GOLD guidelines and may also be stopped. Also it must not be a long acting bronchodilatator. I do not agree that the population described here is necessarily under-prescribed.

- The Discussion section should be re-written and mirror the results. I strongly recommend using a reporting guideline in order to guarantee the structure according to standards of reporting. Also, given that previous results exist (unknown to the authors), the results from this study must be discussed in the light of previous work (not named "audit" but reflecting similar guideline-recommended processes of care) and (optionally) comparing the Spanish healthcare system to the systems where other projects have been carried out.

CONCLUSION
- Page 17 line 17. Again the novelty is stated, see comments above.
- Given the methodological uncertainties on where the variation actually comes from, I would leave the unexplained variation out from the conclusion
- The Conclusion section should be re-written and mirror the main messages from the revised manuscript

TABLES
- Table 1: the numbers outside and inside brackets are not understandable with the given labels (e.g. "Male gender (n) 3,159 (73.3)" -- i suppose 73.3 are %. The label should thus say "Male gender n and (%)"). A similar issue arises with Age: (years) cannot possibly be (12.7) on average. This is likely a measure of variation, i suppose the standard deviation. The label should thus say "Age in years (SD)". Please revise the labels to make the reported numbers unambiguously understandable.
- Table 2: under the label of "Final diagnosis correct" now also the symptoms are evaluated. In my understanding symptoms are a measure of impact of the disease and also allow exacerbation identification if any worsening occurs. Again, however, the labeling under "Diagnosis correct" seem inappropriate to me. Please revise or update my understanding if symptoms contribute to correctness of diagnosis. (Again: I believe that symptoms should
provoke testing for COPD or treatment of COPD (ideally guided by the CAT Test), but they have no role in actual diagnosis since COPD is even possible without any symptoms.

- Please explain "Inhaler Satisfaction" does this maybe translate to "inhaler technique assessed" or is the inhaler technique a component of "treatment adherence". In summary I seem to miss the inhaler technique assessment which I believe is crucial in COPD care.

- Did you include in your set of audited parameters whether smoking status has been determined? As this is the single most important and modifiable prognostic factor I think you should have. Then you should also report this outcome in your audit because doctors should really care about whether their patients do smoke or not and if yes introduce smoking cessation advice and interventions (also not reported in the manuscript [but not audited?]).

- I understand this is hairsplitting but stating to report relative frequencies in brackets, (45.3) actually translates in 45.3 times, not 45.3% (relative frequency 0.453). Please amend by stating "in %" or something similar.

APPENDIX

- Are the used audit forms in the appendix?

Are the methods appropriate and well described?

If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?

If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?

If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?

If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

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