Dear Editor,

We appreciate the thorough review of our manuscript, "Person-centered endoscopy safety checklist: development, implementation and evaluation" (Manuscript NO: 36012), and we have done our best to carefully respond to the reviewers' comments. In the manuscript, we have used the Track Changes function.

Comments from the Reviewers:

We would like to thank the reviewers for their commitment and for their insightful comments and advice. Please see our responses point-by-point below.

Reviewer #1:

The notion that the patient should be more explicitly included in the checklist performance is innovative and should be further developed.

We thank the reviewer for the comments and such a positive response to the project idea.

It may be of most value in open access systems where the caregivers of the day may not know the patient well.

Open access systems in endoscopy are rare in our country, but we agree that these units would be an area where the checklist would be very valuable.

Although attractive the size of the study and the discrimination of the question asked the patient do not demonstrate its potential value.

Our manuscript describes the development, implementation and evaluation of the first step of this checklist concept. As mentioned in the discussion, the patient questionnaire turned out not sensitive enough and we suggest that further research

on patients' experience on the checklist should be undertaken (for example using qualitative methods).

Apart from the active role of the patient the "checklist" is extremely close to the standard operating procedures mandated by regulators in the United States. Although doctors everywhere are notoriously independent if a timeout with patient identification is not completed the technician does not hand the scope to the MD and the procedure does not begin. Similarly if the specimens are not labeled and double checked by both the MD and RN the patient never leaves the room. Consequently compliance is very high despite sometimes reluctant physician training.

We believe that the similarity with the World Health Organization Surgical Safety Checklist (WHO SSC) is a strength in our project, since it has been extensively evaluated and shown to contribute to improved patient outcome. WHO also recommends local adaptation of the SSC, which we interpreted similarly to how our colleagues in United Kingdom in their version of an endoscopy safety checklist[1]. However, as the reviewer mentioned, what differs this checklist from others is the involvement of the patient, which in practice is an important difference. As described in the introduction section (page 7, paragraph 1), patient participation has been identified as a key factor for improved patient safety.

There are most certainly many ways of improving patient safety in endoscopy. The reviewer describes effective safety routines in the United States. In Sweden, as well as in many other countries, work routines are not as uniformly regulated. The implementation concept with team training and group discussions was based on the hypotheses that it would contribute to improved working climate. Satisfactory team communication has been shown to be beneficial for patient outcome[2].

Did the more rigorous checklist of workflow prevent any errors or complications? Were there a near misses?

The reviewer calls for important patient outcome measures, a relevant question. Since the article describes a single center study, the data from the evaluation period would have been too limited for such conclusions. We agree with the reviewer on the usefulness of such measures and we added in our manuscript (page X, paragraph X) that in future work the checklist should be evaluated with patient outcome measures in multiple center studies.

Even though we did not systematically collect data on errors, complications or near misses, our colleagues and we have experienced several near misses that have been prevented by the checklist, including anticoagulant use and patient misidentification. We have included this in the discussion (page x, line x).

The size of study is too small to show meaningful differences or trends. Some difference in a concrete outcome even just accuracy of specimen would be helpful. Greater focus on the patient role and the patient perception of their role plus the potential positive contributions to team work would be valuable.

We agree with the reviewer that patient outcome measures, such as accuracy of specimen, are very useful. In a larger study, it would have been obvious to use such measures. Despite the size of the study, we believe that the increase in patient identity verifications performed by the physicians (0 % to 87 %) is a concrete outcome. We concur with the reviewer that greater focus on the patient role and the perception of their role would be valuable, especially for further development of the checklist concept. We are currently planning a qualitative study with patient interviews.

Reviewer #2:

This is an interesting paper concerning the safety checklist for endoscopy, which is indeed an adaptation of the WHO Surgical Safety Checklist. Any attempt to implement endoscopic examinations by such means is needed and is quite significant. The paper is well written, well

prepared and the results carefully analyzed. Although, as the authors outline, a lack of solid validation is a limit of the study, the project should be encouraged and the improvement of identity check by physicians during the study is not only a good achievement but a proof that such instrument have a critical role in improving the outcome either of the examination or of the patient.

We would like to thank the reviewer for the comments. We are very pleased to notice the enthusiasm shown. Validated patient experience measures were not found for our study purpose, and as mentioned in the manuscript, this is a limitation. In the literature, Thierny et al. [3] discuss the limited value of retrospective patient questionnaires and conclude in their article that patient measures should rather be derived from patient narratives. Brown et al.[4] did not find any patient-derived and validated endoscopy-specific experience measures. We believe that patient experience measures in endoscopy is an important area that should be further developed.

Likely the importance of these attempts are not yet completely realized by physicians, as shown by the low number of them who attended the training and the lunch seminar. The number of patients who answered to the questionnaire is low and this outlines the difficulties of introducing these new tools, a drawback which has been specified. However, the questionnaires themselves appear a little bit convoluted and not always easy to answer, especially for some patients.

In efforts to train staff the cultural differences between the professions sometimes become clear. We did not necessarily experience reluctance from physicians to participate in the training, but possibly a limited understanding of why the training was necessary. These differences in attitude towards team-work training are in themselves a good reason to carry on with the project. With the right instrument, the number of patients participating in the evaluation would maybe have been higher, but as discussed above, the questionnaire turned out not to be sensitive enough.

Although the safety list could be applied to every endoscopic examination, some endoscopic interventions are more complex and certainly need more than others an accurate preparation and explanation to the patient. A checklist is mandatory in my opinion especially for operative endoscopy.

The reviewer points out that some endoscopic interventions are more complex than others and might need more extensive safety routines and explanation to the patient. We agree and think that in endoscopy centers with such needs the checklist should be modified and locally adapted. We are glad to hear that the reviewer has such a positive opinion on the checklist.

1. Matharoo M, Thomas-Gibson S, Haycock A, Sevdalis N. Implementation of an endoscopy safety checklist. *Frontline Gastroenterol* 2014; **5**(4): 260-265 [PMID: 25285191 PMCID: PMC4173736 DOI: 10.1136/flgastro-2013-100393]

2. Davenport DL, Henderson WG, Mosca CL, Khuri SF, Mentzer RM, Jr. Risk-adjusted morbidity in teaching hospitals correlates with reported levels of communication and collaboration on surgical teams but not with scale measures of teamwork climate, safety climate, or working conditions. *J Am Coll Surg* 2007; **205**(6): 778-784 [PMID: 18035261 DOI: 10.1016/j.jamcollsurg.2007.07.039]

3. Tierney M, Bevan R, Rees CJ, Trebble TM. What do patients want from their endoscopy experience? The importance of measuring and understanding patient attitudes to their care. *Frontline Gastroenterol* 2016; **7**(3): 191-198 [PMID: 27429733 PMCID: PMC4941156 DOI: 10.1136/flgastro-2015-100574]

4. Brown S, Bevan R, Rubin G, Nixon C, Dunn S, Panter S, Rees CJ. Patient-derived measures of GI endoscopy: a meta-narrative review of the literature. *Gastrointest*

Endosc 2015; **81**(5): 1130-1140.e1131-1139 [PMID: 25864891 DOI: 10.1016/j.gie.2014.11.047]

Revisions made in the manuscript:

Page 1. Postal codes added

Page 1. ORCID-numbers added

Page 2. Paragraph "supported by" deleted since we cannot provide grant application forms or certificates of funding agency.

Page 2. Conflicts-of-interest statement changed from "*none*" to "*There are no conflicts of interest to report.*"

Page 2. Biostatistics statement included

Page 2. Open-access included

Page 3. Included:

Received: August 30, 2017

Peer-review started: August 31, 2017

First decision: September 11, 2017

Revised:

Accepted:

Article in press:

Published online:

Page 5. Added:

Page 11 and 19. Chi-squared test corrected to χ^2

Page 16. Added:

In future studies, a standardized model of implementation at multiple sites, together with validated instruments for measuring patient outcomes and potentially qualitative methods, could result in a greater understanding of the complexity of an

endoscopy checklist that combines patient safety and person-centeredness and its effects.
Page 18. Deleted in Acknowledgements: "In 2015 AbbVie granted the first author …"
Page 18. Added: Article highlights

Abbreviations corrected first time being used:
n.s → non-significant
GI → Gastrointestinal
US → United States WHO → World health organization

Throughout the document, p-value corrected to *P,* and number of observations and subjects corrected to *n*.

After language editing there have been changes done in the language for clarity, consistency and correctness. We have used "track changes" in our word-document, and highlighted changes in the language in yellow.

Stockholm, September 26. 2017
Hanna Dubois and colleagues