Author’s response to reviews

Title: Patient-related factors associated with an increased risk of being a reported case of preventable harm in first-line health care: a case–control study

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Point by point in file attached, might be easier to read in the file, but are copied here:

Answers point by point

Jose Joaquin Mira (Reviewer 3):

reviewers’ comments responses

This study seeks to identify which patient-related factors are associated with an increased risk of harm in patients with reports of safety incidents. The study has been conducted with primary care and emergency patients. Data have been extracted from Sweden's mandatory damage incident reporting systems. No data are provided on the level of compliance with this reporting duty, nor on the number of incidents reported. The severity of these incidents is not known. They seem to be classified as such by the reporters themselves. The degree of variability and quality of the information that constitutes the starting point of the study is not known.
Clarification added that ALL cases reported during these years (2011-2016) in the whole country are used. Number of reported cases are found under results and in figure 1. Severity is in the text regarding mortality (3% and 28% in these two groups) and the severity for patients that did not die is evaluated by trained nurses and doctors working at the insurance company LÖF that receive the reports. In lex Maria reports, ‘serious’ is defined as a patient safety risk that could lead to long-lasting non-negligible damage, to the patient needing significantly increased care, or to the patient’s death. Now clarified in the text: The compliance to the mandatory reporting system is not known but as with all incident reporting systems there is underreporting.

The study seeks to provide information on both primary care and emergencies. They are quite different settings. For example, although there may be healthcare pressure and haste, in primary care the professional knows their patients and has been providing them with care for some time.

It can be argued that PHC and ED are different settings that we have merged in this study. That is true, but both these settings are the first contact with healthcare when patient experience new symptoms and both settings have a high density of diagnostic decision making. We have added this under setting and under discussion.

The study was not focused on psychiatric illness patients. However, the study at the end revolves around that these patients have a higher risk of suffering an adverse event, specifically based on the results it appears that above all a diagnostic error. This was not the main objective of this study.

Thank you for pointing that out. This in a case-control study with the main objective to assess which patient-related factors are associated with an increased risk of being a reported case of harm. We change the title to:

Patient-related factors associated with an increased risk of being a reported case of preventable harm in first-line health care: a case–control study

The study states that most preventable adverse events were due to diagnostic errors. However, the literature agrees that most are related to medication errors, and this point should be noted.
Yes, seen to frequency, but not harm. When it comes to the causes of severe adverse events in PHC and ED, diagnostic errors are a common type of preventable harm. We have adjusted the text: In first-line health care, diagnostic error—defined as delayed, missed, or incorrect diagnoses [7]—is a common type of serious preventable harm [8-10].

On the other hand, most of the diagnostic errors reported seem to originate in hospitals so I don't quite understand what data are being provided and originating in primary care or emergencies.

The reports of serious incidents and preventable harm in this study are filed in PHC or the ED. The errors occurred in PHC or the ED. The final, correct diagnosis (if the harm was diagnostic error) can have been made in the hospital.

The authors assert that there is a small number of studies on the frequency and causes of safety incidents in primary care and emergencies. It is true, as they point out, that the number of studies is greater in hospitals, but this study does not provide any new information on what is already known (except that unlike the rest, the main cause of preventable adverse events are diagnosis errors), see for example recent systematic reviews Panagoti et al. BMJ 2019;366:l4185) or those cited by the authors themselves. In the introduction, the authors acknowledge that usually the number of adverse events related to medication errors exceeds diagnostic errors.

Thank you, mentioned study only includes 3 studies from primary care but good to include in the references. The new information in our study is that in the population that seek PHC and the ED, there is a greater risk of harm if they have a psychiatric diagnosis, even if it is mild. Previous studies have looked at the risk of harm when patients have serious mental illness and in the hospital setting.

Age, comorbidity, income, diagnosis of mental illness is usually related to an increased risk of suffering a preventable adverse event, so authors should make greater effort to justify the usefulness, novelty and application of the results of their study.

The new information in our study is that in the population that seek PHC and the ED, there is a greater risk of harm if they have a psychiatric diagnosis, even if it is mild. Previous studies have looked at the risk of harm when patients have serious mental illness and in the hospital setting.
Other questions.

Is the severity of adverse events in primary care and emergency care comparable?

*** Yes, they are measured on the same scale of severity. The severity of the preventable harm is evaluated in the same standardized way from PHC and ED, in six levels, sick leave < 3 months, sick leave > 3 months, disability 1–15 %, disability 16–30 %, disability > 30 % and death.

It is stated that 'the preventable harm was mostly somatic harm'. What other type of harm is expected?

***Psychological harm, suicide, is expected when patients with psychiatric diagnosis are subject to preventable harm. We have changed the text to: The preventable harm was mostly somatic harm as opposed to psychiatric harm/suicide, primarily involving diagnostic errors of somatic disease.

What definition of adverse event has been used?

***WHO’s definition: An adverse event or experience is defined as 'any untoward medical occurrence that may present during treatment with a medicine, but which does not necessarily have a causal relationship with this treatment'. The basic point here is the coincidence in time without any suspicion of a causal relationship.

But we have only used the term once, in the background, and now we changed it to adverse safety events - in alignment with the article we used as our reference. Otherwise we have used “Serious safety incidents” and defined in the manuscript: In this context, ‘serious’ is defined as a patient safety risk that could lead to long-lasting non-negligible damage, to the patient needing significantly increased care, or to the patient’s death.

And all cases included in the study has been evaluated as preventable.
Considering the results and that there are fewer studies in mental health, have you considered focusing the study in this direction?

***The study design was case-control with focus on first-line health care so we would like to stick with this direction.

Patients may have a greater risk depending on the geographical area of the country, the type of centre, the experience or other factors of the professional, probably there are factors other than those studied that could be of greater interest. These potential factors are not commented or considered in the Discussion Section.

*** Thank you. We add in the discussion that this is a nationwide material of all reported cases but that there of course can be factors influencing the results that we have not studied:

There might be other factors influencing the results, but the data is all reported cases from the whole country with matched controls which mitigate the risk of effect of geographical area.