PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Adverse events in patients in home health care: a retrospective record review using trigger tool methodology
AUTHORS	Schildmeijer, Kristina; Unbeck, Maria; Ekstedt, Mirjam; Lindblad, Marléne; Nilsson, Lena

VERSION 1 – REVIEW

REVIEWER	Marieke Zegers Radboudumc The Netherlands
REVIEW RETURNED	05-Sep-2017

GENERAL COMMENTS	Thank you for the invitation to review this manuscript. It is an interesting subject; AEs in home care. You used a commonly used method to review records on adverse events and found remarkable results: 37.7% patients experiences an AE, while the incidence in Dutch hospitals is 5.7% (Zegers 2009), in Danish hospitals 9.0% (Schioler 2001) and 12.3% in Swedish hospitals (Soop 2009). So, hospital care is safer than home care? It is remarkable that adverse drug events are missing in your study results, while falls and drug related AEs were the most frequent ones in the Canadian study. Also other types of adverse events that were listed in table 1 as triggers, such as anxiety, severe worry, are lacking. I think the following sentence is incorrect: 'The pattern of AEs originating within or outside home health care is similar and may predominately characterize the risks for this group of elderly fragile patients, irrespective of the health care setting. ' The focus was home care and detect some AEs originating from another settings. To state this, you should set up another design/take another sample of record (records from health care setting outside the home care setting. Some methodological issues/questions: - Record keeping in home care: I have no clue/insight in the record keeping in home care. Is it electronic or paper based? Who is writing what? What are the responsibilities in record keeping. Where is the record located? - Random sample of 600 patients: how big was the total population and is this sample representative for the total sample of patients/clients who receive home care? - Ten teams for 600 records is a lot. With 5 teams, our review process was more efficient. - 10% of the records were reviewed by a second reviewer. What was the inter-rater reliability? - Why using two scales for severity? (NCC MERP Index and HMPS

	method) - Table 5: 'adverse drug event' is missing as AE type. - Table 5: please split this table. It is t large to understand (less columns) There are lots of vague phrases: - Page 2 and 5: 'what do you mean with 'pattern of AEs'? - Page 2 and throughout the hole manuscript 'patients admitted to receiving home healthcare'. Returned to home care', 'discharged from home care'. I would phrase this as: patient who stay at home and receive home care (have an indication for home care). Discharge from home care sounds strange. - Page 2: 'sample of 600 patients was reviewed'. (records were reviewed) - Page 2: 'the types of AEs that occur or are detected in home health care settings imply that we must address and improve how care is provided' - Page 23: 'This implies that we must address how home care is provided' You mean that you want to explore in more detail what the causal factors are of these adverse events. - Page 3: the first point is the aim (not a strength); second point is vague (I cannot follow this point); what is the implication of the third point?; point nr four 'differ from what'? - Page 4 'when planning for the future'?? - Page 6: what do you mean with 'convenience sampling' of the review teams? - Page 6: 'The AE or no-harm incident'. You also included no-harm incidents? The definition of AEs on page 5 is: AE was defined as suffering physical or psychological harm, illness or death caused by health care'. - Page 6: 'randomization...' for what? - Page 9: 'the AE was not related to health care/social care' But the definition of AEs on page 5 is: AE was defined as suffering physical or psychological harm, illness or death caused by health care'. - Page 22: 'we regard this as an improvement from a patient perspective' How?

REVIEWER	Ellen Tveter Deilkås Akershus University hospital, Norway
REVIEW RETURNED	12-Sep-2017

GENERAL COMMENTS	The paper is an important study. The record review method is useful to map risk of adverse events in healthcare services. It is good that this method now also is available for home care services. It will be appreciated by many. The paper is well written. It has few but however important flaws that need to be addressed. 1. To what extent is the sample in this study is representative for the total population of patients with home care services, which the sample has been drawn from. On page 6 lines 55-60 you write that patients with very little home care services were excluded from the study. Please clarify better the criteria for the amount of home care services that patients needed to receive, to be eligible for the study. Please state how many patients with home care services that were randomly drawn, but had to be excluded from the sample because they were not eligible for the study? 2. The paper does not clarify on what legal and ethical conditions the review and research has been performed. Please do so.

	3. Statistics that inform on margin of error for the estimated percentages, like for example confidence intervals should be stated. 4. The adjustments to the severity scale (E-I) are well justified and logic.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

A) You used a commonly used method to review records on adverse events and found remarkable results: 37.7% patients experiences an AE, while the incidence in Dutch hospitals is 5.7% (Zegers 2009), in Danish hospitals 9.0% (Schioler 2001) and 12.3% in Swedish hospitals (Soop 2009). So, hospital care is safer than home care?

B) The studies you refer to are based on another record review methodology. There are many similarities between the trigger tool methodology that we have used and the Harvard Medical Practice Study methodology used in the studies mentioned. However, there are also several differences between them which affect the outcome. These differences include the threshold for inclusion of adverse events, the length of the inclusion period, the length of time for primary review, the exclusion of omission (trigger tools), the review process, the details in the descriptions of triggers/screening criteria etc.

Furthermore, the definition of AE differs somewhat. Zegers writes about temporary or permanent disability, death or prolongation of hospital stay. Schioler defines an AE as injury and further that said injury should have prolonged hospital stay or caused outpatient follow-up or disability at discharge. Soop defines an AE as an unintended injury or complication which results in disability at discharge, death or prolongation of hospital stay. Our definition included more transient and minor AEs. Looking at Zegers' study, it reports only 3.7% of AEs in the group nursing care. In our study, we have identified substantially more AEs that could have belonged to this group.

When comparing severe AEs giving moderate (recovery within 6-12 months) or permanent disability or death, by recalculating their respective prevalence, there seem to be no obvious differences between our study and those the reviewer refers to. The same seems true also for comparisons with earlier studies of home health care. We discuss this in the revised version of the text. There are studies from hospital care looking at specific specialties that report figures higher than in those three national studies. From intensive care, 19.5% of patients had an AE (Nilsson 2012), from orthopaedic care, 30.0% (Unbeck, 2013), from paediatric care, 34.0% (Unbeck 2014), and from hospitalized cancer patients, 24.2% (Haukland, 2017). According to Hibbert 2016, the range of admissions with an AE, for 17 general inpatient (general, general medical, general surgical) studies varied between 7 and 40%, with a cluster of nine studies between 20 and 29%.

A) It is remarkable that adverse drug events are missing in your study results, while falls and drug related AEs were the most frequent ones in the Canadian study. Also other types of adverse events that were listed in table 1 as triggers, such as anxiety, severe worry, are lacking.

B) There is, to our knowledge, no commonly accepted and used list of AEs for comparison between studies. The triggers in the medication module point at different types of AEs. We have chosen not to characterize them as a group "adverse drug event," but instead look at the type of injury the patient had and characterize it from that viewpoint.

The cause of a fall or a haemorrhage might have been a drug overdose. As "adverse drug event" is not seldom used as a separate group, we have expanded on this in the discussion.

The trigger including anxiety, worry etc. is referred to as psychological harm in the list of AEs.
A) I think the following sentence is incorrect: 'The pattern of AEs originating within or outside home health care is similar and may predominately characterize the risks for this group of elderly fragile patients, irrespective of the health care setting. ' The focus was home care and detect some AEs originating from another settings. To state this, you should set up another design/take another sample of record (records from health care setting outside the home care setting.
B) We agree and have deleted this sentence.

A) Record keeping in home care: I have no clue/insight in the record keeping in home care. Is it electronic or paper based? Who is writing what? What are the responsibilities in record keeping. Where is the record located?
B) We have added a description in the methods section.

A) Random sample of 600 patients: how big was the total population and is this sample representative for the total sample of patients/clients who receive home care?
B) The review was closely connected to the development and validation of a trigger tool for patients admitted to home health care. As written, we recruited the review teams using a convenience strategy. Teams interested in patient safety were asked to participate, and they were integrated in the refinement process of the trigger tool. We aimed for a rich patient material and looked for teams representing "basic" as well as advanced home health care. In 2016, approximately 350,000 individuals received home health care in Sweden. Our ambition was not to have a representative sample from the entire country. We have included the fact that our sample cannot be regarded as representative for patients receiving home health care in Sweden as a limitation of the study.

A) Ten teams for 600 records is a lot. With 5 teams, our review process was more efficient.
B) As home healthcare is organized differently in different municipalities and regions, we wanted to capture records from many places across the country - and therefore we chose to include all teams that volunteered. Additionally, the review teams interacted in a Delphi process for the development and validation of triggers suited for home health care. By having ten teams we gained more input on the triggers. We also faced some problems in recruiting teams as managers were reluctant to give "time off" for reviews. Ten teams made the work load more acceptable.

A) 10% of the records were reviewed by a second reviewer. What was the inter-rater reliability?
B) The inter-rater reliability of the primary reviewers' judgements concerning if a record was to be forwarded to secondary review was $\kappa = 0.801$ (substantial). We now include this figure and have changed the reporting of percentage agreement.

A) Why using two scales for severity? (NCC MERP Index and HMPS method)
B) In designing the study we wondered which severity scale would be the most appropriate in this setting. As can be seen in Table 4, the HMPS scale appeared less appropriate. We have added a discussion explaining the use of two scales.
A) Table 5: 'adverse drug event' is missing as AE type.
B) We did not use "adverse drug event" as an AE type. Instead we categorized the harm that was caused by a drug AE, for example fall, haemorrhage, constipation. Allergic reaction is shown in Table 5.

A) Table 5: please split this table. It is t large to understand (less columns).
B) We agree and have reduced the table by removing two columns.

A) Page 2 and 5: 'what do you mean with 'pattern of AEs'?
B) We have changed from "pattern" to "types of AEs."

A) Page 2 and throughout the hole manuscript ‘patients admitted to receiving home healthcare’. Returned to home care’, ‘discharged from home care’. I would phrase this as: patient who stay at home and receive home care (have an indication for home care). Discharge from home care sounds strange.

B) We have looked closely at the phrasings. When describing the inclusion of patients in the study we use “admitted to home health care” as the randomisation was done on admissions. In other cases, we have changed the phrasing to “receiving home health care.” A patient receiving home health care for a limited period of time, for example when recovering after surgery, can be discharged from home health care. A home health care patient can also be discharged from home health care during a period of hospitalisation and readmitted upon returning home.

A) Page 2: ‘sample of 600 patients was reviewed’. (records were reviewed).
B) Thank you, we have changed this.

A) Page 2: ‘the types of AEs that occur or are detected in home health care settings imply that we must address and improve how care is provided’ .
B) This sentence has been rephrased.

A) Page 23: ‘This implies that we must address how home care is provided’ You mean that you want to explore in more detail what the causal factors are of these adverse events.
B) This sentence has been rephrased. We point out the fact that the most frequent AEs could be reduced by improvements in care.

A) Page 3: the first point is the aim (not a strength); second point is vague (I cannot follow this point); what is the implication of the third point?; point nr four ‘differ from what’?
B) We agree and have updated the strengths and limitations of the study.

A) Page 4 ‘when planning for the future’??
B) We have rephrased this sentence.

A) Page 6: what do you mean with ‘convenience sampling’ of the review teams?
B) We have explained this in the revised text.

A) Page 6: ‘The AE or no-harm incident’. You also included no-harm incidents? The definition of AEs on page 5 is: AE was defined as suffering physical or psychological harm, illness or death caused by health care’.
B) We have corrected this mistake. Only AEs are included in this manuscript.

A) Page 6: ‘randomization...’ for what?
B) Randomization of records – this has been added.

A) Page 9: ‘the AE was not related to health care/social care’ But the definition of AEs on page 5 is: AE was defined as suffering physical or psychological harm, illness or death caused by health care’.
B) We have changed the terminology used here.

A) Page 22: ‘we regard this as an improvement from a patient perspective’ How?
B) We believe that it contributes to the identification of risk areas. This explanation has been added to the text.

Reviewer 2
A) To what extent is the sample in this study representative for the total population of patients with home care services, which the sample has been drawn from.
B) We did not use a stratified sample of records for the total number of patients receiving home health care in Sweden. Our review was closely intergraded in a development and validation process for a trigger tool adjusted for home health care. However, the records were randomly chosen from the ten reviewing sites. We have added this information in the revised text.

A) On page 6 lines 55-60 you write that patients with very little home care services were excluded from the study. Please clarify better the criteria for the amount of home care services that patients needed to receive, to be eligible for the study. Please state how many patients with home care services that were randomly drawn, but had to be excluded from the sample because they were not eligible for the study?
B) We agree that this is a limitation. Regrettably, this exclusion criterion was not defined in a more precise manner than by examples of very sparse care interventions. We compare this exclusion criterion to the GTT criterion of excluding hospital stays less than 24 hours. Those figures are not displayed. We did not identify the numbers of records that were excluded.
In a future handbook, this exclusion criterion needs a strict definition, for instance “no more than one assistance per week.”
We have added this as a limitation of the study.

A) The paper does not clarify on what legal and ethical conditions the review and research has been performed. Please do so.
B) We have added this information.

A) Statistics that inform on margin of error for the estimated percentages, like for example confidence intervals should be stated.
B) We have added confidence intervals.
A) The adjustments to the severity scale (E-I) are well justified and logic.
B. Thank you.

VERSION 2 – REVIEW

REVIEWER	Marieke Zegers Radboudumc The Netherlands
REVIEW RETURNED	07-Nov-2017

GENERAL COMMENTS	The authors addressed the review comments well. There are, however, still some minor points. The title stated that this study is a cohort design. I think the design is cross-sectional, while you did not have follow-up measures and don’t report incidence rates, but prevalence rates. I suggest to mention ‘retrospective record review’ as design. At several pages you write ‘types of AEs’. This should be ‘type of AEs’ Please mention in the method section that this study (and thus the results) were part of an validation study to validate the trigger tool (and refer to ref nr 15). This should be more prominent in the article (add subheading study design). In the introduction: ‘ Safe solutions for care outside…are important’. I

	should suggest to delete this sentence, because you do not know if there is a (safety) problem. Therefore, you carried out this study. Review team: did they screen their own records or records of their colleagues? Please mention this in the method section and discuss this in the discussion section. Is there a bias? (not recognizing AEs in their own record, OR they found more AEs because they have more context information that is not stated in the record)? Kappa of the AE determination is more interesting. Do have have that rate? I would suggest to delete the comparison between the two harm scales (more appropriate to report this as a result of the validation study). No relevance for this paper.

REVIEWER	Ellen Tveter Deilkås Akershus University Hospital, Norway
REVIEW RETURNED	23-Oct-2017

GENERAL COMMENTS	1. You have mentioned some examples on page 7, of what cases you would exclude (If a patient in the random sample was receiving limited home health care once or twice a week, for example only blood pressure measurement or delivery of pre-dispensed drugs, this patient was replaced by another random admission.) Please describe more specifically the amount of home care services demanded as a minimum to be eligible for the study. 2. It is not clear if the review process has two primary reviewers reviewing the same sample before comparing their results, as the Global trigger Tool and Nursing facility Trigger tool recommends, or if only one primary reviewer reviews the records in the primary stage. Please comment on this. 3. Page 8 line 18. “ensure” is suggested exchanged to “test”. If you did other inter rater reliability analysis, it would be interesting to see the results.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1:
1)The title stated that this study is a cohort design. I think the design is cross-sectional, while you did not have follow-up measures and don’t report incidence rates, but prevalence rates. I suggest to mention ‘retrospective record review’ as design.
Respons: We have changed the design accordingly. We argue that we report cumulative incidence rates of AEs.

2) At several pages you write ‘types of AEs’. This should be ‘type of AEs’
Respons:We have changed to type of AEs. In some sentences “types” refers to multiple types. This has not been changed.

3) Please mention in the method section that this study (and thus the results) were part of a validation study to validate the trigger tool (and refer to ref nr 15). This should be more prominent in the article (add subheading study design).

Respons: We have added this information in a new subheading.

4) In the introduction: ‘Safe solutions for care outside…are important’. I should suggest to delete this sentence, because you do not know if there is a (safety) problem. Therefore, you carried out this study.
Respons: We have deleted this sentence.

5) Review team: did they screen their own records or records of their colleagues? Please mention this in the method section and discuss this in the discussion section. Is there a bias? (not recognizing AEs in their own record, OR they found more AEs because they have more context information that is not stated in the record)?
Respons:We have added this information in the method section and also as a conceivable limitation.

6) Kappa of the AE determination is more interesting. Do have that rate?
Respons: We do not have this information since our study design did not include double review in secondary review stage. This was due to the fact that all primary as well as secondary review outcomes were thoroughly monitored by a record review expert for completeness and adherence to the trigger and AE definitions, and project manual. Any questions or discrepancies were referred back to the relevant team for resolution to make sure that the AE inclusion followed the project manual. This is explained in the revised version. The determination of AEs in the secondary review was based on a team discussion.

7) I would suggest to delete the comparison between the two harm scales (more appropriate to report this as a result of the validation study). No relevance for this paper.
Respons:We have deleted the comparison between the two scales in our study. We would like to keep the presentation of the two severity scales. The comparison between our findings and studies in home health care in other countries respectively in-hospital studies in Sweden is facilitated by the two scales as some studies use the HMPS scale and other the NCCP MERP scale.

Reviewer 2:
1. You have mentioned some examples on page 7, of what cases you would exclude (If a patient in the random sample was receiving limited home health care once or twice a week, for example only blood pressure measurement or delivery of pre-dispensed drugs, this patient was replaced by another random admission.) Please describe more specifically the amount of home care services demanded as a minimum to be eligible for the study.
Respons:The present study was part of a validation study that aimed to validate a trigger tool for home health care. In order to get a material as rich as possible we used this exclusion criteria. Unfortunately it was not described in a better way than we have written. This is a limitation of our study and in a forthcoming handbook for the trigger tool it is necessary to have a strict inclusion criteria that states the minimum level of home health care (for example at least two times a week equalizing the Global Trigger Tool excluding hospital stay < 24 hours) to be included for review. We have in the revised version more clearly pointed on the fact that the present study is part of a validation study and also expanded on the limitation of minimum of home care services.

2. It is not clear if the review process has two primary reviewers reviewing the same sample before comparing their results, as the Global trigger Tool and Nursing facility Trigger tool recommends, or if only one primary reviewer reviews the records in the primary stage. Please comment on this.
Respons: We have clarified this in the review process section and also added as a limitation of the study that only 10% of the records were reviewed by two reviewers.

3. Page 8 line 18. “ensure” is suggested exchanged to “test”. If you did other inter rater reliability analysis, it would be interesting to see the results.

Respons:We have clarified this in the review process section and also added as a limitation of the study that only 10% of the records were reviewed by two reviewers.

We have exchanged to “test”.
In the first version of our paper we wrote: “The total percentage agreement (range between teams) of the reviewers’ judgements concerning the presence of events in the primary review and whether the record should be forwarded to secondary review was 82.9% (46.2−94.7%) and 92.8% (75.0−100%), respectively.” We changed this to kappa-statistics as requested by reviewer #1 in the first revision. Kappa-statistics was not possible to calculate for the presence of events in the primary review. The explanation is: if both primary reviewers have missed an event, this is an unknown event for us and for them. The outcome will be 0 for that choice (both did not find an event) in the statistic calculations and Kappa statistics cannot be calculated if 0 is present.