PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Effect of involving certified health care assistants in primary care in Germany: A cross-sectional study
AUTHORS	Senft, Jonas; Wensing, M; Poss-Doering, Regina; Szecsenyi, Joachim; Laux, Gunter

VERSION 1 – REVIEW

REVIEWER	Cherian Varghese World Health Organization, Switzerland
REVIEW RETURNED	06-Sep-2019

GENERAL COMMENTS	This is an important study and demonstrates that qualified non
	physician providers can improve care. However it is not clear if this is the factor that made the difference. There may have been a natural selection in that good primary care facilities have non physician providers who went on to have extra qualifications. This can affect the results. There should be more information on a sub sample of the primary care between those with qualified and non
	qualified non physician health care providers.

REVIEWER	Julia Lukewich
	Faculty of Nursing, Memorial University, Canada
REVIEW RETURNED	20-Sep-2019
GENERAL COMMENTS	Thank you for the opportunity to read this interesting and important

GENERAL COMMENTS	Thank you for the opportunity to read this interesting and important manuscript examining the presence of non-physician providers in primary care practice. Please find my comments and suggested revisions below.
	- Title requires revision. Title should reflect specific healthcare provider group examined in study, i.e. "certified health care assistants" rather than "highly qualified non-physician health care professionals" (which is broader).
	- Study would be strengthened by a guiding framework/model that identifies study variables, e.g. employment/organizational structure as a key component in contributing to study outcomes; consider a structure-process-outcome model.
	- Study design: Clarify study design and ensure consistency throughout manuscript. Please use same language to refer to study design throughout the manuscript each time it is mentioned. E.g. Abstract states "cross-sectional study"; methods states "comparative observational study"; discussion states "retrospective data analysis", "secondary data analysis", etc.

- Abstract: Spell out/define abbreviations in abstract (i.e. AOK should be defined). P-value for uneconomic prescriptions is missing in abstract. Be careful with use of comma vs. period when presenting numbers, I think there are errors in the abstract.
- Additional references should be sought to support statements throughout the Introduction and Discussion section. Study needs to be clearly built upon existing evidence. Inclusion of references for points made throughout the Introduction and Discussion would strengthen the overall manuscript. Need to better integrate literature.
- In Canada, the there is a growing body of evidence related to Registered Nurses in primary care (family practice nurses/primary care nurses). In addition to discussing Nurse Practitioners, this should be added to the Introduction.
- Within the Introduction, you summarize literature related to nursing in other countries (US, Australia, Canada). The current state of primary care nursing in Germany should also be presented and/or the current state of practice assistants in these other countries should be summarized.
 Study purpose/aim and specific objectives/research questions are missing and should be presented upfront (end of introduction or beginning of methods section).
- Be careful with wording throughout the entire manuscript. My understanding is that you examined the presence of certified healthcare assistants in primary care practice, specifically the association between at least 1 employed certified healthcare assistant in a practice, to various outcomes (e.g. consultations, hospital stays, etc.). You cannot make conclusions about the their roles/skills/responsibilities (i.e. process) – this was not measured in the study. Wording needs to be changed throughout manuscript to accurately reflect analysis performed.
- Ethics statement (Study Design section) – update to specifically state/indicate whether or not approval was obtained. This is not entirely clear as stated.
- Within methods, explicitly indicate how you identified: (1) whether or not a certified health care assistant was employed within the practice, where was this human resource data obtained?), and (2) how you confirmed the health care assistant had the additional training available since 2008 described in introduction (which seems to be voluntary)?
- Describe in Methods section if there was any linkage required between variables? If so, was this performed by the researchers?
- Clearly define study outcomes. Ensure that you use consistent language each time they are referred to throughout manuscript - e.g. consultations, GP consultations, specialist consultations, prescribed medications, hospital stays, hospital admissions, hospital readmission, etc. Provide a clear list and definition of outcome variables in Method section.
- Include statement addressing sample size/power. E.g. Was a sample size calculation conducted? If not, explain why.

- Within Statistical Analysis section, clearly indicate what statistical tests were used to compare groups (HCA vs. Non-HCA).
- Within Table 1 and Table 2, clarify variable "HCA" Indate in heading that it was the presence of at least 1 HCA in practice.
- Important limitations of study that need to be discussed are: lack of information about the influence of other providers in practice (e.g. nurse practitioners, registered nurses), lack of provider-level data (education, experience), lack of organizational-level data (structural characteristics of practice setting), etc. The results need to be clearly explained within the context of these limitations which are important variables that might influence outcomes studied.
- Within Discussion section, results are compared to a meta- analysis focused on care provided by specialist physicians. I wonder if this is an appropriate comparison and would suggest looking for a more similar group to certified health care assistants (e.g. registered nurses, physician assistants, etc).

VERSION 1 – AUTHOR RESPONSE

Response to Reviewer #1:

"This is an important study and demonstrates that qualified non physician providers can improve care. However it is not clear if this is the factor that made the difference. There may have been a natural selection in that good primary care facilities have non physician providers who went on to have extra qualifications. This can affect the results. There should be more information on a sub sample of the primary care between those with qualified and non qualified non physician health care providers." We would like to thank reviewer#1 for this important remark regarding the limitations of this analysis and the interpretation of its results. As reviewer#1 correctly commented due to the limited nature of claims data potentially confounding structural factors like e.g. educational level and experience of the practice staff were not available and therefore could not be assessed by this study. However, adjustments were made for all available confounding variables, particularly for structural factors like practice size (number of contacts in relevant period), type of practice (single, group) and urbanization (rural, urban). The omission of further practice details was an important element of the data protection contract for participating practices with the objective not to be identifiable by researchers. However, we deliberately chose claims data for this analysis due to the high volume and statistical power necessary to assess the chosen outcomes. Consequently, limitations given by the nature of claims data have to be considered. On the other hand, the available structural factors in our opinion represent an appropriate adjustment for this analysis and the results show that involvement of HCAs has a significant effect on the assessed outcomes. The discussion section was revised to clarify these important hints regarding the limitations of this study.

Page 16, line 17 - Page 17, line 7:

Limitations are given by the study design and the associated risk of confounding factors. Due the nature of claims data, the parameters available for analysis were limited. Consequently, the evaluation of relevant patient-reported outcomes such as e.g. quality of life was not possible in this analysis. Furthermore, the omission of practice details was an important element of the data protection contract for participating practices with the objective not to be identifiable by researchers. Potentially relevant structural factors such as educational level and experience of the staff or structural characteristics of the practices like equipment or procedural factors such as available diagnostics and treatment options, were not available for this analysis. Consequently, limitations given by the nature of claims data have to be considered. On the other hand, we deliberately chose claims

data for this analysis due to the high volume and statistical power necessary to assess the chosen outcomes. Furthermore, in our opinion the available structural factors included in this analysis represent an appropriate and best possible adjustment for the measured outcomes.

Response to Reviewer #2:

"Title requires revision. Title should reflect specific healthcare provider group examined in study, i.e. "certified health care assistants" rather than "highly qualified non-physician health care professionals" (which is broader)."

We would like to thank reviewer#2 for this important comment. The title was revised to reflect the specific professional title of the health care professionals focused in this study:

Effect of involving certified health care assistants in primary care in Germany: A cross-sectional study on quality and efficacy in 861,223 patients

"Study would be strengthened by a guiding framework/model that identifies study variables, e.g. employment/organizational structure as a key component in contributing to study outcomes; consider a structure-process-outcome model."

We would like to thank reviewer#2 for this remark regarding the identification of further variables potentially contributing the outcomes. Unfortunately, due the restrictions given by the nature of the supplied claims data, the available parameters are limited. No conclusions can be drawn with regard to further potentially relevant structural factors like e.g. staff size or equipment or procedural factors like e.g. available diagnostics and treatment options. Consequently, a structure-process-outcome model in our opinion seemed not feasible for this study. However, all available data potentially contributing to the study outcomes like e.g. morbidity or practice size were selected ex ante for adjustment of the statistical analysis.

We further commented limitations given by the nature of the study design in the discussion section. Page 16, line 17 - Page 17, line 7:

Limitations are given by the study design and the associated risk of confounding factors. Due the nature of claims data, the parameters available for analysis were limited. Consequently, the evaluation of relevant patient-reported outcomes such as e.g. quality of life was not possible in this analysis. Furthermore, the omission of practice details was an important element of the data protection contract for participating practices with the objective not to be identifiable by researchers. Potentially relevant structural factors such as educational level and experience of the staff or structural characteristics of the practices like equipment or procedural factors such as available diagnostics and treatment options, were not available for this analysis. Consequently, limitations given by the nature of claims data have to be considered. On the other hand, we deliberately chose claims data for this analysis due to the high volume and statistical power necessary to assess the chosen outcomes. Furthermore, in our opinion the available structural factors included in this analysis represent an appropriate and best possible adjustment for the measured outcomes.

"- Study design: Clarify study design and ensure consistency throughout manuscript. Please use same language to refer to study design throughout the manuscript each time it is mentioned. E.g. Abstract states "cross-sectional study"; methods states "comparative observational study"; discussion states "retrospective data analysis", "secondary data analysis", etc."

We would like to thank reviewer#2 for this valuable remark. The study design was clarified in the methods section and the manuscript was revised for consistent wording in this regard. Page 8, line 3-6:

A cross-sectional study was conducted. Claims data related to patients treated in general practices between January 1 and December 31, 2014 were supplied by the AOK statutory health insurance company (German: "Allgemeine Ortskrankenkasse", Baden-Wuerttemberg, Germany).

"- Abstract: Spell out/define abbreviations in abstract (i.e. AOK should be defined). P-value for uneconomic prescriptions is missing in abstract. Be careful with use of comma vs. period when presenting numbers, I think there are errors in the abstract." The abstract was revised in this regard.

"- Additional references should be sought to support statements throughout the Introduction and Discussion section. Study needs to be clearly built upon existing evidence. Inclusion of references for points made throughout the Introduction and Discussion would strengthen the overall manuscript. Need to better integrate literature. "

We thank Reviewer #2 for pointing this out. To date, high-quality evidence regarding potential effects of involving higher qualified non-physician workforces on quality and efficacy of primary care is scarce to our knowledge. However, we reviewed the whole manuscript and added further literature to statements we made if possible. In our opinion we discussed the most relevant high-quality studies, particularly RCTs and meta-analyses in this regard.

"- In Canada, the there is a growing body of evidence related to Registered Nurses in primary care (family practice nurses/primary care nurses). In addition to discussing Nurse Practitioners, this should be added to the Introduction."

We thank reviewer#2 for this comment. We added this aspect to the introduction section. Page 6, line 13-16:

For primary healthcare registered nurses or nurse practitioners in Canada, there is growing evidence that their involvement in practices is associated with health promotion, particularly in the management of chronic diseases [1–3].

"- Within the Introduction, you summarize literature related to nursing in other countries (US, Australia, Canada). The current state of primary care nursing in Germany should also be presented and/or the current state of practice assistants in these other countries should be summarized." We thank reviewer#2 for this remark, the introduction was revised in this regard.

Page 6, line 17 - Page 7, line 1:

While qualified nurses are well integrated in primary care in other countries, in Germany so far there is no professional role for nurses in general medicine. On the other hand, non-academic workforces like practice or medical assistants have become increasingly involved into active patient care as they have been integrated into treatment monitoring or patient coaching for chronic diseases like diabetes e.g. in the United States [4–6]. In Germany, general practitioners (GP) usually employ certified practice assistants, who absolved professional training for three years and traditionally performed clerical duties like reception and routine tasks, such as blood sampling or electrocardiogram recording.

"- Study purpose/aim and specific objectives/research questions are missing and should be presented upfront (end of introduction or beginning of methods section)."

We thank reviewer#2 for noticing this. The aims of the present study were further clarified at the end of the introduction:

Page 7, line 19-22:

The aim of this study was to assess the influence of involving certified health care assistants on quality and efficacy of primary care in Germany. For this purpose, for the first time a high-volume claims data cross-sectional study was performed.

"- Be careful with wording throughout the entire manuscript. My understanding is that you examined the presence of certified healthcare assistants in primary care practice, specifically the association between at least 1 employed certified healthcare assistant in a practice, to various outcomes (e.g. consultations, hospital stays, etc.). You cannot make conclusions about the their

roles/skills/responsibilities (i.e. process) – this was not measured in the study. Wording needs to be changed throughout manuscript to accurately reflect analysis performed."

We thank reviewer#2 for this comment. We are aware that the professional role of HCAs was not part of this analysis and no conclusions can be drawn in this regard. Consequently, we revised the whole manuscript to clarify wording in this regard. As an example in the discussion section: Page 15, line 19-24:

However, no conclusion can be drawn by this study with regard to the specific role of HCAs within the practice staff. As a recent survey showed, in Germany there is no firmly standardized professional role for HCAs. Performed tasks differ widely from simple patient assessment or basic wound care to tasks with substantial responsibility like emergency home visits, chronic care management or treatment of complex wounds [7].

"- Ethics statement (Study Design section) – update to specifically state/indicate whether or not approval was obtained. This is not entirely clear as stated."

We thank reviewer#2 for this hint. The ethics statement was clarified in this regard: Page 8, line 8-11:

Ethical approval for this study was given by the local institutional Ethics Committee of the University Hospital Heidelberg (No. S-359/2013).

"- Within methods, explicitly indicate how you identified: (1) whether or not a certified health care assistant was employed within the practice, where was this human resource data obtained?), and (2) how you confirmed the health care assistant had the additional training available since 2008 described in introduction (which seems to be voluntary)?"

(1) Practices employing certified HCAs could be unambiguously identified since employment of HCAs is obligatorily reimbursed by state health insurance in the HZV program. We obtained a list of all GP practices from the health insurance that obtained the information on employed HCAs within the particular GP practices.

(2) In order to become a HCA, a well-defined qualification process has to be passed through. This process is mandatory. If a HCA candidate passes the final exam a state-approved certificate will be made out for the candidate.

The methods section was revised accordingly:

Page 9, line 17-19:

Practices employing certified HCAs could be unambiguously identified since employment of HCAs is obligatorily reimbursed by state health insurance in the HZV program.

"- Describe in Methods section if there was any linkage required between variables? If so, was this performed by the researchers?"

The claims data consisted of several data sets containing particular information on patient care (e. g. GP consultations, prescriptions and hospitalisations). These data could be linked on the basis of a unique patient identifier. Data linkage was performed by our research team using a relational database.

This information was added to the methods section:

Page 9, line 19-24:

The claims data consisted of several data sets, containing particular information on patient care (e. g. GP consultations, prescriptions and hospitalizations). These data could be linked on the basis of a unique patient identifier. Data linkage was performed by our research team using a relational database. Subjects cannot be identified, directly or through identifiers linked to the subjects.

"- Clearly define study outcomes. Ensure that you use consistent language each time they are referred to throughout manuscript - e.g. consultations, GP consultations, specialist consultations, prescribed medications, hospital stays, hospital admissions, hospital readmission, etc. Provide a clear list and definition of outcome variables in Method section."

We thank reviewer#2 for pointing this out. The methods section was revised to outline the study outcomes and their definition. Furthermore, the manuscript was revised for consistent labelling of the analyzed outcomes.

Page 10, line 6-22:

To assess the effect of involving HCAs on quality and efficacy of primary care, the following outcome parameters were analyzed: GP consultations, specialist consultations, hospital admissions, hospital readmissions within 4 weeks, hospitalization costs, prescription of follow-on drugs and outpatient medication costs. The number of GP and specialist consultations per patient could be determined by the codes according to the EBM system ("Einheitlicher Bewertungsmassstab") used for accounting of outpatient medical services in Germany. Number of hospital admissions and readmissions per patient as well as per-patient costs for hospitalization in € was determined by the recorded Diagnosis Related Groups (DRG) codes used for reimbursement of inpatient medical services in Germany. The perpatient number of prescriptions of so-called follow-on drugs, patent-secured marginally altered pharmaceuticals with no benefit compared to the prototype drug according to evidence-based criteria [19], was determined by records of the central pharmaceutical numbers of prescribed medications ("Pharmazentralnummer", PZN). Outpatient medication costs per patient in € could be determined by accounting data for prescriptions reimbursed by the AOK state health insurance.

"- Include statement addressing sample size/power. E.g. Was a sample size calculation conducted? If not, explain why."

We did not perform sample size calculation since we performed a full census.

This was clarified in the methods section:

Page 10, line 24:

The full sample of available claims data was used for the analysis.

"- Within Statistical Analysis section, clearly indicate what statistical tests were used to compare groups (HCA vs. Non-HCA)."

Comparison between groups was done by multivariable regression analysis, which took clustering of patients in GPS and GPs in practices into account. Depending on the distribution of each outcome, linear regression, negative-binomial regression or Poisson regression models (for count data) were used.

This was added to the methods section:

Page 11, line 7-11:

Comparison between groups was done by multivariable regression analysis, which the three-level clustering of patients, GPs and practices into account. Depending on the distribution of each outcome, linear regression, negative-binomial regression or Poisson regression models (for count data) were used. "- Within Table 1 and Table 2, clarify variable "HCA" Indate in heading that it was the presence of at least 1 HCA in practice."

We thank reviewer#2 for this hint, Table 1 and Table 2 were revised accordingly.

"- Important limitations of study that need to be discussed are: lack of information about the influence of other providers in practice (e.g. nurse practitioners, registered nurses), lack of provider-level data (education, experience), lack of organizational-level data (structural characteristics of practice setting), etc. The results need to be clearly explained within the context of these limitations which are important variables that might influence outcomes studied."

We would like to thank reviewer#2 for this important comment regarding the limitations of this analysis. As reviewer#2 correctly pointed out, due to the limited nature of claims data potentially confounding structural factors such as educational level and experience of the practice staff were not available and therefore could not be assessed by this study. The omission of practice details was an important element of the data protection contract for participating practices with the objective not to be identifiable by researchers. However, we deliberately chose claims data for this analysis due to the high volume and statistical power necessary to assess the chosen outcomes and adjustments were

made for all available confounding variables, particularly for structural factors like practice size (number of contacts in relevant period), type of practice (single, group) and urbanization (rural, urban). Consequently, limitations given by the nature of claims data have to be considered. On the other hand, the available structural factors in our opinion represent an appropriate adjustment and the results of this study show that involvement of HCAs has a significant effect on the assessed outcomes.

The discussion section was revised to clarify these important hints regarding the limitations of this study:

Page 16, line 17 - Page 17, line 7 as cited above

"- Within Discussion section, results are compared to a meta-analysis focused on care provided by specialist physicians. I wonder if this is an appropriate comparison and would suggest looking for a more similar group to certified health care assistants (e.g. registered nurses, physician assistants, etc)."

We thank reviewer#2 for this comment. We think our argumentation in the discussion section was misleading in this regard. Unfortunately, to our knowledge there are currently no high-quality studies assessing the outcome reduction of hospital admissions in a setting, where only HCAs or other similar qualified non-physician work forces are involved. In our opinion the cited meta-analysis [9] is relevant to show that the effect, which has to be expected in this regard is low-scaled. Moreover, RCTs included in this study assessed disease management programs, in which monitoring is partly performed by higher qualified non-physician work forces. Monitoring of chronically ill patients is a major part of the education and intended work field of HCAs. Thus, based on the high level of evidence (IA) this study in our opinion is noteworthy in this context. However our main intention was to demonstrate that the expected effect of involving higher educated non-physician work forces is probably low and therefore high statistical power like it is given by our study design is needed to prove it.

We revised the discussion to clarify our thoughts in this regard:

Page 15, line 4-11:

The results of our study show a much smaller effect with a reduction of 4% hospitalizations when HCAs were involved, which in our opinion is closer to reality in primary care. As a comparison, even in settings of complex disease management programs for heart failure patients performed by highly educated non-physician work force and specialist involvement, low rates of reduction in all-cause hospitalization are common, with a range of up to 8% as a recent meta-analysis of 12 RCTs showed [9].

References:

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9. Takeda A, Martin N, Taylor RS, Taylor SJ (2019) Disease management interventions for heart failure. Cochrane Database Syst Rev 1:CD002752.

https://doi.org/10.1002/14651858.CD002752.pub4

REVIEWER	Julia Lukewich
	Memorial University
	Canada
REVIEW RETURNED	05-Nov-2019
GENERAL COMMENTS	Thank you for the opportunity to review a revised/updated version of this manuscript. Although, many comments were appropriately addressed, there are still a few places where I feel this manuscript could be strengthened. See comments below.
	Do not need to include sample size in title. Recommended title: "Effect of involving certified health care assistants in primary care in Germany: A cross-sectional study"
	Explicitly provide rationale in manuscript for not applying a guiding framework/model.
	Strengths and Limitations section - "This is the first high-volume data analysis assessing the effect of broadening qualifications of non-physician workforces on quality and efficacy health care indicators"; Discussion section – "For the first time, this cross- sectional study assessed high-volume claims data to evaluate the influence of enhancing qualifications and responsibilities of non- physician health care professionals on quality and efficacy of primary care." Throughout manuscript this wording needs to be changed. Although some changes were made, there are still places where claims made need to align with purpose of study and analysis performed. The presence of certified health care assistants was studied, not the broadening qualifications. No analysis of roles/processes performed. Rather, human resource data regarding staffing of this role in primary care was examined.
	"For primary healthcare registered nurses or nurse practitioners in Canada, there is growing evidence that their involvement in practices is associated with health promotion, particularly in the management of chronic diseases [1–3]." Replace "or" with "and" in this sentence.

VERSION 2 – REVIEW

Purpose statement appropriately added. Should integrate this purpose statement into abstract. "Objectives" of abstract could be revised to integrate the purpose of the study.
Methods section - clearly indicate if there was missing data and how missing data was handled/addressed in the analysis.
Discussion section could be better written. Lack of clarity between comparisons of certified assistants and other providers and certified assistants and healthcare programs. Requires review for improved clarity, sentence structures, etc.
Limitations section – add potential for family wise error.

VERSION 2 – AUTHOR RESPONSE

Response to Reviewer #2:

-"Do not need to include sample size in title. Recommended title: "Effect of involving certified health care assistants in primary care in Germany: A cross-sectional study"

We would like to thank reviewer#2 for this comment. The title was revised accordingly:

Effect of involving certified health care assistants in primary care in Germany: A cross-sectional study

-"Explicitly provide rationale in manuscript for not applying a guiding framework/model."

We would like to thank reviewer#2 for this remark. As already mentioned in our first review response letter, a guiding framework was not feasible due to the limitations given by the nature of the supplied claims data.

We included corresponding information to the discussion section for transparency.

Page 16, line 15 - 24:

Due to the nature of claims data, the parameters available for analysis were limited. The omission of practice details was an important element of the data protection contract for participating practices with the objective not to be identifiable by researchers. Thus, further potentially relevant factors such as educational level and experience of the staff or structural characteristics of the practices like equipment or procedural factors such as available diagnostics and treatment options, were not available for this analysis. Furthermore, the evaluation of relevant patient-reported outcomes such as quality of life was not possible in this analysis. Consequently, in our opinion a structure-process-outcome model was not feasible to be applied in this study.

-"Strengths and Limitations section - "This is the first high-volume data analysis assessing the effect of broadening qualifications of non-physician workforces on quality and efficacy health care indicators"; Discussion section – "For the first time, this cross-sectional study assessed high-volume claims data to evaluate the influence of enhancing qualifications and responsibilities of non-physician health care professionals on quality and efficacy of primary care." Throughout manuscript this wording needs to be changed. Although some changes were made, there are still places where claims made need to align with purpose of study and analysis performed. The presence of certified health care assistants was studied, not the broadening qualifications. No analysis of roles/processes performed. Rather, human resource data regarding staffing of this role in primary care was examined."

We thank reviewer#2 for this important remark. We revised the whole manuscript to clarify wording in this regard. As example:

Page 14, line 2 - 4:

For the first time, this cross-sectional study assessed high-volume claims data to evaluate the influence of involving HCAs on quality and efficacy of primary care in Germany.

Page 17, line 4 - 5:

This high-volume cross-sectional study showed that involving HCAs in primary care in Germany is associated with a reduction in hospital admissions, specialist consultations and overall medication costs.

-"For primary healthcare registered nurses or nurse practitioners in Canada, there is growing evidence that their involvement in practices is associated with health promotion, particularly in the management of chronic diseases [1–3]." Replace "or" with "and" in this sentence.

We revised this sentence: Page 16, line 18 - Page 17, line 2:

-"Purpose statement appropriately added. Should integrate this purpose statement into abstract. "Objectives" of abstract could be revised to integrate the purpose of the study."

We thank reviewer#2 for this remark, the abstract was revised accordingly.

Page 2, line 5 - 7:

This study aimed to assess the influence of involving certified health care assistants (HCAs, German: VERAH) on quality and efficacy of primary care in Germany.

-"Methods section - clearly indicate if there was missing data and how missing data was handled/addressed in the analysis."

We thank reviewer#2 for this comment. There was no missing data within the underlying data set. If there was no utilization for a particular patient, e.g. no hospitalization, this was denoted as "0".

We added this aspect to the methods section.

Page 11, line 2 - 4:

There was no missing data within the underlying data set. If there was no utilization for a particular patient, e.g. no hospitalization, this was denoted as "0".

-"Discussion section could be better written. Lack of clarity between comparisons of certified assistants and other providers and certified assistants and healthcare programs. Requires review for improved clarity, sentence structures, etc."

We thank reviewer#2 for this valuable comment. We revised the discussion section to clarify wording.

-"Limitations section - add potential for family wise error."

We thank reviewer#2 for this remark. The supplied claims data were tested for multiple hypotheses in this analysis. Therefore, we used the Bonferroni correction to counteract potential family wise error. This was further clarified in the methods section.

Page 11, line 13 - 15:

Since multiple hypotheses were tested in this analysis, the Bonferroni correction was used to compensate for multiple comparisons.

VERSION 3 – REVIEW

REVIEWER	Julia Lukewich Memorial University
	Canada
REVIEW RETURNED	21-Nov-2019
	21-1100-2019

GENERAL COMMENTS	I would recommend removing, "Consequently, in our opinion a structure-process-outcome model was not feasible to be applied in
	this study." from the discussion