PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Needs-based provision of medical care to nursing home residents: protocol for a mixed-methods study
AUTHORS	Czwikla, Jonas; Schulz, M; Heinze, Franziska; Kalwitzki, Thomas; Gand, Daniel; Schmidt, Annika; Tsiasioti, Chrysanthi; Schwinger, Antje; Kloep, Stephan; Schmiemann, Guido; Wolf-Ostermann, Karin; Gerhardus, Ansgar; Rothgang, Heinz

VERSION 1 - REVIEW

REVIEWER	Victoria Shepherd Cardiff University, UK
REVIEW RETURNED	19-Oct-2018

GENERAL COMMENTS	This study protocol aims to assess, evaluate, and explain met and unmet medical needs of nursing home residents in German nursing homes, and to develop projects that aim to improve the medical care provision in nursing homes. It uses a mixed-methods approach to analyse routine data, clinical assessments, qualitative interviews and case conferences, and a Delphi study with stakeholders. It aims to identify and develop pilot projects which will be implemented in one nursing home to test for practicability, prior to systematic evaluation during follow-on studies. This is an important topic in an ageing population, with increasing multimorbidity, and complex medical and care needs. It is an ambitious project that reflects similar work being conducted in other countries to develop strategies that address unmet medical needs. The mixed-methods approach is sound, with the steps of the project clearly delineated, and the aims and method for each step summarised in the conceptual framework diagram. The strengths and limitations of the study are clearly stated. General comments: 1. Are there likely to be issues around missing data in the SHI claims dataset in step 1? If so, the protocol should include details about how these missing data will be handled. 2. The sample size of 500 nursing home residents is stated in step 2 - a statement about how the sample size was reached should be included, and whether the sampling strategy will take account of differences between nursing homes (size, geographical location etc) 3. Additional information is required about the process for determining whether or not the medical care needs are met based on the nurse assessment. It currently states ‘Based on these data,

	a geriatrician, a GP and where necessary a medical specialist of the corresponding field (i.e. an ophthalmologist, an ENT specialist, a dentist or a neurologist) determine case by case whether or not medical care needs are met' (step 2, line 191-192). Are these determined independently (blinded) by one or more of the clinicians listed? Will they be following a standardised process (with specific training or guidance) or using clinical judgement? How will any differences or discrepancies be reconciled? 4. The pilot projects identified for practicability testing will number at least 2 (step 5, line 243). The intention appears to be to test them in one nursing home. Is the intention to test them simultaneously, in which case there may be contamination effects? Or sequentially, in which case there are time implications for such an ambitious project? Additional details would be helpful.

REVIEWER	Michele L. Shaffer Department of Statistics, University of Washington, USA
REVIEW RETURNED	15-Nov-2018

GENERAL COMMENTS	The authors have presented the protocol for a mixed-methods study examining needs-based provision of medical care to nursing home residents. The protocol is well-written and substantive comments are related to discussion of planned statistical analyses. Minor Comments: 1) On line 160, it is noted that zero-inflated Poisson, linear, and logistic regression models will be used to examine the number of outpatient visits. It would be helpful to describe generally when each of these models will be employed, and why. 2) The statistical methods for the non-response analysis and estimation of prevalence in Step 4 are not described, but this information would be needed to reproduce the study. Other Comments: 1) The abbreviations GP and ENT should be defined prior to use. 2) On line 260, the word "level" is missing following the word "individual."

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Victoria Shepherd

Institution and Country: Cardiff University, UK

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

This study protocol aims to assess, evaluate, and explain met and unmet medical needs of nursing home residents in German nursing homes, and to develop projects that aim to improve the medical care provision in nursing homes. It uses a mixed-methods approach to analyse routine data, clinical assessments, qualitative interviews and case conferences, and a Delphi study with stakeholders. It aims to identify and develop pilot projects which will be implemented in one nursing home to test for practicability, prior to systematic evaluation during follow-on studies. This is an important topic in an ageing population, with increasing multimorbidity, and complex medical and care needs. It is an ambitious project that reflects similar work being conducted in other countries to develop strategies that address unmet medical needs. The mixed-methods approach is sound, with the steps of the project clearly delineated, and the aims and method for each step summarised in the conceptual framework diagram. The strengths and limitations of the study are clearly stated.

Authors' response: Thank you for reviewing our study protocol and for appreciating our work. We carefully revised our manuscript according to your comments.

General comments:

1. Are there likely to be issues around missing data in the SHI claims dataset in step 1? If so, the protocol should include details about how these missing data will be handled.

Authors' response: Thank you for this comment. We added the following sentence to our "Step 1: Analysis of SHI claims data" section (pages 6-7, lines 152-154 in the clean copy of the revised manuscript):

"From 245,000 insured persons, a subsample of 68,718 insured persons aged 60 years and over is drawn. Insured persons with missing or invalid information on demographic characteristics (n = 124) are not considered."

Furthermore, we modified the following sentence (page 7, lines 164-166):

"Each regression model includes only those insured persons who are diagnosed in the examined disease category and have valid information on all variables included in the model."

2. The sample size of 500 nursing home residents is stated in step 2 - a statement about how the sample size was reached should be included, and whether the sampling strategy will take account of differences between nursing homes (size, geographical location etc)

Authors' response: Thank you for this comment. We revised the "Step 2: Assessment of nursing home residents" section as follows (pages 8-9, lines 178-189):

“Residents are eligible for assessment if a) they are in need for long-term care, b) are aged 60 years and over, c) have been residing in a nursing home located in the federal state of Bremen for at least 12 months and d) are a member of the AOK Bremen/Bremerhaven. The total number of eligible nursing home residents is approximately 1,800. Assuming a realistic response rate of 25-30% results in approximately 500 study participants. The recruitment strategy comprises two stages: At stage one, the total number of nursing homes located in the federal state of Bremen is approached for participation. At stage two, eligible residents (or their legal guardians) are recruited by the nursing homes agreeing to participate and approached for informed consent. In case of reaching considerably less than 500 participants, the recruitment strategy may be extended to the federal state of Lower Saxony to ensure that enough nursing home residents with met and unmet medical care needs are included in the explanation of inappropriate medical care provision (steps 3 and 4).”

3. Additional information is required about the process for determining whether or not the medical care needs are met based on the nurse assessment. It currently states ‘Based on these data, a geriatrician, a GP and where necessary a medical specialist of the corresponding field (i.e. an ophthalmologist, an ENT specialist, a dentist or a neurologist) determine case by case whether or not medical care needs are met’ (step 2, line 191-192). Are these determined independently (blinded) by one or more of the clinicians listed? Will they be following a standardised process (with specific training or guidance) or using clinical judgement? How will any differences or discrepancies be reconciled?

Authors’ response: Thank you for this comment. We added the following additional information on the process for determining whether or not medical care needs are met as requested (page 11, lines 219-227):

“Based on these data, a geriatrician and a GP jointly determine case by case whether or not medical care needs in the areas of vision, hearing, oral health and Parkinson’s disease are met. In cases of uncertainties or discrepancies, geriatricians and GPs may decide to consult a medical specialist of the corresponding field (i.e. an ophthalmologist, an ear, nose and throat (ENT) specialist, a dentist or a neurologist) who independently determines whether or not medical care needs in the respective area are met. The process of evaluating met and unmet medical care needs is based on standardized guidelines and is tested and adjusted before final application. All physicians are trained on how to evaluate met and unmet medical care needs. Intercoder reliability is assessed for a subsample of 50 nursing home residents.”

4. The pilot projects identified for practicability testing will number at least 2 (step 5, line 243). The intention appears to be to test them in one nursing home. Is the intention to test them simultaneously, in which case there may be contamination effects? Or sequentially, in which case there are time implications for such an ambitious project? Additional details would be helpful.

Authors’ response: Thank you for this comment. We added additional details as suggested (pages 13-14, lines 291-295):

“This is expected to result in a more consensual decision. Taking the results of this last round into account, the concept of the pilot projects is revised and at least two pilot projects are implemented simultaneously in one nursing home to test for practicability. To minimize the risk of contamination effects, the pilot projects are implemented in different areas of the nursing home. A systematic evaluation of the pilot projects is planned in a follow-up study.”

Reviewer: 2

Reviewer Name: Michele L. Shaffer

Institution and Country: Department of Statistics, University of Washington, USA

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below

The authors have presented the protocol for a mixed-methods study examining needs-based provision of medical care to nursing home residents. The protocol is well-written and substantive comments are related to discussion of planned statistical analyses.

Authors’ response: Thank you for your valuable time and for your comments on our manuscript. We carefully revised our study protocol according to your comments.

Minor Comments:

1) On line 160, it is noted that zero-inflated Poisson, linear, and logistic regression models will be used to examine the number of outpatient visits. It would be helpful to describe generally when each of these models will be employed, and why.

Authors’ response: Thank you for this comment. We revised the “Step 1: Analysis of SHI claims data” section as follows (page 8, lines 162-171 in the clean copy of the revised manuscript):

“Zero-inflated Poisson regression analyses are conducted to investigate the probability (component I) and intensity (component II) of medical care for the resulting 45 combinations of disease categories and related medical specialties separately. Each regression model includes only those insured persons who are diagnosed in the examined disease category and have valid information on all variables included in the model. The dependent variable is the number of outpatient visits in the related medical specialty in 2015. Independent variables are the remaining 30 disease categories, age, sex, region, death, care setting and dummy variables as a combination of the obtained level of care and the care setting. In a sensitivity analysis, the probability and intensity of medical care is investigated using logistic and linear regression analyses, respectively.”

2) The statistical methods for the non-response analysis and estimation of prevalence in Step 4 are not described, but this information would be needed to reproduce the study.

Authors' response: Thank you for this comment. We added the following descriptions to the "Step 4: Analysis of linked data, non-response analysis and extrapolation" section (pages 12-13, lines 257-272):

"Next, a non-response analysis is conducted. SHI claims data of 1,800 residents are analyzed to identify systematic differences between responders and non-responders. Chi-square tests are used to identify differences in the distribution of age groups, sex, morbidity and long-term care levels. Differences in the mean duration of stays in long-term care and nursing homes are identified using t-tests.

Third, prevalence of met and unmet medical care needs is extrapolated. Controlling for systematic differences between responders and non-responders identified in the non-response analysis, prevalence of met and unmet medical care needs is projected to all nursing home residents insured by the AOK Bremen/Bremerhaven. Using official statistics, systematic differences in the distribution of age groups, sex and long-term care levels between nursing home residents insured by the AOK Bremen/Bremerhaven and the total population of nursing home residents in the federal state of Bremen are identified. Taking into account identified differences, the prevalence of met and unmet medical care needs is then projected to all nursing home residents of Bremen. Finally, the prevalence is projected to all nursing home residents of Germany controlling for identifiable differences in the distribution of age groups, sex and long-term care levels between nursing home residents in Bremen and Germany."

Other Comments:

1) The abbreviations GP and ENT should be defined prior to use.

Authors' response: Thank you for this comment. We replaced the abbreviation GPs in the "Abstract" section and "Strengths and limitations of this study" section by "general practitioners" (page 3, lines 54-55 and page 4, lines 86-89) and now define the abbreviations GP and ENT prior to use (page 5, lines 104-106; page 11, lines 221-224).

2) On line 260, the word "level" is missing following the word "individual."

Authors' response: Thank you for this comment. We added the missing word "level" (page 14, lines 315-316).

VERSION 2 – REVIEW

REVIEWER	Victoria Shepherd Cardiff University, UK
REVIEW RETURNED	03-Jan-2019

GENERAL COMMENTS	This is a revision of a study protocol which aims to assess, evaluate, and explain met and unmet medical needs of nursing home residents in German nursing homes, and to develop projects that aim to improve the medical care provision in nursing homes. The authors have carefully responded to the points raised in a previous review, and have revised the manuscript accordingly. My recommendation is to accept the revised manuscript.

REVIEWER	Wei Du ANU, Australia
REVIEW RETURNED	10-Apr-2019

GENERAL COMMENTS	This project addresses a series of research questions to meet the knowledge gap. I think it is too early to address “inappropriate medical care” for study aim 3 because answers for aforementioned study aims 1 and 2 did not address “inappropriateness”. Besides, please see the following comments. 1) The authors need to describe the population capture by using insurance data. Are all nursing home residents captured? Please give an estimate of % coverage. 2) The authors need to describe how many diagnosis codes there are in the insurance data. Only those conditions being insured will be recorded in the data? please discuss this as one limitation. In fact, the clinical chart review may shed light on the accuracy of insurance data in terms of coding of diagnoses. The authors could add this component into their project. 3) I am not sure about the selection of ZIP model (the authors has already found a lot of zeros for selected conditions?), because its count and inflation components are difficult to interpret together. I am confused by what the authors meant by saying probability (component 1). Probability of what? Inflation of zeros (without a certain condition)?...I would not attempt ZIP or ZINB, unless there is evidence of improvement compared with standard Poisson or NB (rather than compare logistic or linear models). All selected conditions should be common in the aged population if we run full historical chart review, unless the insurance data do not capture all co-existing conditions. Probably it should be the other way around, using ZIP as sensitivity analysis assuming some conditions are rare. 4) The authors need to describe a series of definitions and how they use descriptive stats. Modelling strategy “Independent variables are the remaining 30 disease categories, age, sex, region, death, care setting and dummy variables as a combination of the obtained level of care and the care setting”. Those disease categories are overlapping (see ICD codes for example mental disorders), which contributes collinearity. I am not sure why use “death” as a predictor. How many care settings are there? What is the obtained level of care? 5) For step 2, the authors should give an estimate of the prevalence of vision, hearing, oral health and Parkinson’s disease, then work out the sample size. Or the authors are going to survey

	"ALL" eligible candidate. I am a little concerned of the sample size given vision, hearing, oral health may be quite common in the study population. The study subjects may be clustered in their residency, and it is highly possible this step is underpowered. 6) Survey questions for utilisation should be given with examples. Validation is also needed especially for those with possible cognitive impairment. 7) Quantitative methods are not described for the survey. 8) Sample size for linked data is 1800? But I think the survey subgroup is around 500? what is the impact on linkage to survey data with 1800 rather than 500 subjects? Difference in means based on t-tests would not be appropriate given this small population with a high likelihood of skewed distribution in continuous measures. Prevalence was measured by? Any prevalence rate ratio estimation? 9) Sample size for focus group discussion and sample size for Delphi? Are there any analytic approaches planned for these components?

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Victoria Shepherd

Institution and Country: Cardiff University, UK

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

This is a revision of a study protocol which aims to assess, evaluate, and explain met and unmet medical needs of nursing home residents in German nursing homes, and to develop projects that aim to improve the medical care provision in nursing homes. The authors have carefully responded to the points raised in a previous review, and have revised the manuscript accordingly. My recommendation is to accept the revised manuscript.

Authors' response: Thank you for reviewing the revision of our study protocol. We appreciate your recommendation to accept the revised manuscript.

Reviewer: 3

Reviewer Name: Wei Du

Institution and Country: ANU, Australia

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

This project addresses a series of research questions to meet the knowledge gap. I think it is too early to address “inappropriate medical care” for study aim 3 because answers for aforementioned study aims 1 and 2 did not address “inappropriateness”. Besides, please see the following comments.

Authors’ response: Thank you for reviewing our study protocol and for your valuable comments which were very helpful to further improve our manuscript.

In our study, we quantify met and unmet medical care needs of 500 nursing home residents case by case in the areas of vision, hearing, oral health and Parkinson’s disease (aim 2). For each area, physicians define nursing home residents with met medical care needs as those with appropriate medical care provision and nursing home residents with unmet medical care needs as those with inappropriate medical care provision. To clarify this point, we revised the “Step 2: Assessment of nursing home residents” section as follows (page 12, lines 252-255 in the clean copy of the revised manuscript):

“Based on the case reports (in printed form), a geriatrician and a GP jointly determine case by case whether or not medical care needs in the areas of vision, hearing, oral health and Parkinson’s disease are met, i.e. whether or not the provision of medical care is appropriate.”

1) The authors need to describe the population capture by using insurance data. Are all nursing home residents captured? Please give an estimate of % coverage.

Authors’ response: Thank you for this comment. We modified our “Step 1: Analysis of SHI claims data” section as follows (page 6, lines 147-151):

“The available data comprise information on sex, age, in- and outpatient care as well as on long-term care use of 245,000 insured persons (i.e. 34.7% of the total population in the federal state of Bremen). The data represent 51.8% of the population of community-dwelling individuals with need for long-term care and 54.9% of the population of nursing home residents in Bremen.”

2) The authors need to describe how many diagnosis codes there are in the insurance data. Only those conditions being insured will be recorded in the data? please discuss this as one limitation. In fact, the clinical chart review may shed light on the accuracy of insurance data in terms of coding of diagnoses. The authors could add this component into their project.

Authors’ response: In Germany, the Federal Joint Committee defines which services are reimbursed by the Statutory Health Insurance (SHI) ensuring that all SHI insured persons are treated according to the current standard of care. SHI claims data comprise all diagnoses coded by physicians for reimbursement purposes of services with clear benefits. Services which are not reimbursed by the SHI, such as services with unclear benefits, have to be paid out of pocket and are not included in SHI claims data. We revised the “Step 1: Analysis of SHI claims data” section as follows (pages 6-7, lines 153-158):

“In Germany, the Federal Joint Committee defines which services are reimbursed by the SHI ensuring that all SHI insured persons are treated according to the current standard of care.[20] SHI claims data

comprise all diagnoses coded by physicians for reimbursement purposes of services with clear benefits. Services with unclear benefits, which have to be paid out of pocket, are not included."

We agree that the coding quality in health insurance claims data is an important issue that deserves further investigation. However, our review of diagnoses is based on nursing records whose coding quality is also limited. Therefore, we believe that nursing records are not suitable for investigating the coding quality of health insurance claims data. To avoid any misunderstandings, we revised our wording replacing the term "medical charts" by "nursing records" throughout the manuscript.

3) I am not sure about the selection of ZIP model (the authors has already found a lot of zeros for selected conditions?), because its count and inflation components are difficult to interpret together. I am confused by what the authors meant by saying probability (component 1). Probability of what? Inflation of zeros (without a certain condition)?...I would not attempt ZIP or ZINB, unless there is evidence of improvement compared with standard Poisson or NB (rather than compare logistic or linear models). All selected conditions should be common in the aged population if we run full historical chart review, unless the insurance data do not capture all co-existing conditions. Probably it should be the other way around, using ZIP as sensitivity analysis assuming some conditions are rare.

Authors' response: Thank you for this comment. According to your suggestion, we revised our Step 1: Analysis of SHI claims data section as follows (page 8, lines 178-181):

"Poisson regression analyses are conducted to investigate the intensity of medical care for the 45 combinations of disease categories and related medical specialties separately. In cases of overdispersion, negative binomial regression and in cases of excess zeros, zero-inflated Poisson regression or zero-inflated negative binomial regression analyses are conducted."

4) The authors need to describe a series of definitions and how they use descriptive stats. Modelling strategy "Independent variables are the remaining 30 disease categories, age, sex, region, death, care setting and dummy variables as a combination of the obtained level of care and the care setting". Those disease categories are overlapping (see ICD codes for example mental disorders), which contributes collinearity. I am not sure why use "death" as a predictor. How many care settings are there? What is the obtained level of care?

Authors' response: Thank you for this comment. We included the requested information on our descriptive analyses as follows (page 8, lines 169-177):

"Descriptive analyses are conducted in two steps. First, the prevalence of each single disease category in 2015 is determined among the groups of nursing home residents, community-dwelling elderly in need for long-term care and community-dwelling elderly without need for long-term care. Second, for the 45 combinations of disease categories and related medical specialties, the proportion of prevalent cases with an outpatient visit in the related medical specialty in 2015 is calculated among the three groups (i.e. nursing home residents as well as community-dwelling elderly with and without need for long-term care). Lower proportions of prevalent cases with an outpatient visit in the related medical specialty may indicate, but not prove, unmet medical care needs."

Furthermore, we included more details on our independent variables (pages 8-9, lines 183-191):

“The dependent variable is the number of outpatient visits in the related medical specialty in 2015. Independent variables are age (in five-year groups), sex and dummy variables as a combination of the obtained level of care (no long-term care dependency, level 1, level 2, level 3 of long-term care dependency) and the care setting (community, nursing home). To take account of differences in morbidity and mortality that likely impact the number of outpatient visits, the remaining 30 disease categories and death are included as control variables. Multicollinearity between variables is evaluated on the basis of the variance inflation factor.”

5) For step 2, the authors should give an estimate of the prevalence of vision, hearing, oral health and Parkinson’s disease, then work out the sample size. Or the authors are going to survey “ALL” eligible candidate. I am a little concerned of the sample size given vision, hearing, oral health may be quite common in the study population. The study subjects may be clustered in their residency, and it is highly possible this step is underpowered.

Authors’ response: Thank you for this comment. We are going to invite all nursing homes in the federal state of Bremen for study participation (i.e. no sampling strategy is applied). The nursing homes agreeing to participate then invite all eligible nursing home residents to participate (i.e. also no sampling strategy is applied). Given that not all nursing homes and not all nursing home residents agree to participate, we assume to reach 25-30% of the approximately 1,800 eligible nursing home residents resulting in a study population of 500 nursing home residents. We received funding and ethical approval for assessing these 500 nursing home residents. We revised our “Step 2: Assessment of nursing home residents” section as follows (pages 9-10, lines 200-210):

“The total number of eligible nursing home residents is approximately 1,800. The recruitment strategy comprises two stages: At stage one, the total number of nursing homes located in the federal state of Bremen is approached for participation by the research team (i.e. no sampling strategy is applied). At stage two, all eligible residents (or their legal guardians) are invited for participation and approached for informed consent by the nursing homes agreeing to participate (i.e. also no sampling strategy is applied). We expect that not all nursing homes and not all nursing home residents agree to participate and assume to reach 25-30% of the approximately 1,800 eligible nursing home residents, resulting in a study population of 500 nursing home residents. In case of reaching considerably less than 500 participants, the recruitment strategy may be extended to the federal state of Lower Saxony.”

6) Survey questions for utilisation should be given with examples. Validation is also needed especially for those with possible cognitive impairment.

Authors’ response: All data on utilization of medical care are obtained from the residents’ care nurses (proxy-assessments) and nursing records (see table 2). Therefore, validation for nursing home residents with cognitive impairment is not necessary. We revised our “Step 2: Assessment of nursing home residents” section as follows (page 10, lines 211-222):

“The standardized assessment is carried out by trained study nurses and includes: (1) examinations of residents, (2) self-assessments by residents, (3) proxy-assessments by residents’ care nurses and (4) reviews of nursing records (table 2). The examination of residents comprises the application of a visual test,[21] a whispered voice test[22] and the Oral Health Assessment Tool (OHAT).[23] During

the self-assessments, nursing home residents are asked, inter alia, to rate their vision, hearing and oral health as well as whether they use a visual aid, a hearing device or dentures. Further questions relate to their general health status. The residents' self-assessments are complemented by the proxy-assessments in which the residents' care nurses are asked the same or comparable questions. Information regarding the utilization of medical care (e.g. contacts to general and specialized care), sociodemographic data and nursing home characteristics are obtained from the residents' care nurses and nursing records."

7) Quantitative methods are not described for the survey.

Authors' response: Thank you for this comment. The results of the assessments of 500 nursing home residents are summarized in individual case reports. Based on these case reports, a geriatrician and a GP jointly determine case by case whether or not medical care needs in the areas of vision, hearing, oral health and Parkinson's disease are met. Based on these data, the prevalence of met and unmet medical care needs is quantified for each area. We revised the "Step 2: Assessment of nursing home residents" section as follows (page 12, lines 243-260):

"The assessed data are summarized in individual case reports. These case reports comprise information on age, sex, level of care, date of nursing home admission, in- and outpatient medical care, diagnoses, medication, aids, vital signs, falls, the result of the visual test and self-reported use of visual aids, the result of the whispered voice test and self-reported use of hearing devices, all data of the OHAT, the self- and proxy-assessed oral health, the proxy-assessed availability and use of dentures as well as the result of the Oral Health Impact Profile (OHIP).[24] Moreover, the case reports include the results of the instruments applied for assessing the health-related quality of life,[25] depression,[26-28] functional and cognitive status,[29,30] nutrition,[31-34] as well as all comments made by the trained study nurses during the assessment. Based on the case reports (in printed form), a geriatrician and a GP jointly determine case by case whether or not medical care needs in the areas of vision, hearing, oral health and Parkinson's disease are met, i.e. whether or not the provision of medical care is appropriate. In cases of uncertainties or discrepancies, geriatricians and GPs may access all assessed data (in digital form) and decide to consult a medical specialist of the corresponding field (i.e. an ophthalmologist, an ear, nose and throat (ENT) specialist, a dentist or a neurologist) who independently determines whether or not medical care needs in the respective area are met. Based on these data, the prevalence of met and unmet medical care needs is quantified for each area."

8) Sample size for linked data is 1800? But I think the survey subgroup is around 500? what is the impact on linkage to survey data with 1800 rather than 500 subjects? Difference in means based on t-tests would not be appropriate given this small population with a high likelihood of skewed distribution in continuous measures. Prevalence was measured by? Any prevalence rate ratio estimation?

Authors' response: Thank you for this comment. The sample size for the linked data is 500 and the sample size for the non-response analysis is 1,800 (i.e. 500 responders and 1,300 non-responders). We modified the "Step 4: Analysis of linked data, non-response analysis and extrapolation" section as follows (page 13, lines 285-286):

"In step 4, primary data of the 500 nursing home residents assessed in step 2 and SHI claims data covering the years 2014-2018 are linked at the individual level"

Furthermore, we revised the following sentence (page 14, lines 293-295):

“Next, a non-response analysis is conducted. SHI claims data of 500 responders and 1,300 non-responders are analyzed to identify systematic differences between responders and non-responders.”

Regarding your comment on t-tests, we revised the paragraph as follows (page 14, lines 296-298):

“Differences in the mean duration of stays in long-term care and nursing homes are identified using t-tests for normally distributed variables and Wilcoxon-Mann-Whitney tests for non-normal distributions.”

Regarding your comment on the prevalence of met and unmet medical care needs, we revised the section as follows (page 14, lines 299-303):

“Third, prevalence of met and unmet medical care needs determined in step 2 is extrapolated. Controlling for systematic differences between responders and non-responders identified in the non-response analysis, prevalence of met and unmet medical care needs in the areas of vision, hearing, oral health and Parkinson’s disease is projected to all nursing home residents insured by the AOK Bremen/Bremerhaven”

Prevalence rate ratios are not estimated since we assess only met and unmet medical care needs among the group of nursing home residents and not among the groups of community dwelling elderly with and without need for long-term care.

9) Sample size for focus group discussion and sample size for Delphi? Are there any analytic approaches planned for these components?

Authors’ response: Thank you for this comment. In our “Step 5: Modified Delphi study and pilot projects” section we now provide the sample size for the focus groups and emphasize that the same experts taking part in the focus groups (i.e. the first round of the modified Delphi study) also rate (second round of the modified Delphi study) and re-rate (third round of the modified Delphi study) the pilot projects. Furthermore, we now give more information on the analytic approaches planned for these components (pages 14-15, lines 313-337):

“Based on the factors identified that may explain inappropriate medical care in steps 3 and 4, a modified Delphi study is then carried out. The technique is used with stakeholders from the fields of nursing and medical care and comprises three rounds. The first round is based on face-to-face focus group discussions, while the second and third rounds each consist of a semi-structured online survey. Each survey takes about 20 minutes to complete and is online for up to 2 weeks.

In the first round, a convenience sample of at least two homogeneous and two heterogeneous focus groups of four to six participating stakeholders (i.e., nursing home staff, GPs, medical specialist, SHI employees, nursing home residents and relatives) generate ideas on how medical care provision to

nursing home residents can be improved. The focus groups are led by two experienced project researchers, who feed the results of steps 3 and 4 into the discussions. All focus group discussions are recorded, summarized and discussed within the research team. Based on the results, the project researchers draft at least two potential pilot projects.

In round two, the experts of the first round are given descriptions of the potential pilot projects. They rate and comment on the proposed pilot projects with respect to their feasibility and effectiveness for improving medical care of nursing home residents. These ratings are narratively and visually summarized.

In the third round, the same experts re-rate the projects based on the summarized ratings from the previous round. The re-ratings are summarized using the same method as in round two. Taking the results of this last round into account, the concept of the pilot projects is revised. This is expected to result in a more consensual decision. At least two pilot projects are implemented simultaneously in one nursing home to test for practicability. To minimize the risk of contamination effects, the pilot projects are implemented in different areas of the nursing home. A systematic evaluation of the pilot projects is planned in a follow-up study.”