PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Improving continuity of patient care across sectors: Study protocol of the process evaluation of a quasi-experimental multi-centre study regarding an admission and discharge model in Germany (VESPEERA)
AUTHORS	Forstner, Johanna; Kunz, Aline; Straßner, Cornelia; Uhlmann, Lorenz; Kuemmel, Stephanie; Szecsenyi, Joachim; Wensing, M

VERSION 1 – REVIEW

REVIEWER	Sofie Jakobsson Institute of Health and Care Sciences University of Gothenburg Gothenburg, Sweden.
REVIEW RETURNED	27-May-2019

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. The topic explored is of high relevance as there is limited knowledge from the perspective of inpatient care and continuity of care after hospitalization. The manuscript addresses a process evaluation of a structured admission and discharge program based on relevant literature on process evaluation of complex interventions. The process evaluation is extensive with several different components. The comments contain issues for clarifications of the manuscript and providing details related to the methods. 1. Even though the intervention is described elsewhere the understanding of this manuscript would benefit on a more thoroughly description of: a. In what way do patient themselves access the information given in the Carecockpit? b. Page 9 rows 40-42 conducting the assessment and care planning- what does the assessment include? What does the care planning entail? (Medical interventions? Care planning based on patients goal? care planning related to quality of life) c. Please describe why the process evaluation is completed before the inclusion/evaluation of the VESPEERA study? page 21, row 25. 2. As stated under Patient and Public involvement page 29, patients are included in funding design and so forth. a. Please explain the rational for patients not being part of the three benchmarking reports? If I understand it right patients were part of the consensus discussion? b. Please explain how 10 patients will conclude on saturation of the perceived effects from the patients' perspective? Why only 10 patients, how will they be selected? 3. The aim of the interviews is somewhat unclear. In table 2 the interviews are presented as they will address perceived effects and on page 23-24 the interviews are presented as being used to inform the development of the questionnaire? Please clarify. Please

	reconsider the wording qualitative survey. 4. What is the rationale for including management staff in the interviews? In table 2 it is stated that interviews will be conducted with care givers. 5. Please clarify how the non-participating hospitals can contribute in the interviews (this is related to my comments earlier on clarifying the aim of the interviews) and criteria for how they are included, page 22, rows 2-5, how will it be assessed that they can or cannot provide insight to admission and discharge process, they are not part of the intervention? 6. Data analysis of the interviews: please clarify in what way the CFIR is used as a framework of analysis? Is it a deductive analysis approach? Would not the process evaluation with the aim to explore perceived effects conducted through the interviews benefit from an inductive approach were both foreseen and unforeseen aspects of the intervention could be explored? 7. Data analysis of the quantitative survey: please further describe the descriptive analysis and the outcomes from the process evaluation that will be correlated to outcome measures of the intervention. Is this related to the dose-response associations in table 2? Does this include patient data presented at page 24? Minor comments: • Sentences page 7 rows 47-56 should be rewritten and condensed as they entail the same information. Avoid phrases like some other interventions can this be deleted or further explained? • Page 11, row 39 should be seventh? • The section describing implementation strategies, page 9-11, would gain from having a structure according to first describing strategies in development, then implementation and then ongoing support during the program. • Consider if the paragraphs under the heading VESPEERA outcomes evaluation should be incorporated into the Vespeera program section in the beginning of the manuscript as it otherwise disrupts the reading of the implementation and process evaluation which is the aim of this specific study. This restructuring of content also adherence to the second and third sentences in the abstract which should switch order as it is better to first describe the aim which concerns this paper in the abstract (like the authors have done under methods and analysis). • First sentence under objectives can be deleted or moved to the background which would put focus on objectives. • …*who are interested in participation*, page 10 row 8? are they not included in the intervention before they learn handling of the soft-ware? • Information should be added to table 2 on what 2a), 5a) means. Table 2 is hard to grasp and would benefit on being more condensed or separated in additional columns.

REVIEWER	Anne Deutsch RTI International, Shirley Ryan AbilityLab, Northwestern University, USA
REVIEW RETURNED	22-Aug-2019

GENERAL COMMENTS	The flow of the introduction could be improved. lines 23-29: This could be written more clearly to convey the admission and discharge refers to the hospital stay. Lines 30-32: Are the interventions mentioned in this sentence

	different from the ones described in the subsequent sentences? If so, please clarify. Line 58: In reading the text, I had the impression that only planned admissions were included in the study. I see in Table 1, that both planned and unplanned admissions are included, and the interventions vary based on the planned or unplanned status of the stay. The text should be updated to clarify the study arms. Line 56: when you say “same indication” would that mean admission for the same medical/surgical reason? Can you provide a rationale for why that is the primary outcome? Line 34-48: Has the magnitude of the impact been hypothesized? Table 2: I don’t see patient-reported data listed in this table, but I thought you mentioned patient reported data would be examined. I see patient data mentioned in the text. Is this patient data from the record or patient-reported data?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Sofie Jakobsson
Institution and Country: Institute of Health and Care Sciences, University of Gothenburg, Gothenburg, Sweden.
Please state any competing interests or state ‘None declared’: None declared

Thank you for the opportunity to review this manuscript. The topic explored is of high relevance as there is limited knowledge from the perspective of inpatient care and continuity of care after hospitalization. The manuscript addresses a process evaluation of a structured admission and discharge program based on relevant literature on process evaluation of complex interventions. The process evaluation is extensive with several different components.
The comments contain issues for clarifications of the manuscript and providing details related to the methods.

1. Even though the intervention is described elsewhere the understanding of this manuscript would benefit on a more thoroughly description of:
a. In what way do patient themselves access the information given in the Carecockpit?
◊ Patients themselves do not access the information given in the CareCockpit. The CareCockpit is software solely for general practices. The VERAH however conducts the assessments in dialogue with the patient. The patient does receive the admission letter to hand it over in the hospital and does receive a summary of the results of the assessment for planning of follow-up treatment. No adjustments to the text were made.

b. Page 9 rows 40-42 conducting the assessment and care planning- what does the assessment include? What does the care planning entail? (Medical interventions? Care planning based on patients goal? care planning related to quality of life)
◊ The assessment for planning of follow-up care includes medication plans, referrals to specialists, prescriptions for medication and medical products and devices. We have clarified this in the text in the section ‘VESPEERA programme’.

c. Please describe why the process evaluation is completed before the inclusion/evaluation of the VESPEERA study? page 21, row 25.

◊ Thank you for pointing this out. In fact, there has been a mistake. Evaluation complete by the end of October 2020 includes interviews questionnaires only. The evaluation of all other data sources will be complete by the end of the project period of the VESPEERA project, which will be in March 2021. We have corrected the manuscript in the section 'Study design'.

2. As stated under Patient and Public involvement page 29, patients are included in funding design and so forth.
a. Please explain the rational for patients not being part of the three benchmarking reports? If I understand it right patients were part of the consensus discussion?
◊ The benchmark reports are supposed to be feedback to the participating care providers on their performance and patients' satisfaction with care. Patients are not part of the development of the benchmark reports, they were involved in the design of the intervention components and other material before the start of the intervention. No adjustments to the text were made.

b. Please explain how 10 patients will conclude on saturation of the perceived effects from the patients' perspective? Why only 10 patients, how will they be selected?
◊ We agree that 10 is an arbitrary number. It is based on experience in similar projects and practical considerations of feasibility.
As described and now clarified in the 'Recruitment' section, all participating general practices are asked to recruit all eligible patients for interviews after a chosen starting moment. The study central office does not give any criteria for patient selection other than the eligibility criteria.

3. The aim of the interviews is somewhat unclear. In table 2 the interviews are presented as they will address perceived effects and on page 23-24 the interviews are presented as being used to inform the development of the questionnaire? Please clarify. Please reconsider the wording qualitative survey.
◊ The interviews and questionnaires together address the research questions, except for intervention fidelity, reach, and dose-response associations (which are based on patient data). Some research questions are explored using qualitative methods, others using quantitative methods. Thereby, interviews and questionnaires are complementary. Furthermore, aspects mentioned in the interviews can be quantitatively explored in the questionnaires.
We have changed the wording qualitative survey in table 2.

4. What is the rationale for including management staff in the interviews? In table 2 it is stated that interviews will be conducted with care givers.
◊ The intervention components within hospitals are quite adjustable. Hospitals received information on minimum requirements concerning content of the intervention components. However, the study central office did not give any standards. For example, hospitals could individually decide whether to implement the intervention components paper-based or to digitally include them into their information system. In this conceptual phase management staff such as quality management was involved. We are interested in the rationale for the hospitals' concepts on how to implement the VESPEERA intervention components and therefore included them in the study population We have added text in the manuscript for clarification in the 'Eligibility criteria' section.

Interviews are conducted with care providers, which include hospitals and general practices. We have clarified this in the footnote of table 2.

5. Please clarify how the non-participating hospitals can contribute in the interviews (this is related to my comments earlier on clarifying the aim of the interviews) and criteria for how they are included, page 22, rows 2-5, how will it be assessed that they can or cannot provide insight to admission and discharge process, they are not part of the intervention?
With a new regulation on hospital discharge management which came into effect on October 1st in

2017, hospital discharge management currently is very prominent on the political agenda. We expected this regulation to impact the implementation of the VESPEERA intervention. Therefore, we decided to include interviews with staff from non-participating hospitals in order to explore their approach to improving hospital discharge management and to find out whether the approach is different in hospitals who do participate in the VESPEERA project and those who do not. Non-participating hospitals do not need to provide information on the intervention, as we are interested in their regular admission and discharge processes and their adjustments according to the new regulation. No changes to the manuscript were made.

6. Data analysis of the interviews: please clarify in what way the CFIR is used as a framework of analysis? Is it a deductive analysis approach? Would not the process evaluation with the aim to explore perceived effects conducted through the interviews benefit from an inductive approach were both foreseen and unforeseen aspects of the intervention could be explored?
◊ We have chosen an approach that combines deductive and inductive components. First, sections of the interviews are coded to the CFIR themes and subthemes (deduction). Then, inductive coding within the CFIR themes is carried out and subthemes specific to the project are generated. We have clarified this within the manuscript in the 'Data analysis' section.

7. Data analysis of the quantitative survey: please further describe the descriptive analysis and the outcomes from the process evaluation that will be correlated to outcome measures of the intervention. Is this related to the dose-response Reassociations in table 2? Does this include patient data presented at page 24?
◊ This is correct and it does include patient data. In multivariate regression models, we will relate response (e.g. rehospitalisations within 30 days after discharge) to dose of the implementation interventions (e.g. transmission of an admission letter to the hospital), taking clustering of patients in primary care practices into account. As the analysis is explorative, we refrain from a detailed pre-specified analysis plan, but have included a sentence in the data-analysis section.

Minor comments:
• Sentences page 7 rows 47-56 should be rewritten and condensed as they entail the same information. Avoid phrases like some other interventions can this be deleted or further explained?
◊ We have adjusted the corresponding paragraph.

• Page 11, row 39 should be seventh?
◊ Has been renumbered.

• The section describing implementation strategies, page 9-11, would gain from having a structure according to first describing strategies in development, then implementation and then ongoing support during the program.
◊ We have rearranged the order of the implementation strategies.

• Consider if the paragraphs under the heading VESPEERA outcomes evaluation should be incorporated into the Vespeera program section in the beginning of the manuscript as it otherwise disrupts the reading of the implementation and process evaluation which is the aim of this specific study. This restructuring of content also adherence to the second and third sentences in the abstract which should switch order as it is better to first describe the aim which concerns this paper in the abstract (like the authors have done under methods and analysis).
◊ We have restructured as suggested.

• First sentence under objectives can be deleted or moved to the background which would put focus on objectives.

◊ We have deleted the sentence.

• …*who are interested in participation*, page 10 row 8? are they not included in the intervention before they learn handling of the soft-ware?
◊ GPs and VERAHs sign up for training of the CareCockpit-software and, at the end of the training event, can declare their participation in the VESPEERA project. No changes to the manuscript were made.

• Information should be added to table 2 on what 2a), 5a) means. Table 2 is hard to grasp and would benefit on being more condensed or separated in additional columns.
◊ We agree that table 2 is loaded with information. We have now taken it out of the manuscript and added it as supplementary material (with minor changes: numbering of research questions, clarification of data sources). Instead, we have now illustrated the research questions in a new table. We have elaborated on the data sources used in the data sources section and have added information on the outcomes for reach and intervention fidelity in that same section.

Reviewer: 2
Reviewer Name: Anne Deutsch
Institution and Country: RTI International, Shirley Ryan AbilityLab, Northwestern University, USA
Please state any competing interests or state 'None declared': None

The flow of the introduction could be improved.
The introduction consists of several paragraphs. We made several changes as suggested by reviewer 2 (e.g. changing the order of description of the implementation strategies, moving the paragraph on the VESPEERA outcomes evaluation, minor changes to the text). We hope that by these changes the introduction is smoother to read.

lines 23-29: This could be written more clearly to convey the admission and discharge refers to the hospital stay.
◊ Has been clarified.

Lines 30-32: Are the interventions mentioned in this sentence different from the ones described in the subsequent sentences? If so, please clarify.
◊ They are the same intervention components. We have clarified in the manuscript that an overview on the intervention components is given, more details can be found in the study protocol for the outcomes evaluation.

Line 58: In reading the text, I had the impression that only planned admissions were included in the study. I see in Table 1, that both planned and unplanned admissions are included, and the interventions vary based on the planned or unplanned status of the stay. The text should be updated to clarify the study arms.
◊ We have adjusted the corresponding paragraph.

Line 56: when you say "same indication" would that mean admission for the same medical/surgical reason? Can you provide a rationale for why that is the primary outcome?
◊ Exactly. Rehospitalisations due to the same indication occur for example due to early discharges, insufficient communication with other care providers or insufficient planning of follow-up care and could be prevented. Furthermore, they are relevant for hospital reimbursement according to the German Diagnosis Related Groups. Rehospitalisations within 30 days due to the same indication are counted as one case and hospitals therefore do not receive separate reimbursement. More information on the outcomes of the outcomes evaluation can be found in the corresponding study

protocol (Forstner et al. 2019, https://doi.org/10.1186/s12913-019-4022-4). No changes to the manuscript were made.

Line 34-48: Has the magnitude of the impact been hypothesized?
◊ We expect a reduction of approx. 8% (from 23% rehospitalisations in the control group to 15% in the intervention group). More information on the outcomes evaluation can be found in the corresponding study protocol (Forstner et al. 2019, https://doi.org/10.1186/s12913-019-4022-4). No changes to the manuscript were made.

Table 2: I don't see patient-reported data listed in this table, but I thought you mentioned patient reported data would be examined. I see patient data mentioned in the text. Is this patient data from the record or patient-reported data?
◊ Thank you for pointing this out, the wording was not congruent. We have adjusted table 2. Patient data includes a data-set consisting of data from the CareCockpit, claims-based data, and the hospital process data survey).

VERSION 2 – REVIEW

REVIEWER	Sofie Jakobsson Institute of Health and Care Sciences, University of Gothenburg, Gothenburg, Sweden.
REVIEW RETURNED	27-Sep-2019

GENERAL COMMENTS	Thank you for your response to my earlier comments. Also to issues raised by the other reviewer. The changes that have been made have improved the clarity and focus of the manuscript.

REVIEWER	Anne Deutsch RTI International Shirley Ryan AbilityLab Northwestern University Chicago, IL, USA
REVIEW RETURNED	02-Oct-2019

GENERAL COMMENTS	Thank you for addressing the previous comments/questions.