ZonMw project 'Fostering responsible conclusions and messages in health services research'

Procedure privacy protection and data-handling

16 Juli 2017

Correction: 9 February 2018
Correction to the phases 3 and 4 were made as a result of a change in data collection. Most notably, in addition to interviews, focus groups will be organized. The recruitment process was adapted accordingly. Reports of interviews and focus groups will not be shared with the participants as recordings will be transcribed verbatim. Participants of the interviews will not be informed of the assessment of their articles.

This document explicates the handling of data and the protection of the privacy of participants within the research project 'Fostering responsible conclusions and messages in health services research'. This document is supplementary to the Research Proposal and the Data Management Plan as submitted to ZonMw. The research project is funded by ZonMw, grant number: 20-22600-98-007.

The research project includes six phases of data-collection:

- Qualitative interviews with representatives of 13 Dutch Health Services Research (HSR) groups, including two rounds of interviews *(phase 1 and phase 6)*
- Review of 10 scientific publications of each of the thirteen HSR groups *(phase 2)*
- Electronic survey among the first and last authors of the scientific publications included in the literature review *(phase 3)*
- Focus groups and qualitative interviews with a sample of researchers drawn from the participants of the survey *(phase 4)*
- Review of societal publications linked to the scientific publications of the interview-sample of 40 researchers *(phase 5)*

This procedure addresses privacy protection and data-handling by phase of data-collection for specific issues, and in general for issues concerning all phases.

Researchers with authorized access to the study file

Researchers will have access to the study file for the duration of their involvement in the project. Any changes to persons with access to the study file will be documented.

Name	Role	Period of access
Dr. D.S. Kringos	Project leader	2017/05/01 to -
Prof. dr. N.S. Klazinga	Project leader	2017/05/01 to -
Drs. R.G. Gerrits	Project member	2017/05/01 to -
Drs. T. Jansen	Project member	2017/05/01 to – 2017/12/31 continuation as co-author
Dr. M.J. van den Berg	Project member	2017/05/01 to 2017/09/31 (continuation as project advisor)
Drs. J Mulyanto	Project member	2017/12/15 to -

Mr. Joost Wammes	Intern (access restricted) Research assistant	2018/02/05 -2018/06/01 2018/06/01 -2018/07/01

Phase 1 and 6: Qualitative interviews with HSR groups representatives

Aim

Phase 1: defining Questionable Research Practices (QRP's) in the reporting of conclusions and messages in HSR in order to gain consensus on the definition of QRP's in the reporting of conclusions and messages in HSR, and to elaborate on the conceptual framework of potential factors contributing to QRP's and responsible reporting.

Phase 6: feeding back the preliminary aggregated study results based on the data collected in phase 2 to 5, discussing potential adaptations that the HSR groups are willing and able to make to reduce common QRPs, and to explore perceptions and opinions concerning potential implementation strategies.

Consent to participate

Preceding the research project, 13 heads or representatives of HSR institutes and groups in the Netherlands agreed to participate in this study and take part in two rounds of interviews.

Data-collection

Phase 1: qualitative oral interviews will be conducted according to a topic-list emerging from a kick-off meeting with the project team and HSR group representatives.

Phase 6: qualitative oral interviews will be conducted according to a topic-list based on the preliminary findings resulting from phase 2 to 5.

With permission of the interviewees, the interviews will be recorded to ease processing. The recordings will serve to support the writing of the interview reports. The interview reports will be presented to the interviewees for approval of their reported statements. Therefore, the reports will be securely e-mailed to the interviewee using the 'secure e-mail' option in Outlook. Alternatively, in case the respondents' e-mail provider does not support the secure e-mail option, the file will be sent using the Surf Filesender application (https://filesender.surf.nl/). Consequently, the file will be encrypted by 7-zip, pass-word secured, and uploaded to Surf Filesender. The e-mail recipient receives an e-mail with the link to the application and downloads the file. Interviewees will be encouraged to use the secure e-mail option or Surf Filesender when returning the interview report with their comments.

Phase 2: Review of scientific publications

Aim

To gain an overview of the prevalence of QRP's in scientific publications reporting health services research conducted by Dutch HSR groups.

Sampling

The review involves scientific HSR papers, published in peer-reviewed international scientific journals. For each of the 13 HSR groups, the ten most recent publications before January 1st 2017, by unique first and last authors will be included. The sample thus includes 130 research articles.

Data-collection

The 130 scientific HSR articles will be reviewed using the 'Data Extraction Form (DEF)', that will be developed during the present study. Data thus concerns the results from the review of 130 HSR research articles. Each author will be assigned an unique identification number. Obtained data will be entered in SPSS using this unique identification number, and author information will be separated from the study data.

Phase 3: Electronic survey

Aim

To explore the extent to which QRPs in formulating conclusions and messages in scientific HSR articles are associated with individual factors, research study features, institutional factors and journal/publication/media characteristics.

Sampling & recruitment

We aim to include 130 researchers of the 13 Dutch HSR groups that participate in the project. These will involve the ten researchers for every HSR group, who first- or last-authored a scientific publication that is included in the first part of the study.

Consent to participate

Participants will receive an invitation to participate from the AMC research group. The participating institutions will be asked to encourage their researchers to participate in the survey. Participation is voluntary and participants have the right to stop at any time. Participants of the survey will be informed on the goal of the study and the handling of the data before the start of the survey. Specifically, information is provided concerning the linkage of data sources and protection of their privacy. Respondents will give consent for participation in the project, linkage of their survey data to the scientific and societal publications, and publication of the aggregated results, at the start of the survey. At the end of the survey participants will be asked if they can be contacted for an interview in the qualitative phase of the project and if societal publications have been written about their research that was included in the review phase (1).

Data-collection

The electronic survey will be based on a framework on factors of influence on responsible and questionable reporting of conclusions and messages in HSR. This framework is developed in the first phase of the project. The survey consists of questions concerning the researcher's experience with factors that influence the practice of deriving conclusions from findings, either responsible and questionable. Expected time to complete the survey will not exceed 30 minutes.

Survey data will be collected through the online survey program LimeSurvey and is hosted on the AMC-server. Data-output of the survey will be entered in SPSS and the identification number,

attributed to each researcher in phase 2, will be assigned. Subsequently, identifying data will be separated from the study data. Through this identification number, the data derived from the survey will be connected to the data obtained in the other phases (except phase 1) (for more detail see paragraph 'Data linkages').

Phase 4: Focus groups and qualitative interviews

Aim

To explore more in-depth the answers given in the survey, explore researcher's experiences, and to identify 'good practices' in reporting conclusions and messages in scientific publications.

Sampling & recruitment

At each department a focus group will be organized. Participants will be recruited based on the publications included in phase 2 of this project. Each department head will be asked to encourage their researchers to participate in this focus groups, and facilitate the meeting at their department/institution.

In addition, a number of interviews (to be further defined depending on need) will be held with participants of the survey who have agreed to possibly participate in a follow-up interview. Participants will be contacted through e-mail and invited to an interview by the research group. To achieve insight in the answers given in the survey, a selection of participants will be made purposefully by the AMC research group based on the variation of answers on the survey. Reasons for decline/non-response will be documented to be aware of potential selection bias.

Consent to participate

Participation in the focus groups and interviews is voluntary. Focus groups will be organized at the participating departments/institutions. Potential participants will be invited by the AMC research group to participate in the focus group or interviews by e-mail. If no answer is received a reminder may be sent, and contact can be sought by telephone. Potential interviewees will be informed on the goal of the study and the handling of the data in the invitation. Specifically, information is provided concerning the linkage of data sources and protection of their privacy. Participation is voluntary and participants have the right to stop at any time. Interviewees will give consent for participation in the project, linkage of the interview report to the survey data, and publication of the aggregated results by agreeing to participate in the interview or focus group.

Data-collection

With permission of the focus group participants and interviewees, the interviews will be recorded to ease processing. The recordings will be transcribed verbatim.
The intended duration of the focusgroups is 2 hours. The intended duration of the interview will be thirty minutes to one hour.

To facilitate an open conversation, researchers who are invited for an interview will not receive a report on the findings of their publication.
The interview reports will be assigned the identification number that was attributed to each researcher in phase 2. Subsequently, identifying data will be separated from the study data. Through

the identification number, the data derived from the interview will be connected to the data obtained in the other phases (except phase 1) (for more detail see paragraph 'Data linkages').

Phase 5: Review of societal publications

Aim

To assess the prevalence and nature of questionable messages broadcasted in societal publications, and to explore how this practice relates to quality of conclusions and messages in the original scientific publication.

Sampling

From the sample of scientific publications, a sub-sample of 40 publications will be selected to retrieve related societal publications, such as press-releases and public reports. Preferably, the sample includes 20 publications with QRPs, and 20 publications without QRPs. Moreover, each of the HSR groups will be represented by at least one scientific publication. For each selected scientific publication, the researchers will be contacted to retrieve any societal publications related to the scientific publication.

Data-collection

The societal publications will be assessed applying an adapted version of the FIAT-Health instrument, developed by the project members in a previous research project. Data retrieved from the assessment of the societal publications will be entered in SPSS. Identifying data will be separated from the study data. The societal publications will be assigned the identification number attributed to each researcher in phase 2. Subsequently, identifying data will be separated from the study data. Through the identification number, the data derived from the interview will be connected to the data obtained in the other phases (except phase 1) (for more detail see paragraph 'Data linkages').

General issues

The remainder of this document addresses data-handling and privacy-issues concerning all phases of data-collection.

Reporting

Although studied scientific and societal publications are publically available and traceable to individual researchers, and the review instruments will be made publically available as well, the findings of the research project will be reported on aggregate level only. None of the findings will be reducible to single publications, researchers, or HSR groups. Findings resulting from the survey and interviews will be reported in conjunction with the findings from the reviews. Nevertheless, to specific outcomes that may lead to identification of single subjects or institutions will not be reported.

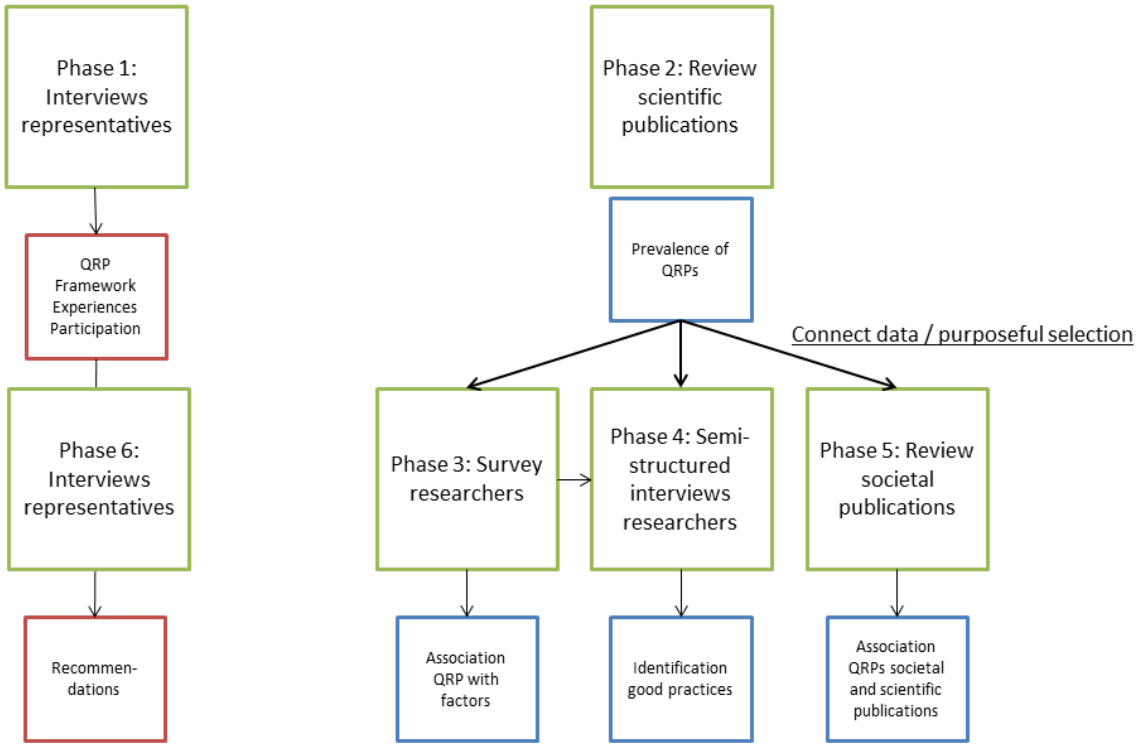
Subject identification & privacy protection

Throughout the data collection phases, an identification number will be used to refer to participants. In addition, this number will be used to be able to link data obtained from the different data collection phases (for more detail see paragraph 'Data linkages'). Identifying information from the participants, such as name, contact details, and affiliation, will be separated from the study data and,

supplemented with the identification number, stored in a separate pass-word secured excel file. This link table will be stored in a separate folder within the project folder (for more detail see Data storage & archiving). The pass-word will be administered by the departments secretary, and is available only to the executive researcher(s) for the purpose of recruiting participants and feeding them back their input (interviews, and upon request the assessment of their scientific publication). After the project is finished, the link table will be securely deposited on a secured drive of the Clinical Research Unit (CRU), an independent research support department within the AMC.

Data linkages

To be able to analyze which factors are associated with the occurrence of QRPs in reporting conclusions and messages, we will link the findings from the review of both the scientific and the societal publications to the survey data and the findings from the interviews. We will then be able to determine whether specific QRPs are associated with what individual, institutional, and societal factors to identify good practices. The linkage of the data can be pictured as the following:



To secure the privacy of the involved researchers, the linked data will be additionally checked for identifiable information. In case the conjunction of data leads to effortless disclosure of the researchers' identity, the referring information will be removed. Nevertheless, complete anonymity cannot be guaranteed and is not feasible, since the project researchers are working in the research field that is studied. Consequently, the researchers will handle the data with great precaution.

Data storage & archiving

Data will be stored on the G-drive of the department of Social Medicine, which is subject to the central AMC back-up regime. The project folder is accessible only for the project members. Data and

related study materials are only approachable in the AMC or the secured central digital workspace (Centrale Digitale Werkplek) and will not be stored in the cloud, nor on portable devices.

Just one exception was made for audio files that contain a recorded interview, concerning phase 1. Interviews were recorded using the audio recorder of the researchers' cell phones, secured by pin code. To prevent the recoding to be transferred to other devices or the cloud, Bluetooth and back-up services were turned off. The phone only was used to store the recording until transfer to the AMC-drive, using a USB-cable. Once the recording was stored on the AMC-drive, the audio-file on the phone was deleted immediately. The interviews with researchers, and the second round of interviews with the institutions representatives will be recorded using an audio-recorder, to minimize the risks accompanied with recording by phone.

After completion of the project, the data will be electronically archived on the L-drive for long-term storage within the AMC. The retention period for the de-identified study data will be 15 years. The identifying information, raw data-files, review data-extraction forms and interview reports will be retained for ten years, according to the VSNU-guidelines.

Data sharing & access

Raw anonymized data files will be made available to third parties, upon reasonable request. These data files include anonymized literature review data, survey data and summaries of interview reports. No linked data files, nor identifiable data, e.g. data reducible to individual researchers, single scientific or societal publications, or single institutions, will be shared with third parties. No open access of raw data will be provided. However, data-files with aggregate data will be made publically available upon completion of the project. The data-extraction form for the assessment of QRPs in scientific publications, and the adapted FIAT-Health to assess societal publications, will be made publically available upon completion of the project as well, or possibly within the project through scientific publications.

Declaration by the Medical Ethics Review Committee of the AMC

Referring to our letter of July 27, 2017 (reference number W17_286 # 17.338) we are pleased to confirm that the Medical Research Involving Human Subjects Act (WMO) does not apply to the above mentioned study and that an official approval of this study by our committee is not required.

Development ethical code of conduct for HSR not involving human subjects

We are currently exploring possibilities to involve the Medical Ethic Review Committee in assessing the participant protection of the current study and future HSR projects. We aim to develop an ethical code of conduct for conducting Health Services Research that does not involve human subjects according to the Medical Research Involving Human Subjects Act. For research projects involving human participants, we however think there may be a need for a common ground in performing Health Services Research.