1. Working title

'Exploring factors associated with responsible and questionable reporting of conclusions in Health Services Research'

2. Anticipated authors (in expected order for publication)

Reinie Gerrits1, Joko Mulyanto 1, Joost Wammes12, Michael van den Berg1, Niek Klazinga1, Dionne Kringos1.

3. Problem statement and relevance

- 3.1. Relevance: which specific public health problem is so important that it needs further study?

Conclusions drawn in Health Services Research (HSR) may fuel the public and policy debate (4), and impact citizens, health care providers and policymakers' decisions (7-9). The broad societal interest in HSR is explained by its aim to optimize policy and management. The HSR domain covers topics such as co-payments, evaluation of quality improvement efforts, cost-effectiveness of medications, patient empowerment, compliance with therapy and effects of policies. In 2009 it was estimated that 85% of research funding in biomedical sciences was avoidably wasted (1), particularly in the biomedical sciences the evidence has been building up for questionable research practices (QRPs) in imbalanced research question selection, poor study design and execution, non-publication, and poor reporting (1). Although in most individual cases QRPs are considered less serious violations than cases of deliberate fraud, the problem in itself and its impact on science and society is possibly greater (2-4), particularly in the phase of research where scientists have the most freedom to give their own interpretation and have potentially the largest impact on their work, i.e.: making inferences from results by drawing conclusions in scientific publications (21-24, 9).

There are various ways researchers can (un)intentionally conduct QRPs in reporting messages and conclusions from their research in their scientific publications and that may be missed in the peer review process of journals, e.g. selectively reporting positive results; generalizing findings to the present time while the study is based on older data, selectively setting results in the context of previous research, or claiming a causal relationship though problems of confounding and reverse causality had not been resolved.

- 3.2. Knowledge need: which gap in knowledge do we need to address this problem?

HSR institutions have made their own choices and developed their organizational practices in how to support responsible conduct of research, including responsible reporting. This variety in practices offers the opportunity to learn from each other, and identify good practices that are associated with a relatively low occurrence of QRP in the reporting of messages and conclusions HSR. This will provide insight for HSR institutions in how to better support researchers in producing responsible conclusions that are usable for policy and practice.

- 3.3. Previous studies: why is this question yet not sufficiently addressed in the scientific literature?

From studies conducted in biomedical research, we have some evidence on what factors are related to responsible reporting in scientific publications. Such studies however, have not been conducted in relation to the policy and management-oriented field of HSR.

Previous studies researching the factors that contribute to questionable research practices are mainly aimed at biomedical research(5, 6), and do not take into account the specific characteristics that are specific for HSR research. Moreover, factors related to the reporting of messages and conclusions in scientific literature in particular have not been previously identified.

4. General objective (in one sentence)

The aim of this study is to explore the individual, institutional and research environment factors that are associated with QRPs in the reporting of messages and conclusions in scientific HSR publications, and to identify good practices that seem to promote good practices at institutional level in reporting of messages and conclusions in HSR publications.

5. Research questions (about three)

- To what extent are individual, institutional and research environment factors associated with the number of QRPs in the reporting of messages and conclusions in HSR publications?

6. Key hypothesis (if any)

- Positive individual, institutional, and research environment factors are associated (significantly) with a lower number of QRPs in the reporting of messages and conclusions in HSR publications.

7. **Design, study population and variables (max 3 paragraphs)**

Design

This study is part of a mixed methods study combining results from a focus group study among researchers of the 13 participating institutions, with the aim to identifying good practices at Dutch HSR institutions and factors that may contribute to questionable and responsible reporting.

Based on a theoretical framework we developed an electronic survey to ask health services researchers about their experience of factors that influence (for the better and worse) the practice of deriving conclusions from findings. In a previous phase of this study, we identified QRPs in the reporting of messages and conclusions through an assessment of 116 HSR publications, authored by

13 different HSR institutions in the Netherlands (methods and results published elsewhere). First and last authors of these publications were asked to fill in the survey with questions on their perceptions on publication practices in their respective institutions. Results from the survey will be linked to the number of QRPs in the assessed publications.

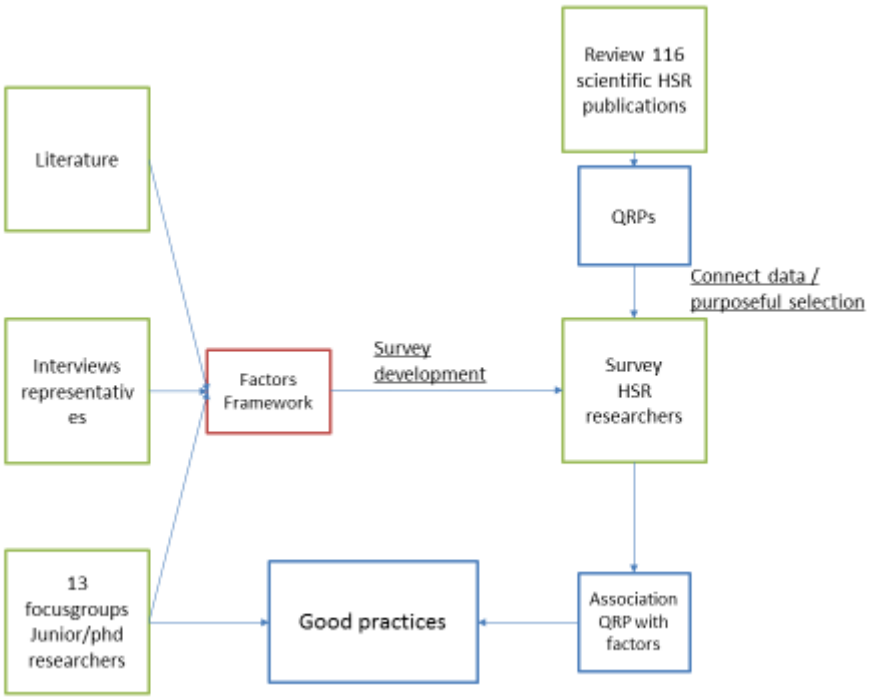


Figure: data sources and outcomes

Study population

We identified a total 202 authors (116 first authors and 86 last authors) as the sample of our study. 30 authors were excluded due to unavailability of contact information, and we invited 172 authors for the final sample. Participants were invited through e-mail. E-mail addresses were obtained through the institutions or the included scientific publication. The participating institutions were asked to encourage their researchers to participate in the survey. Participation is voluntary and participants could stop at any time. Participants of the survey were informed on the goal of the study and the handling of the data at the start of the survey. The response rate until 10 Dec. 2018 was 45% (78 respondents).

Measures

Outcome

The main outcome of this study is the number of QRPs in the HSR publications. Number of QRPs in conclusion section for each of 116 HSR publications were identified in previous study and available to be used as the outcome in this study.

Explanatory variables

a. Factors associated with QRPs

First, factors potentially associated with QRP in the reporting of HSR were identified in scientific literature, through a literature review, and validated through semi-structured interviews with the leaders of 13 HSR institutions/groups, additional factors mentioned during the interviews were added to the list of factors.

Factors were organized in a framework existing of three levels: individual, institutional and research environment factors. Within these three levels, factors fall under 14 domains, as follows:

Individual

- Motivation for scientific career
- Capability
- Self perception
- Ideology

Institutional

- Role of supervisors
- Supporting structural conditions
- Social support at the institution
- Informal organisation culture

Research culture

- Independence of funder
- Idependence scientific society
- Indepence from media
- Journal policies and practices
- Collaboration
- Stakeholder involvement

b. Good practices

Good practices are a set of facilitating factors at institutions that are associated with the lower occurrence of QRPs. We identified potential good practices as perceived by researchers through analyses of the 13 focus groups. With the results from the analyses on what factors are associated with a lower number of QRPs, we will determine what are good practices that could be implemented by HSR institutions.

Survey questionnaire

Based upon the resulting framework we developed a questionnaire. Two existing validated surveys were used as a basis for the questionnaire: the SORC (10), and publication pressure questionnaire (11). However, these questionnaires did not align with our target population and did not cover our framework fully. Using the example of these questionnaires, we developed a questionnaire in line with our theoretical framework. Using notes from six focus groups that were conducted at this the time of survey development, the questionnaire was fine tuned. The factors that were identified during these six focus groups, were added to the framework if not already included. Specific questions fitting these factors were developed and subsequently added to the survey. Moreover, some questions included in the survey were rephrased to fit the concepts brought forward during the group sessions.

For each identified factor, one or multiple survey questions were designed. Questions were evaluated on their face validity by all co-authors, and two project advisors (A. Kunst / T. Plochg). Answers to the survey questions were given on a Likert-scale (1 to 5). The score from multiple

questions in each identified factor will be aggregated into a single domain score. A higher domain score indicates a better/desirable situation.

A 'think out loud' test was performed with two people from the target population. RG sat down with two researchers individually as they answered the survey questions and commented on their interpretation. The survey was designed in English, and checked by a native speaker.

Controlled variables

Several individual characteristics are collected in the survey, and will be used as control variables. Those are age, working duration, academic background, and number of publications.

8. Analytic techniques (max 2 paragraphs)

We will describe the basic characteristics of study population based on the measurement scale of the variables. Categorical variables (nominal / ordinal) will be presented as frequency and percentage, while the numerical variables (interval/ratio) will be presented using mean/median and standard deviation/IQR.

To explore the association between individual, institutional, research environment factors with the number of QRPs in HSR publications, we will firstly conduct bivariate analysis using simple Poisson regression to explore the association of each domain to the outcome (number of QRPs). Poisson regression is chosen considering the nature of the outcome (number of QRPs) as count data with a relatively small value of mean. The analysis is also intended to reduce the number of domains which will be included in the multivariate model and address the concern of relatively small sample size (lack of statistical power). Domains which have p-value less than 0.25 will be included in the multivariate model. Following the bivariate analysis, we will apply multiple Poisson regression to conduct the multivariate analysis using the aforementioned criteria. All the domains will be included in single equation in the same time (enter method). To measure the association, the coefficient of each explanatory variables and 95% CI will be provided.

9. Check for quality and relevance (optional)

9.1. Are you sure that you can answer the research questions? If not, what are the main risks?

9.2. Has the analysis particular strengths? Is it innovative? If not, what can you add to literature?

9.3. Will the results be of interest to readers in other countries? If, not why publish internationally?

9.4. Could you regard any of the potential results as 'negative'? Are you sure that you would publish these as well?

10.References (only key publications)

11.Draft of introductory tables (to describe population and/or variables)

Sample characteristics	
Age	Mean/Median, SD/IQR
Working duration	Mean/Median, SD/IQR
Number of Publications	Mean/Median, SD/IQR
Training background	
Quantitative	n, %
Qualitative	n, %
Institution	
University	n, %
Non-university	n, %

12.Draft of key tables and graphs (to answer the research questions)

Table 1

Domain	**Mean/median, SD/IQR**	**Bivariate**		**Multivariate**	
		Coefficient	**95%CI**	**Coefficient**	**95%CI**
Domain 1					
…					

12. Attachment: draft(s) of the Methods section (if available).

1. Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, et al. Reducing waste from incomplete or unusable reports of biomedical research. The Lancet. 2014;383(9913):267-76.
2. Bouter LM. Commentary: Perverse Incentives or Rotten Apples? Accountability in Research. 2015;22(3):148-61.
3. Caulfield T. The Commercialisation of Medical and Scientific Reporting. PLoS Med. 2005;1(3):e38.
4. Burstein P. The impact of public opinion on public policy: A review and an agenda. Polit Res Quart. 2003;56(1):29-40.
5. Ioannidis JPA, Greenland S, Hlatky MA, Khoury MJ, Macleod MR, Moher D, et al. Increasing value and reducing waste in research design, conduct, and analysis. The Lancet. 2014;383(9912):166-75.
6. Ochodo EA, de Haan MC, Reitsma JB, Hooft L, Bossuyt PM, Leeflang MM. Overinterpretation and misreporting of diagnostic accuracy studies: evidence of "spin". Radiology. 2013;267(2):581-8.
7. Lavis JN, Ross SE, Hurley JE, Hohenadel JM, Stoddart GL, Woodward CA, et al. Examining the role of health services research in public policymaking. Milbank Q. 2002;80(1):125-54.
8. Hanney SR, Gonzalez-Block MA, Buxton MJ, Kogan M. The utilization of health research in policy-making: concepts, examples and methods of assessment. Health Res Policy Syst. 2003;1.
9. Kuruvilla S, Mays N, Walt G. Describing the impact of health services and policy research. J Health Serv Res Policy. 2007;12 Suppl 1:S1-23-31.
10. Martinson BC, Thrush CR, Lauren Crain A. Development and validation of the Survey of Organizational Research Climate (SORC). Science and engineering ethics. 2013;19(3):813-34.
11. Tijdink JK, Verbeke R, Smulders YM. Publication pressure and scientific misconduct in medical scientists. J Empir Res Hum Res Ethics. 2014;9(5):64-71.