PARTICIPANT INFORMATION LEAFLET

[11 April 2017, version 2.2]

Study Title: Publication and related bias in health services and delivery research (HSDR): a systematic review of literature and evaluation of empirical evidence and methodology, and key informant interview

Investigator(s): Dr Yen-Fu Chen & Dr Iestyn Williams

Introduction

You are invited to take part in a study. Before you decide, you need to understand why the study is being carried out and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study)

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the study about?

It is important that the people who are responsible for making decisions about the ways our health services are delivered have the best and most reliable evidence available. Sometimes, however, the evidence available doesn't tell the 'full story' or may be biased. For example 'publication bias' happens when only certain studies, usually those which are more exciting or are 'positive,' are published. Other forms include 'outcome reporting bias', which happens when a study collects lots of data, but only the 'positive' or interesting results are published.

Despite its importance, publication bias seems to be infrequently discussed in health services and delivery research (HSDR), which produces evidence on the quality, accessibility and organisation of health services. This study looks at publication bias in this area of research. It aims to explore the issue of publication bias in HSDR and to promote good research practice among the HSDR

community to minimise its future occurrence and impact. In this part of the research we want to ask individuals involved in undertaking, publishing or using research to give their views and experiences on this topic.

Do I have to take part?

Participation in the study is entirely voluntary and you are under no obligation take part.

What will happen to me if I take part?

We will contact you to arrange an interview that can be undertaken either face-to-face or through a telephone call, in which an experienced researcher will ask you questions about your views and personal experience related to publication bias in HSDR. The interview is expected to last about 30 minutes to an hour.

What are the possible disadvantages, side effects, risks, and/or discomforts of taking part in this study?

There are few if any risks in taking part in this study, as all you are required to do is share your thoughts and experiences. We would like to assure you that all the contents of the interview will be anonymised and so you can feel free to talk about any issues without needing to worry about being subsequently identified. The subject matter of this study includes activities that might be construed as poor academic practice. You are not required to discuss any specific examples of these but if you do so we will remove any identifying information (e.g. names, institutions and job titles) before including the data within the study.

What are the possible benefits of taking part in this study?

Given the potentially significant impact of publication bias on decisions made on the organisation and delivery of health services and the paucity of existing evidence in this field, the opinions and experiences that you share with us in the interview will help us to understand the nature and scale of the problem in HSDR and to develop recommendations to help prevent publication bias and/or minimise it impact. We would also be happy to share early findings with you if that would be useful to you in your work.

Expenses and payments

No expenses will be incurred by you beyond the time taken to complete the interview. We are not able to offer remuneration to interviewees.

What will happen when the study ends?

You will be given an opportunity to hear about the results of the study and will receive a copy of the final report.

Your personal information will be kept in a password-protected file saved on a secure University server with limited access only to key study personnel. Transcripts of the interviews will be

anonymised and will also be kept on a secure University server. Paper information will be shredded and electronically-held data will be retained for 10 years in line with the University of Warwick's Research Data Policy before being removed.

Will my taking part be kept confidential?

Yes. We will follow strict ethical and legal practice and all information about you will be handled in confidence. Further details are included in Part 2.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm that you might suffer will be addressed. Detailed information is given in Part 2.

This concludes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

Who is organising and funding the study?

This study is funded by the UK National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) Programme. It is led by experienced researchers at the University of Warwick in collaboration with colleagues at the University of Birmingham and the University of East Anglia.

What will happen if I don't want to carry on being part of the study?

Participation in this study is entirely voluntary. Refusal to participate will not affect you in any way. If you decide to take part in the study, you will need to sign a consent form, which states that you have given your consent to participate.

If you agree to participate, you may nevertheless withdraw from the study at any time up until the point at which the data from your interview are anonymised. At this stage we will be unable to identify the source of individual statements and so unable to remove them from the data.

What if there is a problem?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact the Chief Investigator of the study:

Dr Yen-Fu Chen, Warwick Centre for Applied Health Research & Delivery (W-CAHRD), Division of Health Sciences, Warwick Medical School, University of Warwick, Coventry CV4 7 AL, United Kingdom [redacted]

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services

University House

University of Warwick

Coventry

CV4 8UW

[redacted]

Will my taking part be kept confidential?

We will anonymise interview transcripts and names and details of interviewees will be stored separately from their data. As noted above, your personal information will be kept in a password-protected file saved on a secure University server with access limited only to key study personnel. In all outputs from the research, participants will be referenced via a unique identifier code only. As we will interview a relatively small sample of interviewees, some of whom may have a high profile, we cannot guarantee that respondents will be entirely unidentifiable. In recognition of this, you will be given the opportunity to comment on a draft report of the interview findings so that you can be assured that all identifying features are removed.

What will happen to the results of the study?

We intend to write up the findings of the study as academic journal article(s). The results will also be presented in national and international conferences and will be included in the final report for the NIHR HS&DR Programme, which will be published with free open access on their website

http://www.nets.nihr.ac.uk/programmes/hsdr. We will supply a copy of the report/paper summarising findings of this study to you if you have expressed your interest in receiving one.

Who has reviewed the study?

This study has been reviewed and approved by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): REGO-2017-1918

What if I want more information about the study?

If you have any questions about any aspect of the study, or your participation in it, not answered by this participant information leaflet, please contact:

Dr Yen-Fu Chen, Warwick Centre for Applied Health Research & Delivery (W-CAHRD), Division of Health Sciences, Warwick Medical School, University of Warwick, Coventry CV4 7 AL, United Kingdom [redacted]

Thank you for taking the time to read this participant information leaflet.