**Journal Editor Semi-structured Interview Guide**

INTRODUCTION

Good Morning/Afternoon/Evening (NAME OF PERSON BEING INTERVIEWED).

This is (NAMES OF INDIVIDUALS CONDUCTING THE INTERVIEW), calling from the University of Maryland, Baltimore.

We are scheduled to conduct the interview with you today, is now still a good time for us to talk?

If yes, continue.

If no: What alternative date and time will work better for you? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Thank you again for taking time out of your busy schedule to participate in this interview. The purpose of this interview is to better understand journal editors’ views toward the value of real-world evidence typically obtained through observational studies and/or the analyses of secondary data sources. We also aim to better understand the manuscript submission, review, and publication process for these types of studies. We will be spending about 45- 60 minutes discussing various issues that will help us better understand the factors associated with the review and publication process for studies with real-world evidence findings.

For the purpose of this project, the term “real-world evidence” or “RWE” means information derived from studies using what has been called “real-world data” about the use, benefits, or risks of a treatment (for example, a drug or procedure) or other type of intervention (like a payment system). When we talk about “real-world data,” we mean those data derived from sources other than randomized controlled trials (for example, patient registries, patient cohorts, administrative claims, or electronic health records).

DISCLOSURES

Your specific responses will be de-identified, and will not be associated with or stored with your name and/or journal name, or other identifiable information. Study results will include main ideas from all participating editors in aggregate, and findings will be presented to all participants at an Editors’ Roundtable meeting in the fall of 2015, where we will solicit feedback and recommendations.

As the University of Maryland is committed to transparency and dissemination of results, our intent will be to publish these results in a peer reviewed journal. The University of Maryland received funding for this research from the National Pharmaceutical Council ([www.npcnow.org](http://www.npcnow.org))

Do you agree to participate in this interview? (*Wait for participant to respond*)

In order to accurately capture our discussions, we would like to audio-record all interviews. These audio-recordings will be permanently deleted after the notes are transcribed.

Are you okay with this? *(Wait for participant to respond)*

Do you have any questions about what we have just covered? (*Wait for participant to respond and provide clarification if needed.)*.

If there are no further questions, we would like to begin the discussion and will begin recording now. *(Start recording)*

**General Perception of RWE/RWD**

We are going to begin with your general perceptions of real-world evidence studies.

There are merits and drawbacks for all study designs, including those that produce real-world evidence. Our goal is to understand the value, or lack thereof, of real-world studies, and more specifically, what aspects of these studies are useful, which aspects are not, and why?

GP-1: For the purpose of this interview, we have defined RWE as information derived from studies using “real-world” data about the use, benefits, or risks of a treatment (such as drugs or procedures) or other type of intervention like payment systems. Is this consistent with the way your journal defines RWE?

Are you comfortable using this as a working definition for the purpose of this interview?

GP-2: In your view, do real-world evidence studies provide value?

* This is why your opinion is particularly important
* Part of the difficulty I’m having in responding is that my section of the journal in contrast to other sections of the journal is that I get typically
  + Example, how did diabetes get onto the political agenda in Mali as opposed to Mauritania. The health economics section of our journal might get more of the econometric type studies
  + I would typically look for biases or inferences improperly made, but I look to statisticians to tell me these, since I am not an expert

Probe: When do they provide value? When do they not provide value?

GP-3: What determines whether or not real-world evidence studies are valuable?

Probe: Is it due to:

* the real-world aspect of the study?
* the outcomes considered
* the characteristics of the studies (e.g., design, multi-cohort vs single, statistical premise)?
* potential confounders
* transparency of analysis
* a priori specification
* the relevance to your readership?
* funders/researchers?
* the context of other data (e.g., they complement existing RCT? they extend the population, they look at studies unlikely to be in a RCT)
* factors extraneous to the research (e.g., their readers, etc.)

GP-4: Has the value of real-world evidence changed over the last 5 to 10 years? If so how?

GP-5: Do you expect the value of RWE to change over the next 5 to 10 years? If so how?

**Description of manuscript submissions**

Next, we’d like to talk about the manuscript submissions you typically receive.

MS-1: Please describe to me your perspective on what constitutes a high-quality manuscript with RWE findings? How do you distinguish a poor-quality RWE manuscript from a high quality RWE manuscript?

Probe: For example: type of endpoints, certainty of outcomes, analytic rigor or approaches to considering confounding, transparency, quality of reporting, generalizability of findings, relevance of findings?

Do you associate any particular research designs with higher quality RWE?

Probe: Patient registry or cohort study, analysis of electronic health records, analysis of administrative claims.

MS-2: Do these features differ from what constitutes a high-quality manuscript with data from a randomized controlled trial? If so how?

**Manuscript submission and review procedures (criteria for acceptance, rejection)**

MR-1: What factors into the decision to send manuscripts out for peer-review?

Probe: Please describe some of the most common reasons why manuscripts are not sent out for peer review (determine whether criteria are relevant to RWEs, RCTs, or both) :

MR-2: What factors into the decision to accept RWE manuscripts?

Probe: Please describe some of the most common reasons RWE manuscripts are not accepted for publication?

MR-3: How do these factors differ - or not differ - as compared to other types of research manuscripts based upon RCTs? *(consider reading back answers from MR-2 and asking if these are e.g., similar or in what ways they are different)*

MSMS 4: - Does your journal have specific or additional guideline recommendations for authors to follow when submitting RWE manuscripts? Are there recommendations for RWE that differ from other types of studies? [Do not offer - but they may refer to STROBE, GRADE, RECORD, etc.]

**Skills and capabilities**

Now we will move on to the skills and capabilities of reviewers when it comes to RWE studies.

SC-1: Have you encountered challenges in finding external peer reviewers to review RWE manuscripts? If so what are the challenges?

Probe: Are there sufficient numbers of qualified reviewers for these studies?

SC-2: Do you have reviewers who self-identify as having expertise in RWE studies? If yes, how do they commonly describe their expertise?

(This might include such terms as observational study design experts, claims or secondary data experts)

SC-3: What constitutes sufficient training and expertise in RWE?

(This might include such terms as observational study design experts, claims or secondary data experts)

SC-4: What tools, if any, does your journal have available to assist a reviewer in assessing the quality of a real-world evidence study?

Probe: tools could include STrengthening the Reporting of OBservational studies in Epidemiology (STROBE), GRADE, RECORD, etc.

How are these tools made available and how are these tools being used?

What are the benefits and potential drawbacks of having tools for reviewing RWE studies?

If they do not have any tools: Are you aware of any tools or resources available for reviewers? Would additional tools be useful? If so what would those be?

**Readership skills and capabilities**

Now we’d like to ask about your readership’s skills and capabilities when it comes to using RWE studies.

RS-1: When it comes to reading, understanding and using evidence from RWE studies, how would you describe your readership’s level of expertise?

Probe: Could you give the readership a rating? Very expert, moderate, little expertise?

Why do think this? What are contributing factors?

Does this factor into your decision to accept RWE manuscripts? If so how?

RS-2: What tools, if any, does your journal make available to assist a reader in assessing the quality of a RWE study?

Probe: Please describe what these tools; How they are made available and how are they being used?

Probe: What tools would assist a reader in assessing the quality of a RWE study?

**Final/closing questions**

We have just a few general final questions for you.

FQ-1: What would improve the value of RWE, either the studies themselves or the manuscripts describing their finding s?

FQ-2: What would facilitate the review and acceptance of RWE studies?

FQ-3: How long have you been an editor> Why did you choose to become an editor? How much time do you spend on editorial duties? How long do you plan to continue serving in this role?

FQ-4: Do you have any additional comments or questions, or anything you would like to add? (possible probe: thoughts on venues to publish RWE studies)

This concludes our interview. As previously mentioned, we will share the results of our findings from the interviews at the Roundtable meeting. In appreciation for your time, we will provide an honorarium of $1,250 for participation in the Roundtable meeting and will also cover travel expenses.

Can you please confirm that you will attend the meeting? *(Wait for participant to respond).*

Once again, I/we want to thank you for your time. Goodbye.