Appendix 1 (as supplied by the authors)

Interview Guide

Instructions for interviewer:

This section is a semi structured, open-ended interview. Use the questions here to guide the conversation. Probes are provided to help you explore the questions with the participant and to provide some bearing on what is important to explore in the conversation. Your questions may branch into other topics not covered in the interview questions. This information is important as well and it is ok to depart from the interview questions in order to explore these elements.

Before ending the interview review the questions provided here to be sure you discussed all of the topics outlined.

Hello [participant]. Thank you very much for your participation in this study. We are going to ask you some questions about real world evidence. The information you provide us with will help us better understand how real world evidence can be used in cancer drug funding decisions. Your participation is completely voluntary, you can stop at any time and you can opt out of any questions you do not wish to answer or discuss. Your answers are confidential. We would like to record this conversation. To protect confidentiality please do not use names or other identifiers during the interview or other. Once this interview is completed we will have it transcribed, at which time we will remove any references to names or places that could identify you. Once the transcription is verified we will erase the audio recording. Please note that if for any reason in this interview you inform us of your intent to harm yourself or other we will have to report this information. It is ok to record this conversation?

If yes: turn on recorder

If no: proceed with out recording

Instructions for Interviewer:

This interview guide has **two** sets of questions. The first set of questions is for all the stakeholders except patient representatives, and the second set of questions are for only patient representatives.

Question Set I – For stakeholders except patients/patient representatives

I. General Background

1. Please tell us about your background in the healthcare industry.

(Probe: What is your role/position in the healthcare industry? What is your area of study/area of expertise?)

II. Current Understanding of RWE

Objective*: The goal of this section is to assess stakeholders overall opinions on RWE.*

2. What are your general thoughts about RWE?

(Probe: Have you ever been involved in any studies/work using RWE? Do you know anyone who has involved RWE in his or her work? Do you use it yourself? Where do you think that RWE is most needed/lease needed**?** What does RWE mean to you and/or your organization?

3. What do you see as the current state RWE in heath care decision-making?

(Probe: Who and where do you see using it? How do healthcare professionals react to RWE? What potential does RWE have?).

4. Often RWE and RWD are terms that can be interchangeable. What do you think are the differences between RWE and RWD (Real World Data)?

5. What are the barriers to the use of RWE?

(Probe: What factors limit RWE uptake, RWE utilization or knowledge translation? Is there difficulty when transforming RWD into RWE?)

6. What has facilitated RWE uptake, implementation and utilization?

(Probe: What efforts do you think have facilitated the use of RWE so far? What factors can you think of that may improve the utilization of RWE?)

III. Past Experiences

Objective: The goal of this section is to have an in-depth knowledge of stakeholders' past experiences and how his/her experiences shape his/her views regarding RWE.

7. Please tell us about your past experiences with RWE. (*If the stakeholder has no experience related to RWE, please skip the entire section III.)*

(Probe: For what purpose have you pursued RWE? In what ways were the RWE used, if any? What efforts you have taken to incorporate RWE into your work/studies?)

8. What are lessons learned from your experiences?

(Probe: How can the RWE system be improved? At what stage do you think RWE system can be improved, for example, data selection, data collection, data analysis, and knowledge translation? Would you use RWE again, If so, why or why not?)

IV. RWE Framework

Appendix to: Clausen M, Mighton C, Kiflen R, et al. Use of real-world evidence in cancer drug funding decisions in Canada: a qualitative study of stakeholders' perspectives. *CMAJ Open* 2020. doi: 10.9778/cmajo.20200118.

***Objective**: The goal of this section is to gain stakeholders' opinions on the framework for the incorporation of RWE into Canada drug funding decisions.*

The goal of this research is to get key stakeholders perspectives on RWE. This information will be used to develop a framework to guide the incorporation of RWE in health care decision making for cancer drugs. These next questions ask about your thoughts regarding the development of this framework.

A. Data Uptake

9. What types of data source do you think are or could be valuable for uptake?

(Probe: Data source example: administrative database, hospital, pharmacy and claim data, electrical medical record, etc. Why are those data source valuable? Please explain.)

10. Do you think there should be some general data requirements in the process of RWE uptake?

(Probe: How important is it that RWE is generated from Canadian jurisdiction? In case of data gaps, could RWE from other provinces or countries be useful? Does it matter to you which organization generates the RWE?)

B. Implementation/Incorporation

11. From your perspective, what is the current state of system readiness for the incorporation of RWE in the Canadian health system?

(Probe: What factors limit the healthcare system from pursuing RWE uptake, RWE utilization or knowledge translation? What factors can you think of that may improve the utilization of RWE?)

12. How could RWE be incorporated into the drug funding decisions in general or in Canadian pricing and reimbursement process?

(Probe: At what steps would you like to see RWE generated/used, for example, at the stage of research/pre-regulatory approval/post-approval? How might researchers/government effectively balance RWE with other types of research (e.g., clinical trials)?)

C. Guidance Documents

13. Is a guidance document for the use of RWE in supporting drug funding decisions desirable and feasible?

(Probe: What is the potential scope of the guidance document? Where are these accompanying guidance most needed and least needed?)

D. Personnel

14. Who do you think should be involved in this initiative?

(Probe: Who needs to be involved at all stages (Development, testing, implementation, uptake, KT) for this initiative to be successful? Which agencies/organizations are necessary or do you think would benefit the most from RWE work?)

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E. Expectations of Utility and Purpose

15. What kind of healthcare issues could RWE address when RWE is incorporated into Canada drug funding decisions?

(Probes: In what way could RWE: 1) refine/inform/revisit drug/technology funding decisions (Streamline/hinder drug approval); 2) reduce gaps in the cancer drug funding process & needs of the recommendation/decision-makers: Funding decisions 3) assess drug treatment effectiveness; 4) Address increases in drug prices)

16. What do you see as risks and benefits to the Canada healthcare system to incorporate RWE into drug funding decisions?

17. From your perspective, what will you do to maximize the impact of RWE in the decision-making process?

(Probe: Do you think there are any incentives for researchers/decision makers/industry to adopt RWE?)

V. Closing

18. Thank you for your time, do you have any other thoughts you would like to share with us?

Turn off recorder

19. Can you recommend someone you think it would be important for us to talk to about Real world evidence?

Question Set II – For patients/patient representatives

Instructions for interview: Some interviewees will have a good knowledge of RWE while others may not. The beginning of the interview may require a more in-depth discussion of RWE and how it works. Please take the time to describe RWE to the interviewee and answer their questions.

I. Perspective on RWE

Objective: The goal of this section is to assess the patient's (or patient representatives) current level of understanding of RWE.

1. What are your thoughts about of RWE and its use in decision making.?

(Probe: What is your first thought about RWE? Do you have any past experiences with RWE? If you do not know what is RWE, what aspects of RWE system are important to you (E.g., some vital information such as the ownership of patients' data after consent, RWE data standards, data oversight mechanism and privacy measures)?

2. From your perspective, how would RWE change patients' medical experiences?

(Probe: what kinds of change would RWE bring to the medical experiences? Do you think RWE can improve the medical experience?)

3. **What do you think should be considered in creating framework for use if RWE in cancer drug funding decision?** (Who should be involved, what potential impact would this have on patients, what might patients be most concerned with).

III. Expectations

Objective: The goal of this section is to gain knowledge in patients' (or patient representatives) expectations in the establishment of the future RWE system and what RWE could bring to the society.

4. From a patient perspective, do you think there will be any benefits and risks associated with RWE in Canadian healthcare system?

(Probe: After the implementation of RWE, do you think patients will be provided with better-informed health services? Do you think clinical practices can be improved by incorporating RWE? Can you think of any risks associated with the implementation of RWE?)

5. Can you think of any factors that may encourage you adopting/accepting RWE? Or are there any factors that prevent you from trusting RWE?

(Probe: Do you think the incorporation of RWE into health service evaluation will improve physicians' clinical practices? Do you think RWE provides you with more treatment options for comparison? Do you think RWE provides convenience for you to check the coverage of drug products/treatments and associating reimbursement?

III. Data Confidentiality and Consent

Objective: The goal of this section is to know about patient's (or patient representatives) view on the confidentiality of personal health information and the privacy consent of personal medical information disclosure.

6. To what extent should patients be willing medical information for research/decision making purpose? .

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(Probe: What kind of personal medical information would you be willing to authorize for RWE research? If you are not willing to share your medical information, what concerns do you have that stop you from sharing the information?)

7. In your opinion, who would have the right to access/use patients' medical information and why?

(Probe: This may include researchers/physicians/government/insurance companies/drug companies/etc.)

8. What is your preference for the medical information disclosure policy of RWE system? How would patients give their permission to healthcare professionals to allow them using patients' medical information for studying RWE?

(Probe: Patient Permission Type may include: 1) No Permission Needed; 2) Assume Permission but with opt-out option; 3) Ask for Permission; 4) No permission for RWE research)

IV. Closing

9. Thank you for your time, do you have any other thoughts you would like to share with us?

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