# Checklist for Reporting Real-World Evidence

CADTH's *checklist for reporting real-world evidence* can be used as a tool to ensure submissions adhere to *Guidance for Reporting Real-World Evidence*. The guidance was written in a manner that allows for flexibility in its use for a variety of real-world evidence (RWE) applications. As such, some recommendations in the checklist will not apply to all RWE studies. This checklist is not intended to replace a careful review of the guidance, which contains critical information needed to develop adequate reporting.

| Section | Checklist item | Reported on page number(s) | If not reported or not applicable, justify why |
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| Section 1: Study design and research questions | 1. Report a clearly stated aim and study question. | | |
| | 2. Report the overall study design. | | |
| | 3. Provide a rationale for the choice of study design. | | |
| | 4. Provide a relevant review of the literature to evaluate pertinent information and gaps in knowledge. | | |
| | 5. Describe key elements of the study design (e.g., matching). | | |
| | 6. Consider the use of study diagrams to illustrate key aspects of the study design. | | |
| | 7. Strongly recommend to develop and reference an a priori protocol. | | |
| | 8. Describe all study team members, including the role of patient partners, and any conflicts of interest. | | |
| | 9. Describe the study governance structure, especially who was responsible for final decision-making. | | |
| | 10. Report any research ethics approval (or equivalent). | | |
| | 11. Disclose sources of funding. | | |
| Section 2: Setting and context | 1. Describe important information to contextualize the data source, including: | | |
| | 1.1. type of care setting | | |
| | 1.2. geographical location. | | |
| | 2. Describe all relevant study period dates, including periods of recruitment, exposure, follow-up, and data collection. | | |
| | 3. Clearly identify missing data components in the data collection. | | |

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| | 4. For studies that propose the use of a data source from a country other than Canada, provide: | | |
| | 4.1. a rationale for selecting the data source | | |
| | 4.2. an explanation of how these factors might affect the generalizability of the study results to the population in Canada | | |
| | 4.3. background information about the health care system | | |
| | 4.4. a description of prescribing and utilization practices | | |
| | 4.5. information on the use and market availability of the intervention and comparators of interest throughout the study period. | | |
| Section 3: Data specifications — access, cleaning methods, and linkage | 1. Describe the extent to which the investigators had access to the database population used to create the study population and major aspects of data provenance. | | |
| | 2. Provide information on the data-cleaning methods used in the study. Share any data-cleaning code leveraged. If not provided, justify. | | |
| | 3. Report whether data were organized by a Common Data Model structure. | | |
| | 4. Describe the usage of data and consent for data sharing. Provide consent documents, if relevant. | | |
| | 5. Describe data collection methods. | | |
| | 6. Quality of the data and relevant metrics to assess the data quality should be reported. | | |
| | 7. Describe any variability between data sources and the impact of changes over time in the data. | | |
| | 8. Describe if any data linkage was conducted and the methods used for the linkage. | | |

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| | 9. Report who (e.g., which organization) performed the data linkage, if applicable. | | |
| | 10. Describe the performance characteristics of the data linkage and the number of individuals linked at each stage of linkage. | | |
| Section 4: Data sources, data dictionary, and variables | 1. Provide and describe all data sources, including the specific version and date of the last update of the database. | | |
| | 2. Describe the characteristics of the health setting and context of data collection. | | |
| | 3. Describe details of data continuity and completeness. | | |
| | 4. Include the names, dates, and/or version numbers of when data were extracted for research use by the data vendor or organization. | | |
| | 5. Include the search and/or extraction criteria applied if the source data are a subset of the data from the vendor or organization, and provide calendar date ranges. | | |
| | 6. Provide source(s) of data for each variable of interest. | | |
| | 7. Describe how variables of interest were measured and if they have been adjudicated or validated in the population of interest. | | |
| | 8. Provide a data dictionary that includes information on data sources, validity, and definitions for all variables, as applicable. | | |
| | 9. Specify definitions and lookback windows for all variables. | | |
| | 10. Report whether any variables could be time-varying (e.g., how the variable could change over time and when it was redefined in relation to time-varying exposures). | | |

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| | 11. Report important variables that could not be captured and their anticipated impact on study results. | | |
| | 12. Provide information on deviations from the a priori protocol in variable measurement. | | |
| Section 5: Participants | 1. Provide inclusion criteria used to identify the study population. | | |
| | 2. Justify exclusion criteria and how they may affect the overall interpretation of the research. | | |
| | 3. Describe study population characteristics relative to the target population in Canada. | | |
| | 4. Provide all codes or algorithms used to define the inclusion and exclusion criteria, where possible. | | |
| | 5. Specify the time period (e.g., lookback window) over which inclusion and exclusion criteria were assessed. | | |
| | 6. Recommendations for specific study designs: | | |
| | 6.1. For cohort studies, provide details leading to the analyzed cohort, including definitions for exposure groups, cohort entry and end dates, matching criteria, and censoring/follow-up. | | |
| | 6.2. For prospective cohort studies, describe recruitment processes. | | |
| | 6.3. For case-control and case-crossover studies, provide details of case and control ascertainment, the source population for nested studies, sampling methods, and matching criteria. | | |
| | 7. Report the numbers of participants at each stage of the study and reasons for nonparticipation. Consider illustrating this information using a flow diagram. | | |

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| | 8. Provide characteristics of study participants. If not available or feasible, explain why. | | |
| | 9. Indicate missing data for each variable of interest. | | |
| | 10. Compare treatment or exposure groups. | | |
| | 11. Specify the number of participants included in each analysis and the analysis strategy (e.g., per-protocol, ITT) and provide details on the number or proportion of subjects excluded from each analysis, and the reasons for exclusion. | | |
| Section 6: Exposure definitions and comparators | 1. Define the requirements for the exposure definition (e.g., single, multiple, or continuous exposure) and relevant start and stop windows for assessing exposures. | | |
| | 2. Specify the data source(s) from which exposure information was obtained, including validity and any limitations in exposure measurement. | | |
| | 3. Specify the exposure-outcome risk window and discuss how it aligns with the known or anticipated relationship between the exposure and outcome timing. | | |
| | 4. If no comparator was used, justify why not. | | |
| | 5. Define the comparator group(s) (e.g., active comparator, historical comparator). | | |
| | 6. Provide justification for the comparator used, including potential implications on the study findings. | | |
| | 7. Discuss any changes in patterns of use of the exposure and comparator(s) over time and how they may affect the results. Report any methods used to adjust for these changes. | | |

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| | 8. Specify how adaptations to the intervention and/or comparator were permitted and recorded. | | |
| Section 7: Outcomes | 1. Report definitions for all study outcomes (primary, secondary, and exploratory), where possible. | | |
| | 2. Provide a rationale for the outcomes studied and discuss relevant outcomes not included in the study. Consider the use of a core outcome set if one is available for the condition of interest under study. | | |
| | 3. Provide information about the validity of all outcome definitions. | | |
| | 4. Describe whether the timing of the outcome can be accurately measured. | | |
| | 5. Specify whether the outcome studied is a surrogate measure of a clinical (patient-centred) outcome and, if so, the strength of the relationship between the surrogate outcome and major clinical outcome(s) of interest. | | |
| | 6. Discuss whether outcome misclassification could occur between treatment groups. | | |
| | 7. Report whether a control outcome was used and justify the control outcome(s) selected. | | |
| Section 8: Bias, confounding, and effect modifiers or subgroups effects | 1. Report all procedures used to address potential sources of bias. | | |
| | 2. Specify how potential sources of bias could influence the outcomes of the analyses. | | |
| | 3. Specify variables that were considered known or potential confounders in the analysis. | | |
| | 4. Describe how confounder variables were selected and if they were informed by a causal diagram. | | |
| | 5. Describe and compare the distribution of measured baseline confounding variables between treatment groups. | | |

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| | 6. Report whether any potential confounders could not be measured and specify the anticipated impact of these confounders on study results. | | |
| | 7. Report whether time-varying confounding was considered and, if not, justify why not. | | |
| | 8. Specify the methods used to conduct sensitivity analyses that test key assumptions and limitations of the data and, if no sensitivity analyses were conducted, explain why not. | | |
| | 9. Specify known or potential effect modifiers. | | |
| | 10. Describe any effect modification or subgroup analyses that were conducted and if they were specified a priori. Include if they were identified and conducted based on prespecified rationale such as previous studies or biological rationale. If no effect modification or subgroup analyses were used, justify why they were not needed. | | |
| | 11. If effect modification or subgroup analyses were used, describe the methods and present separate results for each subgroup. | | |
| Section 9: Statistical methods | 1. Indicate the software used for the statistical analysis, including software package, version, and analytic tools employed (e.g., macros). | | |
| | 2. Provide access to the statistical code used or, if the code cannot be shared, explain why not. | | |
| | 3. Report all statistical methods used and justify their selection, including, as applicable: | | |
| | 3.1. all variables included in regression models | | |
| | 3.2. the method of variable selection for regression models | | |

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| | 3.3. methods used to control for confounding | | |
| | 3.4. methods used to account for missing data | | |
| | 3.5. how follow-up time and changes in exposures were handled | | |
| | 3.6. subgroup analyses and effect modification | | |
| | 3.7. as applicable: stratification, propensity score estimation and assumptions, meta-analysis methods, validity of instrumental variables. | | |
| | 4. Quantify the precision of all estimates using confidence intervals. | | |
| | 5. Report the threshold of statistical significance used. | | |
| Section 10: Study findings | 1. Summarize key results (estimated effect measures, measures of precision) with reference to each study objective and/or hypothesis for primary and secondary outcomes, and delineate these results by each treatment or exposure group. | | |
| | 2. Provide numbers of outcome events or summary measures of outcomes (or exposures in case-control studies). | | |
| | 3. Report both absolute and relative effect measures for binary outcomes, including their measure of precision. | | |
| | 4. Report category boundaries when continuous variables are categorized, and consider translating estimates of relative risk into absolute risk. | | |
| | 5. Report unadjusted and adjusted estimates, including their measure of precision and confounders used for adjustment. | | |
| | 6. Report other prespecified analyses conducted (e.g., subgroup analyses, interactions, sensitivity analyses). | | |

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| | 7. Describe any unplanned analyses performed secondarily (not defined a priori) and indicate these as exploratory. | | |
| | 8. Avoid selective reporting of results. | | |
| Section 11: Interpretation and generalizability | 1. Provide an interpretation of the primary and secondary study results, as applicable. | | |
| | 2. Interpret the findings from adjusted and unadjusted results, as applicable. | | |
| | 3. Discuss the precision of the effect measure(s). | | |
| | 4. Discuss how potential biases and sensitivity of study assumptions may impact the results and subsequent interpretation. | | |
| | 5. Discuss the implication of findings for clinical practice, including the risk-benefit profile of the treatment, if applicable. | | |
| | 6. Interpret study findings in relation to current literature. | | |
| | 7. Discuss the generalizability (external validity) of study results to the population in Canada. | | |
| Section 12: Limitations | 1. Provide a consideration of limitations of the study, including the data source, missing data, bias and confounding, imprecision or sample size limitations, and whether results are clinically meaningful. | | |
| | 2. Discuss the plausibility of results and whether results could be due solely to bias, chance, or confounding. | | |

**Reference:** *Guidance for Reporting Real-World Evidence*. Ottawa: CADTH; 2023.