

# Real-World Evidence on the Rise: Evaluating the Use of Real-World Evidence in ICER Assessments of Comparative Clinical Effectiveness

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## Objectives

- To evaluate the use of real-world evidence in published Institute for Clinical and Economic Review (ICER) assessments of pharmacological interventions.

## Background

- ICER is an independent research organization that objectively evaluates the clinical and economic value of prescription drugs and other healthcare innovations.<sup>1</sup>
- Real-world evidence (RWE) refers to observational data obtained outside the context of randomized controlled trials and generated within routine clinical practice.<sup>2</sup>
- Inclusion of RWE when evaluating the value of a pharmacological intervention often provides additional data on the effect of the intervention both in a wider and more representative population than a clinical trial, and often over a longer time period.

## Methods

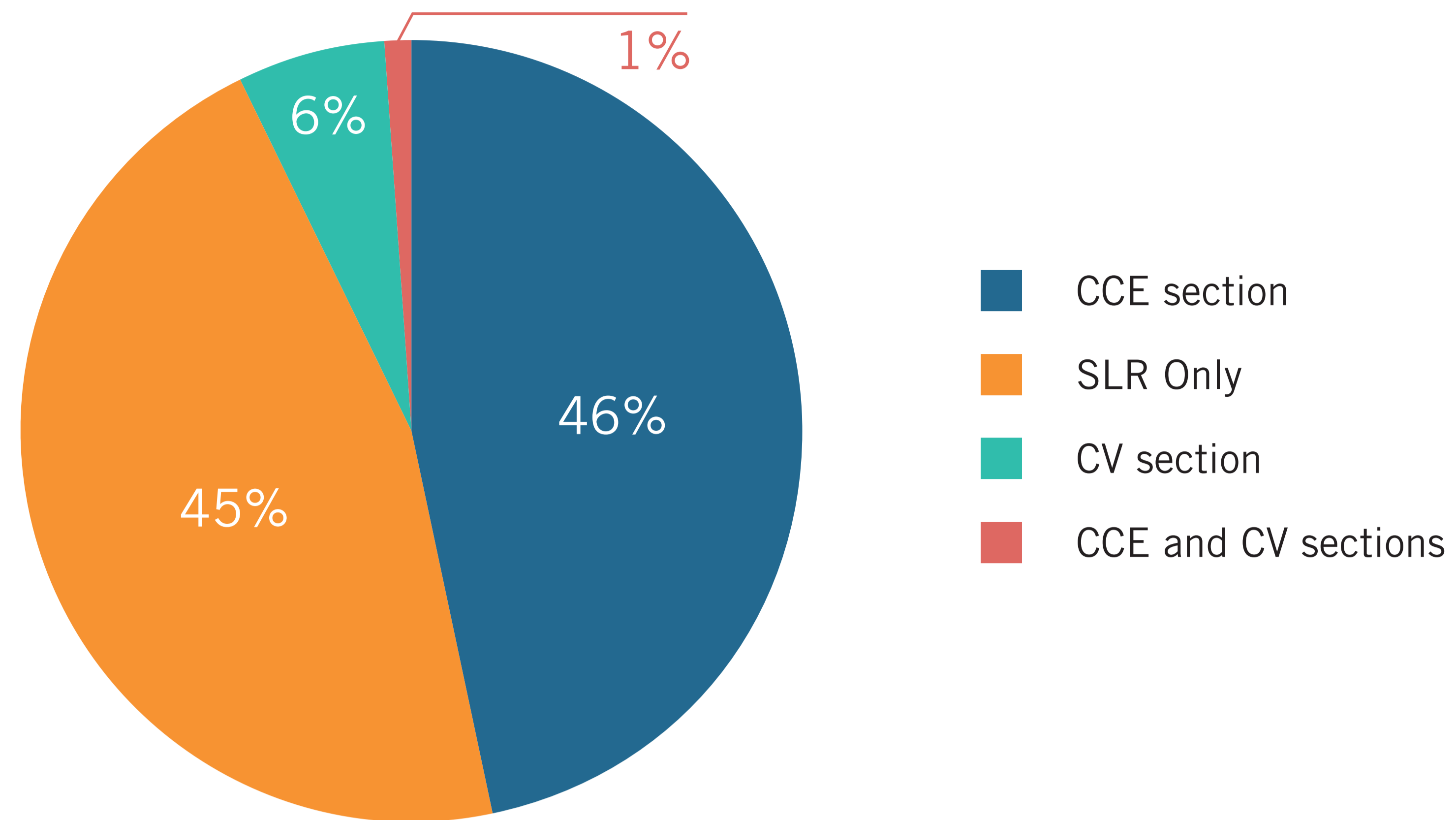
- The ICER website was searched in November 2018; all past assessments that reviewed pharmacological interventions and were published from 2014 onwards were included in this review.
- The Final Evidence Report of each assessment was reviewed to determine whether RWE had been identified in the systematic literature review (SLR) and used in the evaluation of Comparative Clinical Effectiveness (CCE) section of the report.
- Study details of RWE included in each assessment, including publication date and study design, were extracted by a single reviewer.

## Results

### Inclusion and Use of RWE Studies

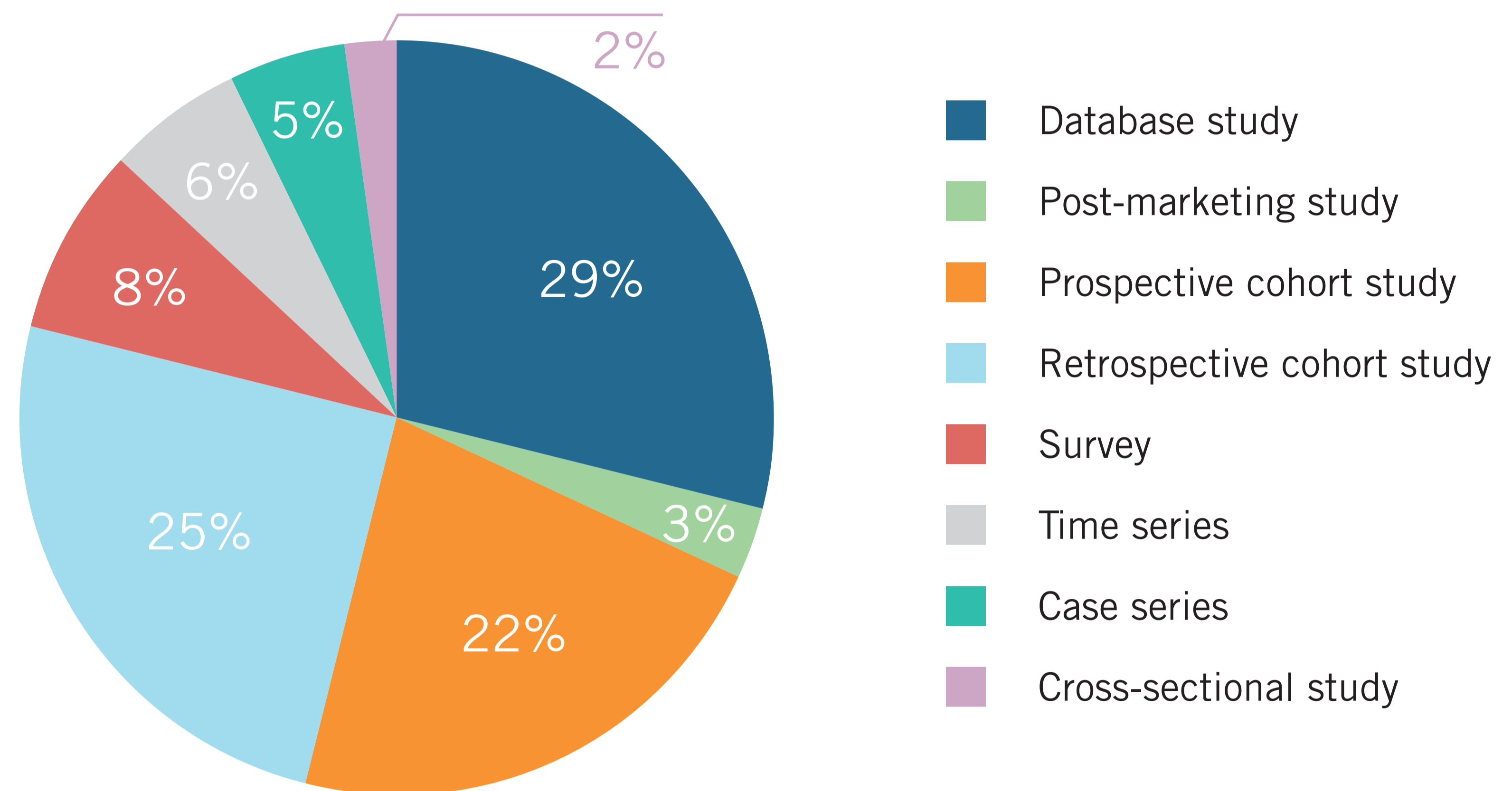
- Of the 27 assessments published since 2014, 15 identified RWE studies in the SLR, and 12 of these included RWE in the assessment of CCE.
- Across all RWE studies identified in assessments (N=93), RWE studies were more frequently referenced or discussed in the CCE section (46%), compared to the Comparative Value (CV) (6%), and only one study (1%) was included in both (Figure 1). A relatively high proportion of RWE studies (45%) were not, however, referenced or discussed as part of the Final Evidence Report, beyond their inclusion as a relevant study from the SLR.

Figure 1 | Use of RWE studies in ICER assessments



The section in which each RWE study (N=93) was referenced or discussed in ICER assessments was evaluated. RWE studies were observed to be referenced or discussed in either the CCE section alone, the CV section alone, both or neither (listed as an included study in the section detailing the SLR results only), as shown above. CCE: comparative clinical effectiveness; CV: comparative value; ICER: Institute for Clinical and Economic Review; RWE: real-world evidence; SLR: systematic literature review.

Figure 2 | Design of RWE studies included in ICER assessments



RWE studies included in ICER assessments (N=93) were broadly categorized into 8 types of study design, based on descriptions used in the ICER assessments or evaluation of study abstracts by the reviewer. ICER: Institute for Clinical and Economic Review; RWE: real-world evidence.

- Of the 12 assessments that did not identify RWE studies, 2 actively excluded RWE and only included randomized controlled trials.

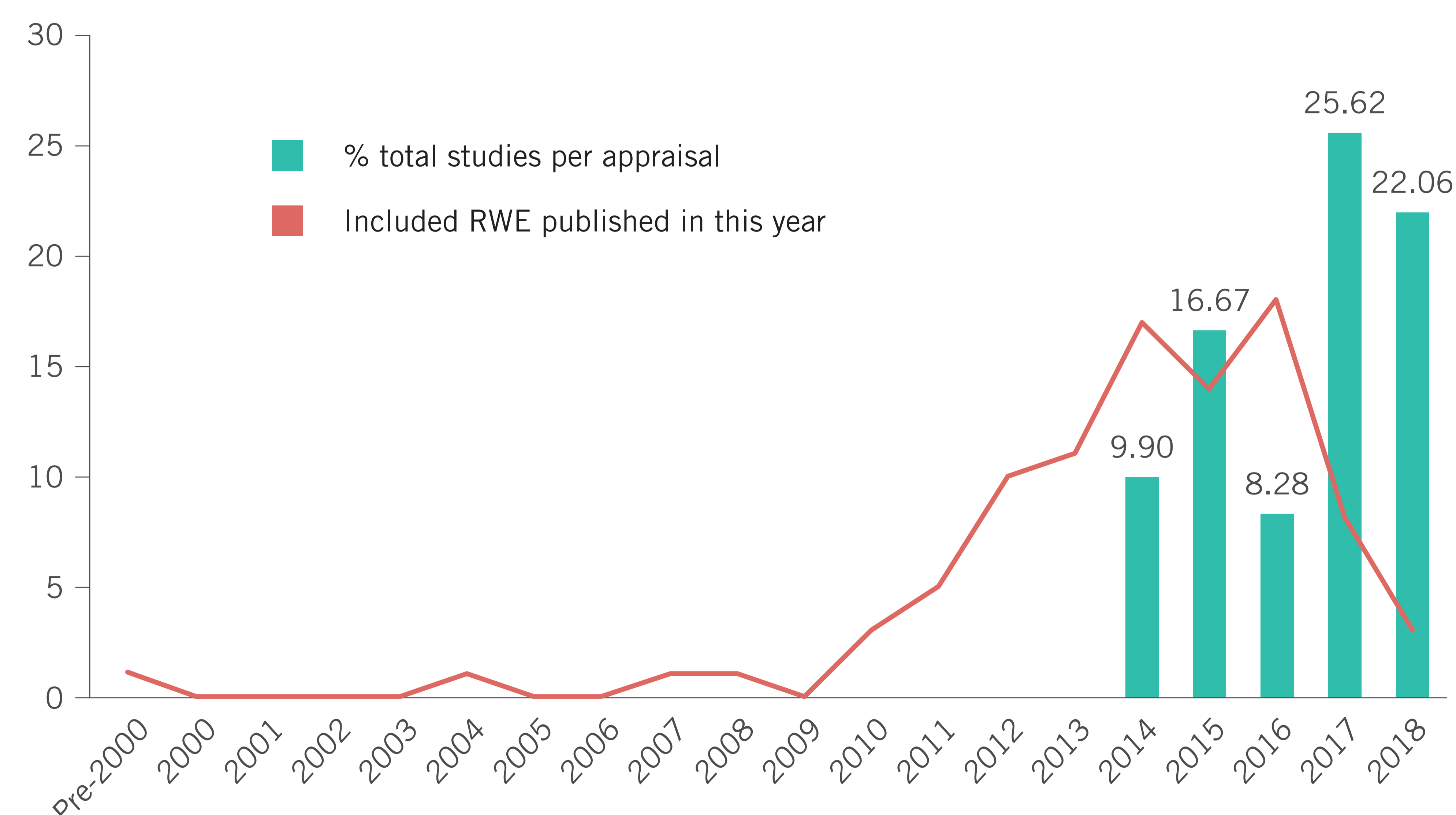
### Design of RWE Studies

- Across the 15 assessments that identified RWE in the SLR, database studies were the most frequently cited study design (29%), followed by retrospective cohort (25%) and prospective cohort studies (22%) (Figure 2).
- Of those RWE studies that reported a funding source (N=63), 58% were industry sponsored.

### Inclusion of RWE Over Time

- The majority of RWE studies identified in the ICER SLRs (86%) were published in or after 2012, with almost no studies published before 2008 (Figure 3).
- The average number of RWE studies included in ICER assessments, as a proportion of all included studies, also increased over time (9.90% in 2014 and >20% in both 2017 and 2018) (Figure 3).
- For the assessments of hepatitis C and migraine, both of which were reassessed by ICER, the more recent assessment contained an increased proportion of RWE studies compared to the original (hepatitis C, 0% increased to 1.9%; migraine, 0% increased to 3.3%).

Figure 3 | Rising inclusion and incidence of RWE studies



For ICER assessments (N=15) published in each year, the average number of RWE studies included in the ICER assessments of CCE, as a proportion of all included studies is shown (see bars and data labels), in addition to the date of publication for each RWE study (N=93; see line). CCE: comparative clinical effectiveness; ICER: Institute for Clinical and Economic Review; RWE: real-world evidence.

## Conclusions

- In ICER assessments, RWE studies are most commonly being used to inform judgements on CCE with fewer RWE studies being used in assessments of CV.
- Varied RWE study designs have informed ICER assessments, and the inclusion of RWE studies in ICER assessments has increased over recent years. This increase is likely a reflection of the increased availability of published RWE.

The abstract reported that 26 assessments were published since 2014 and 11 of these assessments did not identify RWE studies in their SLR; this has been corrected in this poster to 27 assessments and 12 studies, respectively.

## References

- ICER. About. Available at: <https://icer-review.org/about/> [Last accessed: March 12, 2019];
- Suvarna VR. Real world evidence (RWE) - Are we (RWE) ready? *Perspect Clin Res* 2018;9:61-63.

## Acknowledgements

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