"Real-World" Evidence for Drugs and Devices: 2017 Literature Reviewed

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BACKGROUND

- The term real-world evidence (RWE) has become increasingly common in recent years.
- There is little known about what constitutes RWE in published literature and whether RWE is similar across therapeutic interventions such as drugs and devices.

OBJECTIVE

- Evaluate the use of RWE in 2017 publications overall and for drugs and devices separately

METHODS

- A review of English-language 2017 titles and abstracts in PubMed and Embase was performed. The search was broad and limited to the term "real world." Titles and abstracts were reviewed, with the assumption that high-level study design should be adequately captured within the abstract of a peer-reviewed publication.
- The following were extracted based on information in the title/abstract: therapeutic area, exposure type, study design, primary outcome, timing of outcome, country, and data source.
- Descriptive analyses were performed.

RESULTS

- There were 1,045 hits for real-world publications in 2017.
  - Of these, 315 were excluded because they lacked an abstract (n = 93) or were not related to provision of health care (n = 222); 730 remained in the analysis.
- Overall, most studies were retrospective (67%) versus prospective (31%); 67% evaluated outcomes of a drug, and 15% evaluated devices (Figure 3).
- In total, 44% of countries reported data for drugs only, 44% presented data on both drugs and devices, 3% reported devices only, and 6% reported other outcomes (e.g., behavioral) (Figure 1).
- Of the 488 RWE studies reporting data related to drugs:
  - Most were retrospective (72%) versus prospective (26%), with 2% not reported.
  - Nearly half (48%) used an existing data source (medical records [34%] or administrative/ pharmacy data [14%]), and 23% utilized primary data collection (Figure 2).
  - The majority of studies evaluated efficacy (56%) or treatment patterns (13%).
- By comparison, among the 108 RWE studies reporting data related to devices:
  - They split between retrospective (52%) and prospective (47%), with 1% not reported.
  - 36% used an existing data source (medical records [31%] or claims [5%]), 34% utilized primary data collection, and 17% used registries (Figure 4).
  - Most evaluated efficacy (53%) or safety (19%).
- Drug studies tended to focus on longer-term outcomes (5% ≤ 30 days). Device studies assessed shorter-term outcomes more often than drug studies (19% ≤ 30 days) (Figure 5).
- More drug studies focused in 1 of 4 therapeutic areas (oncology [22%], infectious disease [20%], cardiovascular [15%], or metabolic [10%]). Most device studies were focused on the cardiovascular therapeutic area (63%) (Figure 6).

Figure 1. Real-World Data Around the Globe by Intervention Type

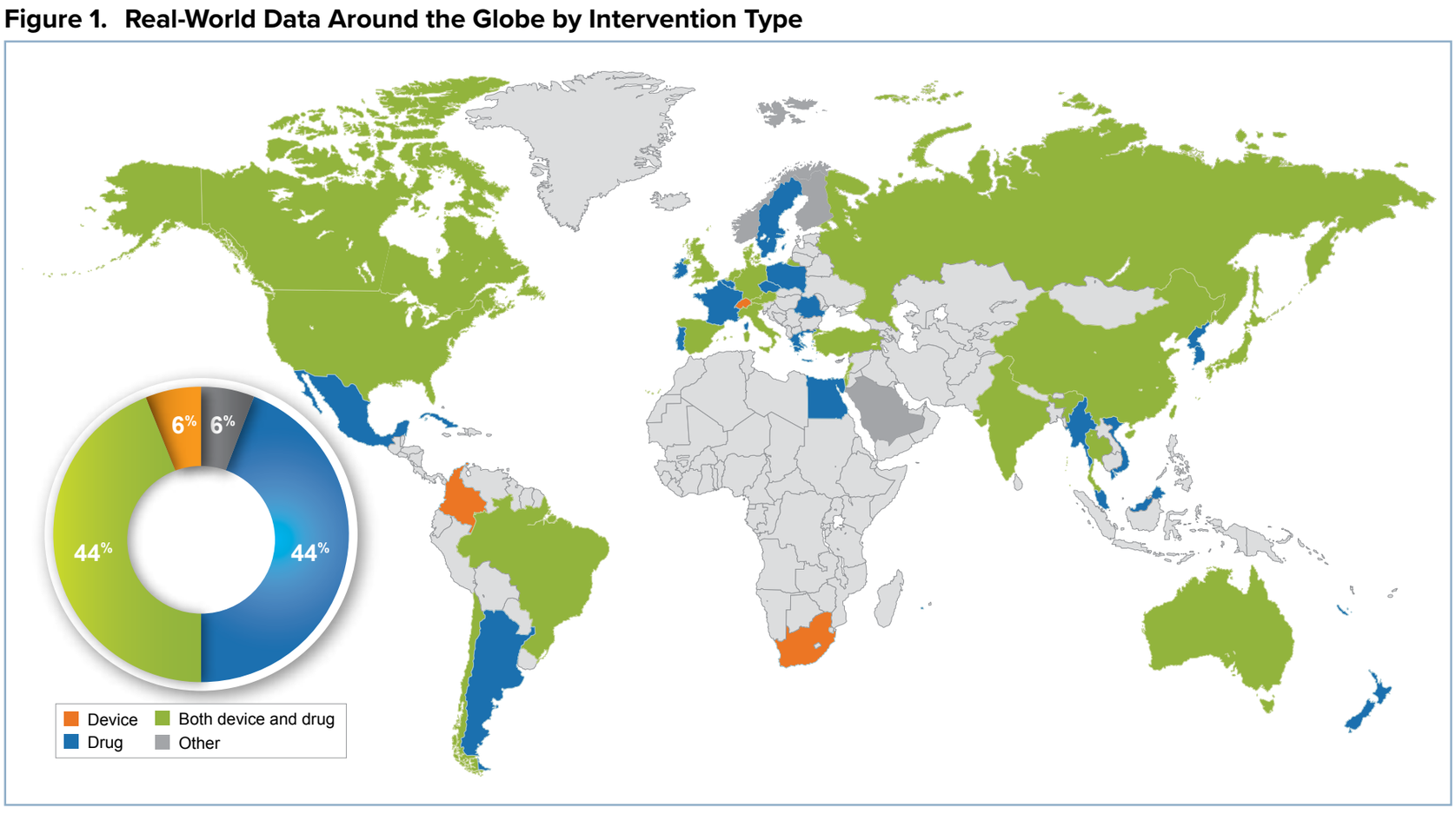


Figure 2. Data Sources in Drug Studies

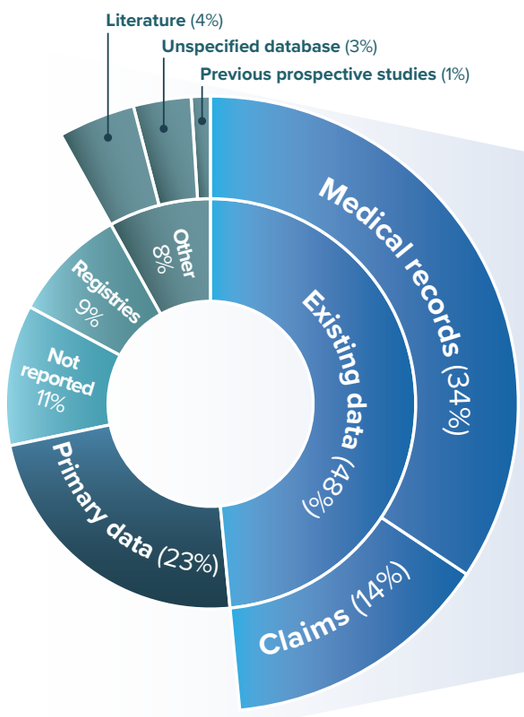
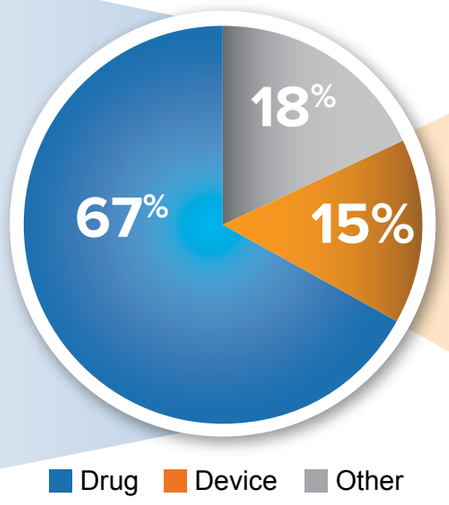


Figure 3. Exposure Type, Overall



Note: Examples of other exposure types include behavioral interventions, procedures without devices, and biomarkers.

Figure 4. Data Sources in Device Studies

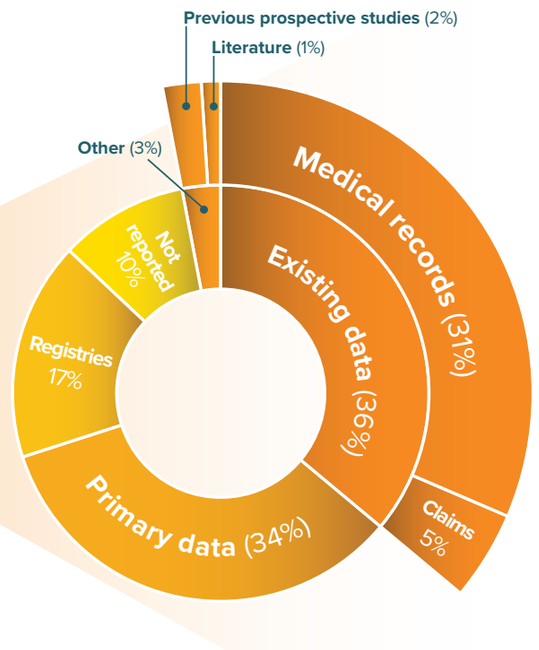
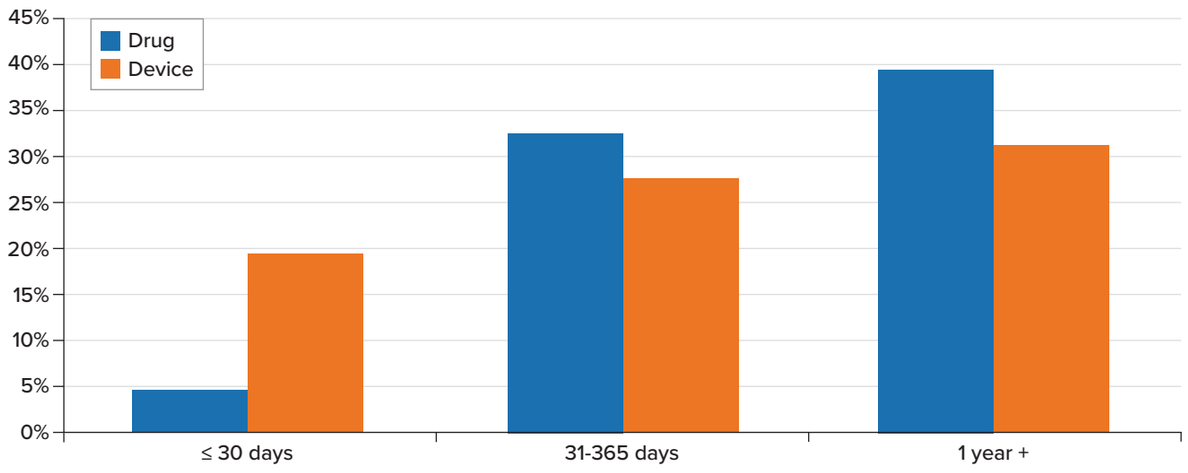
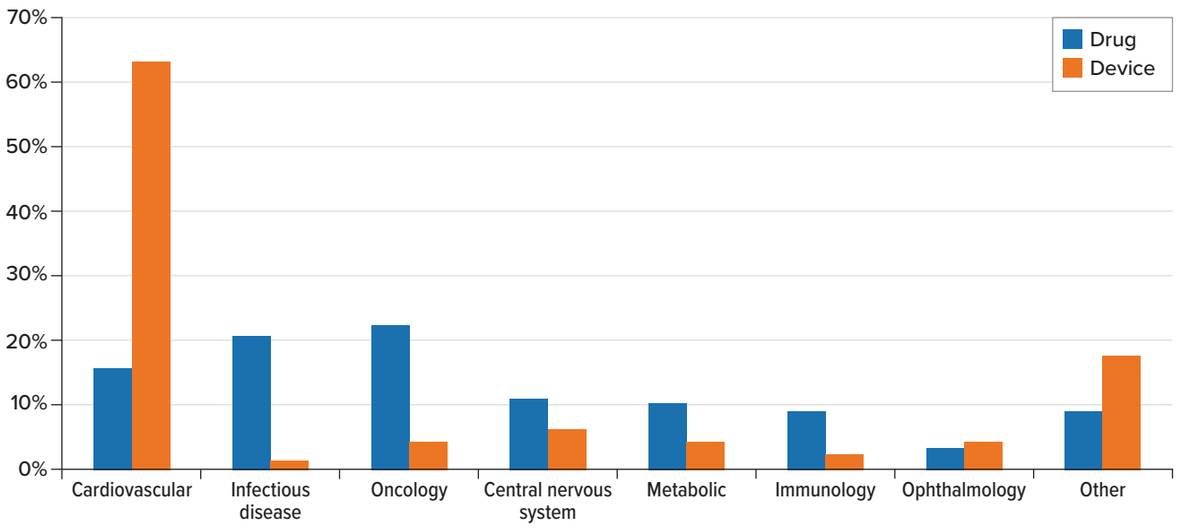


Figure 5. Exposure Periods, Drug vs. Device Studies



Note: 23% of drug studies and 21% of device studies did not report exposure periods.

Figure 6. Therapeutic Areas, Drug vs. Device Studies



Note: Other therapeutic areas include nephrology, radiology, respiratory, dermatology, diagnostic, general health, hematology, genitourinary system, musculoskeletal, neurology, psychology, women's health, hormonal, and gastrointestinal.

DISCUSSION

- Registries and prospective data collection were used more frequently for device studies than for drug studies.
- As expected, more device studies were published for cardiovascular conditions; drug studies were seen more frequently for infectious disease and oncology.
- Exposures were assessed over a shorter time period in device studies and across longer time periods in drug studies.

CONCLUSIONS

- In 2017, the published literature on RWE studies reported using a wide variety of outcomes and methods, with important differences between drugs and devices. Efforts to standardize reporting of RWE studies should cover this breadth and apply across therapeutic interventions.

REFERENCES

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