Getting Real About EHR Data

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Real-World Data

Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources (e.g., registries, wearables, EHRs, etc.)

Real-World Evidence

Clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.

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Health System Uses of EHR Data to Inform Patient Care Delivery

- Survey of n=16 respondents across a nationally representative sample of US health systems (survey conducted in 2022)
- All respondents (n= 20) reported using an EHR
  - Epic (n = 19; 95%)
  - Cerner (n = 4; 20%)
  - MEDITECH (n = 3; 15%)
  - Allscripts (n = 3; 15)
  - GE Healthcare (n = 2; 10%)
  - EClinicalWorks (n = 2; 10%)
  - athenahealth (n = 1; 5%)

Supporting diagnostic and therapeutic decision making	100%
Accessing and documenting patient information	100%
Accessing and using clinical support tools	88%
Providing clinical alerts and reminders to patients	88%
Prescribing treatments and follow-up regimes	88%
Communicating with colleagues about matters related to patient care	88%
Accessing or creating aggregated information about patient outcomes	81%
Distributing and/or obtaining questionnaires or measures	69%
Accessing and searching medical literature	56%
Obtaining feedback about care experiences from patients	38%

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Operationalizing EHR-Sourced Data for Quality, Relevancy, and Reliability

Generate actionable recommendations for stakeholders to improve the quality, relevancy, and reliability of data found in EHRs.
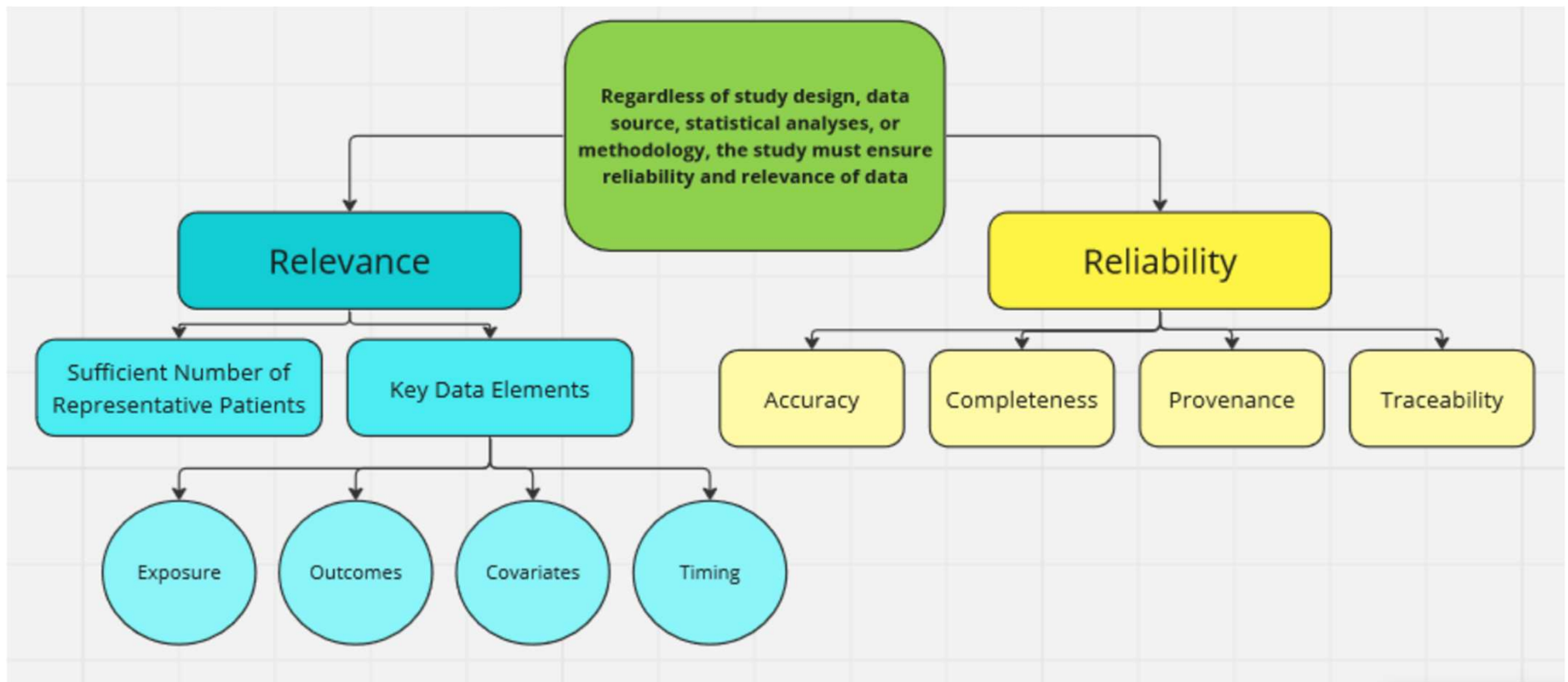
Operationalizing EHR-Sourced Data for Quality, Relevancy, and Reliability, cont.

- Structured text (e.g., ICD-10 codes)
- Unstructured/free text (e.g., clinical notes)
- PGHD uploaded through patient portals
- Lab data uploaded as pdfs
- Pharmacy data included in the EHR

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- **Quality:** Accurate, complete, well-sourced, etc.
- **Relevancy:** Useful for the question and generalizable
- **Reliability:** Represents what it claims to represent

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How does FDA determine if data are fit-for-purpose?

Regardless of study design, data source, statistical analyses, or methodology, the study must ensure reliability and relevance of data

Relevance
- Sufficient Number of Representative Patients
- Key Data Elements
  - Exposure
  - Outcomes
  - Covariates
  - Timing

Reliability
- Accuracy
- Completeness
- Provenance
- Traceability

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Challenges with EHR-Sourced Data

- EHRs are not a monolith. All considerations/recommendations are **context dependent.**

    - There is great **heterogeneity** in how data is collected and processed even within a single health system site.

- **Context lost** and **bias introduced** along the EHR data life cycle of source data, curated data, transformed data, and analytic dataset.

    - Lack of **standards** and lack of **data expertise** across stakeholders.

- The entire patient journey is not captured.

General Considerations

- EHRs were/are designed for billing and patient care management

- Mostly generated at the point-of-care by overburdened physicians who want clinically relevant information.

- Aggregated EHR datasets is often curated and transformed by engineers who don't have a health care research background.

- FDA wants to ensure EHR data are of sufficient quality, reliability, and relevancy to inform decisions regarding the safety and efficacy of medical products.

Thank You!

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