ComparativeEvidence FHIR Resource Proposal

Comprehensive Evidence

1.1 Owning work group name

Clinical Decision Support

1.2 Committee Approval Date:

Initial PSS for EBMonFHIR project: June 22, 2018 Resource Approval by CDS WG: May 7, 2019

1.3 Contributing or Reviewing Work Groups

Clinical Quality Information Biomedical Research and Regulation

1.4 FHIR Resource Development Project Insight ID

1422

1.5 Scope of coverage

The scope of the ComparativeEvidence resource is to describe the statistics comparing two or exposure states.

A common type of statistic that will be reported is an effect estimate characterizing the estimate of an effect of an exposure (often a therapeutic intervention) compared to an alternative exposure (often not receiving the therapeutic intervention) on a measured variable (often a health outcome) in a group (often a population of people with specific characteristics).

Expressing effect estimates and other comparative evidence reports is done throughout reporting of biomedical research, systematic reviews, and clinical reference across all disciplines.

1.6 RIM scope

1.7 Resource appropriateness

1.8 Expected implementations

1.9 Content sources

1.10 Example Scenarios

1.11 Resource Relationships

1.12 Resource Boundaries

1.13 Timelines

1.14 gForge Users

1.15 When Resource Proposal Is Complete

1.16 FMG Notes
Across the evidence-based medicine community (hundreds of thousands of people communicating the results of healthcare research through original research and systematic reviews and expressing the findings from a body of evidence), the summary of findings (summary of effect estimates synthesized from a body of evidence) is the primary method of expressing quantitative results. Standardization is necessary to support interoperability across the evidence-based medicine domain.

Expected implementations

Many knowledge producers who express the biomedical research community knowledge will be the implementers using this resource. Examples of these knowledge producers include Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Cochrane, Duodecim Medical Publications Ltd (from the Finnish Medical Society), EBSCO Health, MAGIC (stands for Making GRADE the Irresistible Choice), and numerous guideline development organizations.

Content sources

None expected beyond the standard source specifications. However, the method for expressing citations (eg referring to a publication) is not yet defined and may require additional source specifications.

Example Scenarios

A systematic review and meta-analysis combines 17 trials comparing Superdrug against Placebo in 12,356 study participants with Stressitis and finds that Superdrug reduces the Stressiness Score by a mean of 4.6 points but increases headache by 50% (ie 4% of people taking Placebo and 6% of people taking Superdrug had a headache).

The effect estimates that may be reported from this example include:

- Mean reduction of 4.6 points in a score
- Relative risk increase of 50% (or risk ratio 1.5) for the risk of headache
- Absolute risk increase of 2% (or risk difference 0.02) for the risk of headache

The ComparativeEvidence resource describes:

- descriptions of the population (eg Stressitis), exposure (eg Superdrug), alternative exposure (eg Placebo), and outcome (eg, Stressiness Score, or risk of headache) that the effect estimates are about
- the statistics for these effect estimates where statistic datatype can include classification of the statistic type, sample size for the statistic, quantity of the statistic, a precision estimate (such as a 95% confidence interval), and ratings of the certainty of the statistic descriptions of the source of the effect estimates (eg author, citation, type of research)

Resource Relationships

The ComparativeEvidence Resource will reference Group Resource (to describe intended and actual population cohorts) and EvidenceVariable Resource (to describe exposures and measured variables)

Resource Boundaries

To be determined if implementers have questions that need explanations to support distinction and clarification. ComparativeEvidence will describe comparative statistics where one measured variable is analyzed with multiple exposures. A similarly structured resource (CohortSummary) will describe association statistics where multiple measured variables are analyzed with one exposure. The ComparativeEvidence and CohortSummary resources are purposefully created as separate resources to simplify the compound nesting relationships of exposures and measured variables for classifying statistics.

Timelines

First STU Ballot 2019 September

When Resource Proposal Is Complete

When you have completed your proposal, please send an email to FMGcontact@HL7.org