RiskEvidenceSynthesis FHIR Resource Proposal

Owning work group name

Clinical_Decision_Support

Committee Approval Date:

- Initial PSS: June 22, 2018
- CDS WG: September 12, 2018

Contributing or Reviewing Work Groups

- Clinical Decision Support
- Clinical Quality Information
- Biomedical Research and Regulation

FHIR Resource Development Project Insight ID

1422

Scope of coverage

The scope of the RiskEvidenceSynthesis resource is to describe the likelihood of an outcome in a population with an exposure where the risk estimate is derived from the combination of research studies. Risk estimates are not effects and do not represent a difference between exposure states.

Expressing risk estimates is done throughout reporting of biomedical research, systematic reviews, and clinical reference across all disciplines.

Risk estimates as a “synthesis” of research studies is a different concept for risk estimation than risk estimates for an individual person.

RIM scope

Resource appropriateness

Across the evidence-based medicine community (hundreds of thousands of people communicating the results of healthcare research through systematic reviews and expressing the findings from a body of evidence), the risk estimate 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[edit | edit source]

Many knowledge producers who express the biomedical research community knowledge will be the implementers using this resources. 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[edit | edit source]

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

Example Scenarios[edit | edit source]

EXAMPLE 1 IN THE CONTEXT OF SUPPORTING AN EFFECT ESTIMATE SYNTHESIS

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% (i.e., 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 risk estimates that may be reported could include:

- with Superdrug – mean Stressiness score of 13.2, and risk of headache of 6%
- with Placebo – mean Stressiness score of 17.8, and risk of headache of 4%

The RiskEvidenceSynthesis resource describes:

- the point estimate for the risk or specific value with one exposure (without comparison to or difference from an alternative exposure)
- classification of the risk type (continuous or dichotomous, mean, median, proportion, etc.)
- a precision estimate (such as 95% confidence intervals)
- rating of certainty of the risk estimate
- descriptions of the population (e.g., Stressitis), exposure (e.g., Superdrug or Placebo), and outcome (e.g., Stressiness Score, or risk of headache) that the risk estimate is about
- descriptions of the source of the risk estimate (e.g., author, citation, type of research, sample size)

EXAMPLE 2 IN THE CONTEXT OF RISK ESTIMATE AS PRIMARY FOCUS

A systematic review and meta-analysis combines 13 studies reporting the risk of Tuberculosis in people with HIV Infection who are exposed to Homelessness. The focus is determining the risk (e.g., is this a high-risk group for screening?) rather than the measure of the effect of homelessness.

Resource Relationships[edit | edit source]

The RiskEvidenceSynthesis resource will reference:

- PicoElementDefinition
- citation (an expected resource for future proposal)

Resource Boundaries[edit | edit source]

To be determined if implementers have questions that need explanations to support distinction and clarification.

EffectEvidenceSynthesis is about the difference (or "effect") between an exposure and alternative exposure state on an outcome in a population. RiskEvidenceSynthesis is about the "risk" of an outcome with an exposure state in a population. RiskEvidenceSynthesis does not include an alternative exposure state of difference between states.

Timelines[edit | edit source]

First STU Ballot 2019 May

gForge Users[edit | edit source]

brynrhodes (github user)

KhalidShahin-EBSCO (github user)
When Resource Proposal Is Complete

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

FMG Notes