BACKGROUND

• Throughout a medical product’s life cycle, decisions about its use are evaluated as a balance between patients’ anticipated benefits and risks.
• Both qualitative and quantitative methodologies have been developed to assess benefit-risk (Table 1); however, reporting of benefit-risk assessments by medical device researchers can often be vague.

Table 1. Benefit-Risk Methodologies Identified by the Innovative Medicines Initiative (IMI) Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) Benefit-Risk Group1

<table>
<thead>
<tr>
<th>Methodology Brief Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive framework</td>
<td>Qualitative or semiquantitative guidelines to conduct benefit-risk assessment</td>
</tr>
<tr>
<td>Quantitative framework</td>
<td>Measuring trade-offs between benefits and risks</td>
</tr>
<tr>
<td>Metric indices</td>
<td>Indicators used to define thresholds (cut points)</td>
</tr>
<tr>
<td>Estimation</td>
<td>Infer benefit-risk trade-offs on metrics, considering evidence, data, and assumptions</td>
</tr>
<tr>
<td>Utility survey</td>
<td>Elicit utilities and preference distributions (not a formal benefit-risk assessment)</td>
</tr>
</tbody>
</table>

OBJECTIVE

• This literature review aimed to evaluate the medical device literature and evaluate how benefit-risk is reported across therapeutic areas.

METHODS

• Using MeSH terms for a broad capture, PubMed was searched for English-language articles published between 2008 and 2017 in which IMI-PROTECT benefit-risk methodologies were employed for medical devices.
• Titles and abstracts were reviewed to identify relevant articles.
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RESULTs

• Most abstracts (n = 44, 76%) used descriptive frameworks; 13 (22%) were quantitative frameworks.

DISCUSSION

• This review of published articles’ abstracts suggests that the term benefit-risk is used broadly across medical device publications, with little context given to methodology.
• Oncology studies most often employed quantitative frameworks.
• CV studies provided more study design information, were more often randomized (vs. nonrandomized) studies, and more often employed descriptive methodologies.

CONCLUSIONS

• The lack of detail included in article abstracts limits clarity regarding which benefit-risk assessment was conducted.
• Differences observed across therapeutic areas further limit interpretation.
• There is a need for improved standardization in reporting benefit-risk assessments for medical devices overall and across therapeutic areas to facilitate readers’ understanding and interpretation of results.

REFERENCES


CONTACT INFORMATION

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Figure 2. Therapeutic Area and Type of Benefit-Risk Analysis Reported or Inferred (Left) and Therapeutic Area and Study Type (Right)

Figure 3. Therapeutic Area and Target Audience

Therapeutic Areas

Predominant therapeutic areas for the 58 selected articles were cardiovascular (CV; 50%) and oncology (55%). Less common other therapeutic areas (OTAs; 40%) included injury/poisoning/procedural complications (n = 4), endocrine disorders (n = 3), eye disorders (n = 3), nervous system disorders (n = 2), respiratory/Thoracic/mediastinal disorders (n = 2), surgical/medical procedures (n = 2), musculoskeletal/Connective tissue disorders (n = 2), gastrointestinal disorders (n = 1), blood/lymphatic system (n = 1), renal/urinary disorders (n = 1), and metabolism/nutrition disorders (n = 1).

Determining Methodology

• Due to the limited details described within the abstracts, benefit-risk methodology (e.g., PmOACT-URL, MCD) had to be inferred for most of the abstracts (91%) or could not be determined (2%).

Figure 1. PRISMA Flow Diagram for Article Screening

Figure 2. Table 2. Specific Frameworks by Therapeutic Area

Table 2. Specific Frameworks by Therapeutic Area

<table>
<thead>
<tr>
<th>Framework</th>
<th>Total</th>
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<th>Oncology</th>
<th>OTAs</th>
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</tr>
</tbody>
</table>

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