日本薬剤疫学会
「日本における傷病名を中心とするレセプト情報から得られる指標のバリデーションに関するタスクフォース」

FDAミニセンチネルFDAのsystematic reviewで使われた検索式

2017年1月10日(火) 18:00～
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臨床疫学研究システム講座
小出 大介
82 Mini-Sentinel's Systematic Reviews of Validated Methods for Identifying Health Outcomes Using Administrative and Claims Data: Methods and Lessons Learned
R. M. Carnahan and K. G. Moores

90 Mini-Sentinel's Systematic Reviews of Validated Methods for Identifying Health Outcomes Using Administrative Data: Summary of Findings and Suggestions for Future Research
R. M. Carnahan
Background

・Health outcomes of interest (HOI)として140種類の候補を以下から選んだ
  ・薬剤疫学の教科書
  ・FDAのSafety Reporting Requirementsのルール
  ・OMOPで実施
・140種類からFDAが20種類を選定し、さらに重複の多いものは1つにして19種類とした（Table 1）
・用いたデータベース
  ・PubMed
  ・Embase
  ・Iowa Drug Information Service（IDIS/Web）
・見つからない時はGoogle Scholar searchを利用
Table 2 検索式 #1
Terms to identify drug adverse event studies and other studies thought likely to contain validation of an outcome measure

Table 2 検索式  #2 前半
Terms to identify administrative and claims database studies from the USA or Canada

Terms to identify administrative and claims database studies from the USA or Canada


Limits: humans, English, publication date from 1 January 1990 to 1 January 2011
Table 2 検索式 #3
Terms to exclude studies not likely to utilize administrative and claims data

Table 2 検索式 #4~#6

4. Combining Searches 1 and 2, excluding Search 3
#1 and #2 not #3

5. Health outcome of interest search terms (specific to outcome)
Details provided in individual articles and reports


例: 心不全(p130): Heart Failure [Mesh]

6. Combining base search with health outcome of interest search terms
#4 and #5

9.
Abstract exclusion criteria

(1) Did not study the HOI
(2) Not an administrative or claims database study. Eligible sources included insurance claims databases and other secondary databases that identify health outcomes using billing codes.
(3) Data source not from the USA or Canada

Each abstract was reviewed independently by two investigators to determine whether the full-text article.

If the reviewers disagreed on whether the full-text should be reviewed, then it was selected for review.
Full-text exclusion criteria

(1) Poorly described HOI identification algorithm that would be difficult to operationalize
(2) No validation of outcome definition or reporting of validity statistics

Full-text articles were reviewed independently by two investigators, ....

If there was disagreement on whether a study should be included, the two reviewers attempted to reach consensus on inclusion by discussion. If the reviewers could not agree, a third investigator was consulted to make the final decision.

- Mini-Sentinel collaborator input
- Clinician or topic-expert consultation
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今後のバリデーション研究の優先度

一般的なPPVの分類

• PPV 70%以上でHigh
• 50%以上～70%未満でModerate
• 50%未満でLowまたはPoor

＜注意＞

• 予測値は対象集団の有病率（Prevalence）に依存する
• 推定値の信頼区間は、サンプルサイズの影響を受ける
• 今後の研究の優先度は、エビデンスの量と一貫性、特定できるか（ability to identify）や調査対象集団などによる
<table>
<thead>
<tr>
<th>アウトカム</th>
<th>論文</th>
<th>優先度</th>
<th>PPV</th>
<th>感度</th>
<th>備考</th>
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<td>Low</td>
<td>&gt;=70%</td>
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<td>IC10</td>
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<td>心房細動</td>
<td>16本</td>
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<td>70〜97%</td>
<td>57〜95%</td>
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<td>5〜100%</td>
<td>77%以上</td>
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