# 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

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# バリデーションの検索式に関するセクション

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

# Table2 検索式 #1

## Terms to identify drug adverse event studies and other studies thought likely to contain validation of an outcome measure

("Pharmaceutical preparations/adverse effects" [Mesh] OR "Pharmaceutical preparations/contraindications" [Mesh] OR "Pharmaceutical preparations/poisoning" [Mesh] OR "Pharmaceutical preparations/therapeutic use" [Mesh] OR "Pharmaceutical preparations/toxicity" [Mesh] OR "Pharmaceutical preparations/therapy" [Mesh] OR "Pharmaceutical preparations/analysis" [Mesh] OR "Chemical actions and uses/adverse effects" [Mesh] OR "Chemical actions and uses/contraindications" [Mesh] OR "Chemical actions and uses/poisoning" [Mesh] OR "Chemical actions and uses/therapeutic use" [Mesh] OR "Chemical actions and uses/toxicity" [Mesh] OR "Chemical actions and uses/therapy" [Mesh] OR "Chemical actions and uses/analysis" [Mesh] OR "Chemical actions and uses/epidemiology" [Mesh] OR"Drug toxicity" [Mesh] OR "Diseases Category/chemically induced" [Mesh] OR "Diseases Category/drug therapy" [Mesh] OR "Diseases Category/epidemiology" [Mesh] OR "Validation Studies" [pt] OR "Validation Studies as Topic" [Mesh] OR "Sensitivity and Specificity" [Mesh] OR "Predictive Value of Tests" [Mesh] OR "Reproducibility of Results" [Mesh] OR "Predictive Value" [tw]). Limits: humans, English, publication date from 1 January 1990 to 1 January 2011

## Table 2 検索式 #2 前半

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

("Premier" [All] OR "Solucient" [All] OR "Cerner" [All] OR "Ingenix" [All] OR "LabRx" [All] OR "IHCIS" [All] OR "marketscan" [All] OR "market scan" [All] OR "Medstat" [All] OR "Thomson" [All] OR "pharmetrics" [All] OR "healthcore" [All] OR "united healthcare" [All] OR "UnitedHealthcare" [All] OR "UHC" [All] OR "Research Database" [All] OR "Group Health" [All] OR "HCUP" [All] OR ("Healthcare Cost" [All] AND "Utilization Project" [All]) OR ("Health Care Cost" [All] AND "Utilization Project" [All]) OR "MEPS" [All] OR "Medical Expenditure Panel Survey" [All] OR "NAMCS" [All] OR "National Hospital Ambulatory Medical Care Survey" [All] OR "National Ambulatory Medical Care Survey" [All] OR "NHIS" [All] OR "National Health Interview Survey" [All] OR "Kaiser" [All] OR "HMO Research" [All] OR "Health Maintenance Organization" [All] OR "HMO" [All] OR "Cleveland Clinic" [All] OR "Lovelace" [All] OR "Department of Defense" [All] OR "Henry Ford" [All] OR "i3 Drug Safety" [All] OR "i3" [All] OR "Aetna" [All] OR "Humana" [All] OR "Wellpoint" [All] OR "IMS" [All] OR "Intercontinental Marketing Services" [All] OR "IMS Health" [All] OR "Geisinger" [All] OR "GE Healthcare" [All] OR "MQIC" [All] OR "PHARMO" [All] OR "Institute for Drug Outcome Research" [All] OR "Pilgrim" [All] OR "Puget Sound" [All] OR "Regenstrief" [All] OR "Saskatchewan" [All] OR "Tayside" [All] OR "MEMO" [All] OR "Veterans Affairs" [All] OR "Partners Healthcare" [All] OR "Mayo Clinic" [All] OR "Rochester Epidemiology" [All] OR "Indiana Health Information Exchange" [All] OR "Indiana Health" [All] OR "Intermountain" [All] OR "blue cross" [All] OR "health partners" [All] OR "health plan" [All]

## Table 2 検索式 #2 後半

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

OR "health services" [All] OR "Nationwide Inpatient Sample" [All] OR "National Inpatient Sample" [All] OR "medicaid" [All] OR "medicare" [All] OR "MediPlus" [All] OR "Outcome Assessment" [All] OR "insurance database" [All] OR "insurance databases" [All] OR "Data Warehouse" [All] OR "ICD-9" [All] OR "international statistical classification" [All] OR "international classification of diseases" [All] OR "ICD-10" [All] OR "Database Management Systems" [Mesh] OR "Medical Records Systems, Computerized" [Mesh] OR "CPT" [All] OR "Current procedural terminology" [All] OR "drug surveillance" [All] OR ("claims" [tw] AND "administrative" [tw]) OR ("data" [tw] AND "administrative" [tw]) OR "Databases, Factual" [Mesh] OR "Databases as topic" [Mesh] OR "Medical Record Linkage" [Mesh] OR "ICD-9-CM" [All Fields] OR "ICD-10-CM" [All Fields] OR (TennCare [tiab]) OR (RAMQ [tiab]) OR (Cigna [tiab]) OR ((british columbia [tiab]) AND ((health [tiab]) OR (data [tiab]) OR (database [tiab]) OR (population [tiab])))) OR (CIHI [All Fields]) OR ((manitoba [tiab]) AND ((center for health policy [all fields]) OR (population [tiab]) OR (health insurance [tiab]))) OR ((ontario [tiab]) AND ((population [tiab]) OR (OHIP [tiab]) OR (registered persons database [tiab]) OR (health insurance [tiab]) OR (ICES [All Fields]) OR (Institute for Clinical Evaluative Sciences [All Fields])))) OR ((Alberta [tiab]) AND ((health [tiab]) OR (data [tiab]) OR (database [tiab]) OR (population [tiab]) OR (Alberta Health and Wellness [All Fields])))) Limits: humans, English, publication date from 1 January 1990 to 1 January 2011

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# Table2 検索式 #3

## Terms to exclude studies not likely to utilize administrative and claims data

("Editorial" [pt] OR "Letter" [pt] OR "Meta-Analysis" [pt] OR "Randomized Controlled Trial" [pt] OR "Clinical Trial, Phase I" [pt] OR "Clinical Trial, Phase II" [pt] OR "Clinical Trial, Phase III" [pt] OR "Clinical Trial, Phase IV" [pt] OR "Comment" [pt] OR "Controlled Clinical Trial" [pt] OR "case reports" [pt] OR "Clinical Trials as Topic" [Mesh] OR "double-blind" [All] OR "placebo-controlled" [All] OR "pilot study" [All] OR "pilot projects" [Mesh] OR "Review" [pt] OR "Prospective Studies" [Mesh]). Limits: humans, English, publication date from 1 January 1990 to 1 January 2011

# Table2 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.CVA/TIA (p101) : ("Brain Ischemia" [Mesh] OR "Basal Ganglia Cerebrovascular Disease" [Mesh]) OR "Carotid Artery Thrombosis"[Mesh]) OR "Intracranial Embolism and hrombosis"[Mesh]) OR "Intracranial Hemorrhages"[Mesh]) OR "Stroke" [Mesh]) OR "Vasospasm, Intracranial"[Mesh].

例: 心不全(p130): Heart Failure [Mesh]

6. Combining base search with health outcome of interest search terms

#4 and #5

# 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.

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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 thatwould 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 the 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

| アウトカム | 論文 | 優先度 | PPV | 感度 | 備考 |
|---|---|---|---|---|---|
| 脳卒中/TIA | 35本 | Low | >=70% | | ICD10 |
| うっ血性心不全 | 35本 | Low | >=90% | | ICD10 |
| 心房細動 | 16本 | Moderate | 70～97% | 57～95% | 心電図 |
| 心室性不整脈 | 9本 | L～M | 5～100% | 77%以上 | 死亡診断 |
| 静脈血栓症 | 15本 | Low | >=70% | | |
| うつ病 | 11本 | Moderate | 31.5～98.8% | | 過小診断 |
| 自殺/自殺念慮 | 6本 | High | 36.5～100% | 14～65% | 死亡診断 |
| 発作/痙攣/てんかん | 11本 | Moderate | >=80% | | 入外ER |
| 膵炎 | 8本 | Moderate | 60～80% | | 検査値 |
| リンパ腫 | 1本 | High | <=62.8% | 55.2～88.7% | がん登録 |
| 血液製剤や移植による感染 | 1本 | High | | 21～83% | |
| 多形紅斑/スティーブンス・ジョンソン症候群/中毒性表皮壊死症 | 4本 | High | 44～51% | | |
| アナフィラキシー（含:血管性浮腫） | 6本 | Low | 15～95.3% | 95% | エピ注 |
| アナフィラキシー以外の過敏反応 | 4本 | High | >90% | 95% | |
| 関節置換や除去 | 5本 | High | 32% | 77.2～97.6% | CPT |
| 肺線維症/間質性肺疾患 | 0本 | High | | | |
| 輸血関連の敗血症 | 0本 | High | | | |
| 輸血関連のABO不適合反応 | 0本 | High | | | |
| 急性呼吸不全 | 0本 | High | | | Google |