

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～
東京大学大学院 医学系研究科
臨床疫学研究システム講座
小出 大介

Pharmacoepidemiology and Drug Safety, Supplement: The U.S. Food and Drug Administration's Mini-Sentinel Program January 2012 Volume 21, Issue Supplement S1 Pages 1–303 <http://onlinelibrary.wiley.com/doi/10.1002/pds.v21.S1/issuetoc>

CONTENTS

ORIGINAL REPORTS

- 1 The U.S. Food and Drug Administration's Mini-Sentinel Program: Status and Direction
R. Platt, R. M. Carnahan, J. S. Brown, E. Christilles, L. H. Carris, S. Hennessy, J. C. Nelson, J. A. Racosta, M. Robb, S. Schneeweis, S. Tob and M. G. Weiner
- 9 The US Food and Drug Administration's Sentinel Initiative: Expanding the Horizons of Medical Product Safety
M. A. Robb, J. A. Racosta, R. E. Sherman, T. P. Gross, R. Ball, M. E. Reichman, K. Midshun and J. Woodcock
- 12 The Organizational Structure and Governing Principles of the Food and Drug Administration's Mini-Sentinel Pilot Program
S. Farrow, D. M. Campbell, L. J. Herrinson, V. P. Natr, M. A. Robb, M. Wilson and R. Platt
- 18 A Policy Framework for Public Health Uses of Electronic Health Data
D. McGraw, K. Rosant and B. Evans
- 22 Design Considerations, Architecture, and Use of the Mini-Sentinel Distributed Data System
L. H. Carris, M. G. Weiner, D. M. Boudreau, W. O. Cooper, G. W. Dantel, V. P. Natr, M. A. Rabeil, N. U. Beaulieu, R. Rosoff, T. S. Woodworth and J. S. Brown
- 22 Design Considerations in an Active Medical Product Safety Monitoring System
J. J. Gagne, B. Fireman, P. B. Ryan, M. MacLure, T. Gerhard, S. Tob, J. A. Rassen, J. C. Nelson and S. Schneeweis
- 41 Using High-Dimensional Propensity Scores to Automate Confounding Control in a Distributed Medical Product Safety Surveillance System
J. A. Rassen and S. Schneeweis
- 50 When should Case-Only Designs be Used for Safety Monitoring of Medical Products?
M. MacLure, B. Fireman, J. C. Nelson, W. Hua, A. Shoaib, A. Paredes and D. Madigan
- 62 Challenges in the Design and Analysis of Sequentially Monitored Postmarket Safety Surveillance Evaluations Using Electronic Observational Health Care Data
J. C. Nelson, A. J. Cook, O. Yu, C. Dominguez, S. Zhao, S. K. Greene, B. H. Fireman, S. J. Jacobsen, E. S. Weintraub and L. A. Jackson
- 72 Statistical Approaches to Group Sequential Monitoring of Postmarket Safety Surveillance Data: Current State of the Art for Use in the Mini-Sentinel Pilot
A. J. Cook, R. C. Tsiatis, R. D. Wellman, S. R. Heckbert, L. Li, P. Heagerty, T. Marsh and J. C. Nelson
- 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. Moors
- 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
- 100 A Systematic Review of Validated Methods for Identifying Cerebrovascular Accident or Transient Ischemic Attack Using Administrative Data
S. E. Andrade, L. R. Harrold, J. Tjia, S. L. Curova, J. S. Saczynski, K. S. Dodd, R. J. Goldberg and J. H. Gurwitz
- 129 A Systematic Review of Validated Methods for Identifying Heart Failure Using Administrative Data
J. S. Saczynski, S. E. Andrade, L. R. Harrold, J. Tjia, S. L. Curova, K. S. Dodd, R. J. Goldberg and J. H. Gurwitz
- 141 A Systematic Review of Validated Methods for Identifying Atrial Fibrillation Using Administrative Data
P. N. Jensen, K. Johnson, J. Floyd, S. R. Heckbert, R. Carnahan and S. Dublin
- 148 A Systematic Review of Validated Methods for Identifying Ventricular Arrhythmias Using Administrative and Claims Data
L. Tamartz, T. Harkins and V. Natr
- 154 A Systematic Review of Validated Methods for Identifying Venous Thromboembolism Using Administrative and Claims Data
L. Tamartz, T. Harkins and V. Natr
- 163 A Systematic Review of Validated Methods for Identifying Depression Using Administrative Data
L. Townsend, J. T. Walkup, S. Crystal and M. Olfion
- 174 A Systematic Review of Validated Methods for Identifying Suicide or Suicidal Ideation Using Administrative or Claims Data
J. T. Walkup, L. Townsend, S. Crystal and M. Olfion
- 183 A Systematic Review of Validated Methods for Identifying Seizures, Convulsions, or Epilepsy Using Administrative and Claims Data
V. R. Kee, B. Gilchrist, M. A. Ganner, N. R. Sarrazin and R. M. Carnahan
- 194 A Systematic Review of Validated Methods for Identifying Pancreatitis Using Administrative Data
K. Moore, B. Gilchrist, R. Carnahan and T. Abrams
- 203 A Systematic Review of Validated Methods for Identifying Lymphoma Using Administrative Data
R. A. Herman, B. Gilchrist, B. K. Ltok and R. Carnahan
- 213 A Systematic Review of Validated Methods for Identifying Infection Related to Blood Products, Tissue Grafts, or Organ Transplants Using Administrative Data
R. M. Carnahan, K. G. Moors and E. N. Perencevich
- 222 A Systematic Review of Validated Methods for Identifying Transfusion-related Sepsis Using Administrative and Claims Data
R. M. Carnahan, R. A. Herman and K. G. Moors
- 230 A Systematic Review of Validated Methods for Identifying Transfusion-related ABO Incompatibility Reactions Using Administrative and Claims Data
R. M. Carnahan and V. R. Kee
- 236 A Systematic Review of Validated Methods for Identifying Erythema Multiforme Major/Minor/ not otherwise Specified, Stevens-Johnson Syndrome, or Toxic Epidermal Necrolysis Using Administrative and Claims Data
G. Schneider, S. Kachroo, N. Jones, S. Crean, P. Roviella, R. Avestyan and M. W. Reynolds
- 240 A Systematic Review of Validated Methods for Identifying Anaphylaxis, Including Anaphylactic Shock and Angioneurotic Edema, Using Administrative and Claims Data
G. Schneider, S. Kachroo, N. Jones, S. Crean, P. Roviella, R. Avestyan and M. W. Reynolds
- 246 A Systematic Review of Validated Methods for Identifying Hypersensitivity Reactions other than Anaphylaxis (Fever, Rash, and Lymphadenopathy), Using Administrative and Claims Data
G. Schneider, S. Kachroo, N. Jones, S. Crean, P. Roviella, R. Avestyan and M. W. Reynolds
- 256 A Systematic Review of Validated Methods for Identifying Pulmonary Fibrosis and Interstitial Lung Disease Using Administrative and Claims Data
N. Jones, G. Schneider, S. Kachroo, P. Roviella, R. Avestyan and M. W. Reynolds
- 261 A Systematic Review of Validated Methods for Identifying Acute Respiratory Failure Using Administrative and Claims Data
N. Jones, G. Schneider, S. Kachroo, P. Roviella, R. Avestyan and M. W. Reynolds
- 265 A Systematic Review of Validated Methods for Identifying Orthopedic Implant Removal and Revision Using Administrative Data
J. A. Singh, J. A. Kundukulam and M. Bhandari
- 274 Design for Validation of Acute Myocardial Infarction Cases in Mini-Sentinel
S. L. Curova, S. Tob, A. Iyer, S. Fey, E. Cavagnaro, S. Farrow, J. A. Racosta, R. Goldberg and J. H. Gurwitz
- 282 A Protocol for Active Surveillance of Acute Myocardial Infarction in Association with the Use of a New Antidiabetic Pharmaceutical Agent
B. Fireman, S. Tob, M. G. Butler, A. S. Go, H. V. Joffe, D. J. Graham, J. C. Nelson, G. W. Dantel and J. V. Selby
- 291 The Food and Drug Administration's Post-Licensure Rapid Immunization Safety Monitoring Program: Strengthening the Federal Vaccine Safety Enterprise
M. Nguyen, R. Ball, K. Midshun and T. A. Lieu

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**

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 thrombosis"[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.

.....

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 the decision.

- Mini-Sentinel collaborator input
- Clinician or topic-expert consultation

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

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%	エビ注
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