JE編集委員会企画

疫学研究に求められる観察研究の報告ガイドライン

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第28回日本疫学会学術総会

2018/2/1 (木) 16:30~18:30

コラッセ福島

報告ガイドライン (reporting guidelines),
論文に**必要不可欠な最小限の情報**リスト

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	

Simera I, Altman DG: Int J Clin Pract. 2013 Aug;67(8):710-6.

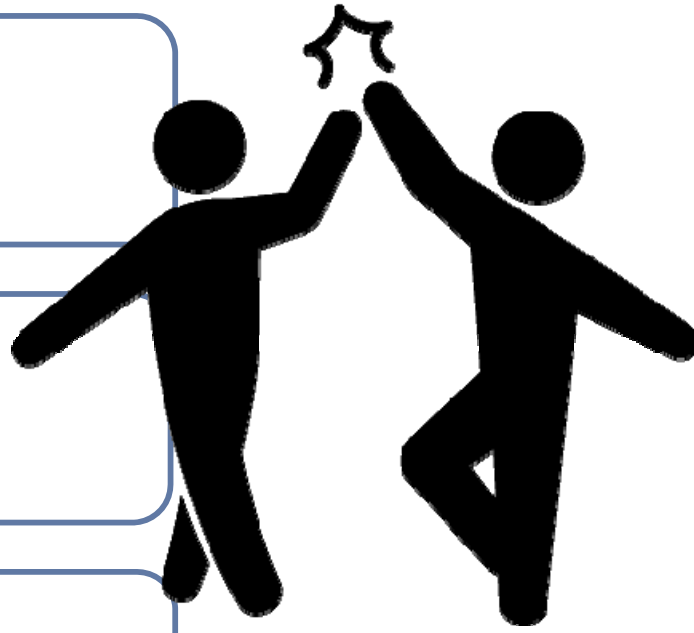
報告ガイドライン，**4つ**のメリット

読者が**理解**しやすくなる

研究者が**追試**しやすくなる

医師が**治療意思決定**に使いやすくなる

系統的レビューに参照されやすくなる

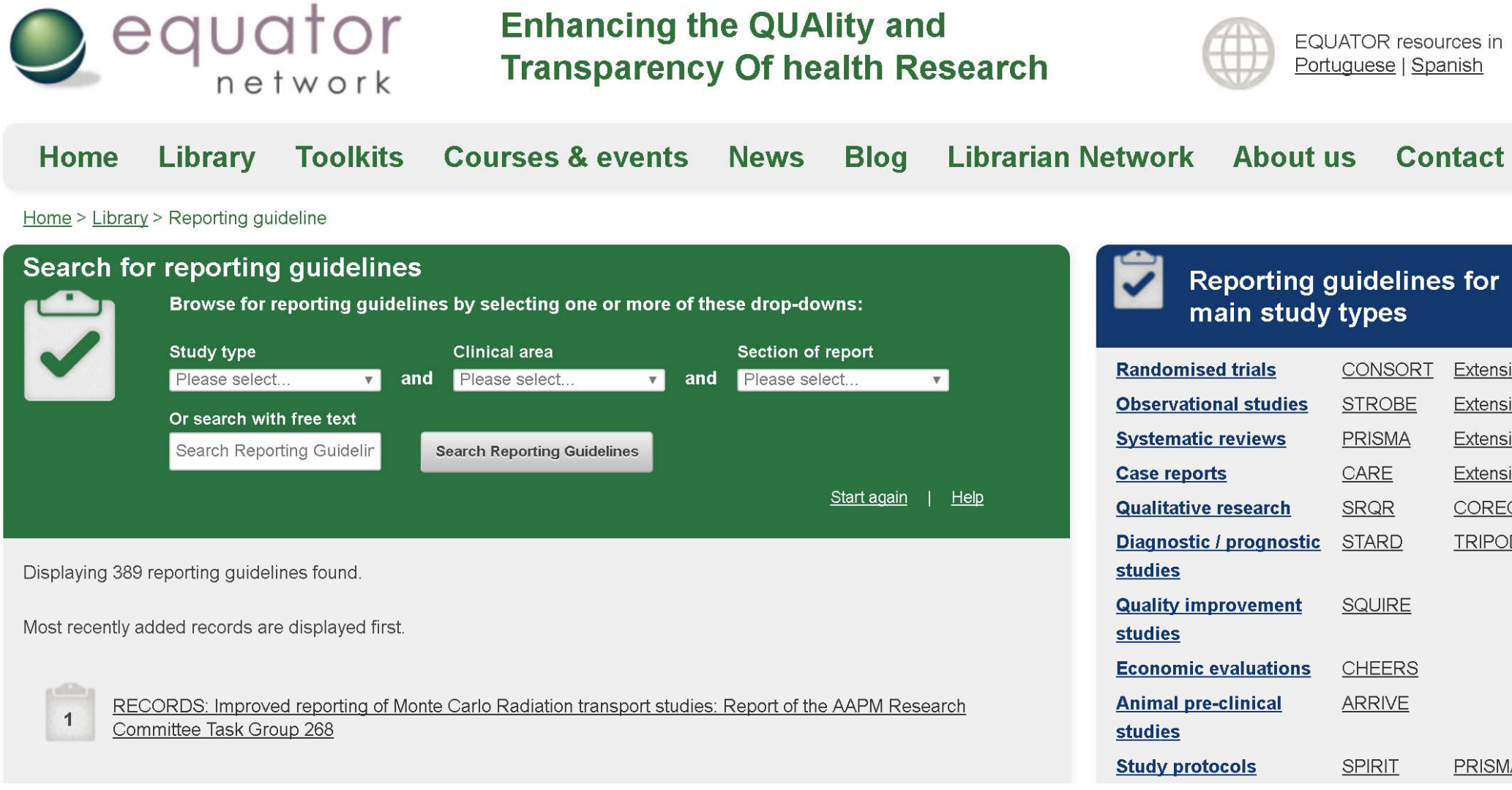


EQUATOR Network (http://www.equator-network.org/toolkits/reporting-guidelines-in-peer-review/#PRandRG)

主な報告ガイドライン

研究法	報告ガイドライン
無作為化比較試験	**CONSORT**
観察研究	**STROBE**
系統的レビュー	**PRISMA**
症例報告	CARE
質的研究	SRQR／COREQ
診断精度研究／予測モデル	**STARD／TRIPOD**
医療の質向上の活動	SQUIRE
医療経済評価	CHEERS
動物による非臨床試験	ARRIVE
研究計画書	SPIRIT／PRISMA-P
診療ガイドライン	AGREE／RIGHT

389の報告ガイドライン



EQUATOR Network (http://www.equator-network.org/reporting-guidelines/)

投稿規定，
報告ガイドライン参照を**推奨**

The Journal of Epidemiology encourages authors to follow statements of reporting guidelines for authors.

STROBE Statements: reporting observational studies
http://www.strobe-statement.org/index.php?id=strobe-home

CONSORT Statements: reporting the results of randomized controlled trials.
http://www.consort-statement.org/

PRISMA: reporting systematic reviews and meta-analysis of randomized trials.
http://www.prisma-statement.org/

The Journal of Epidemiology (http://jeaweb.jp/journal/pdf/Guide_for_Authors.pdf)

CONSORT声明への**低い**遵守率

605試験，日本発のRCT，出版年2010

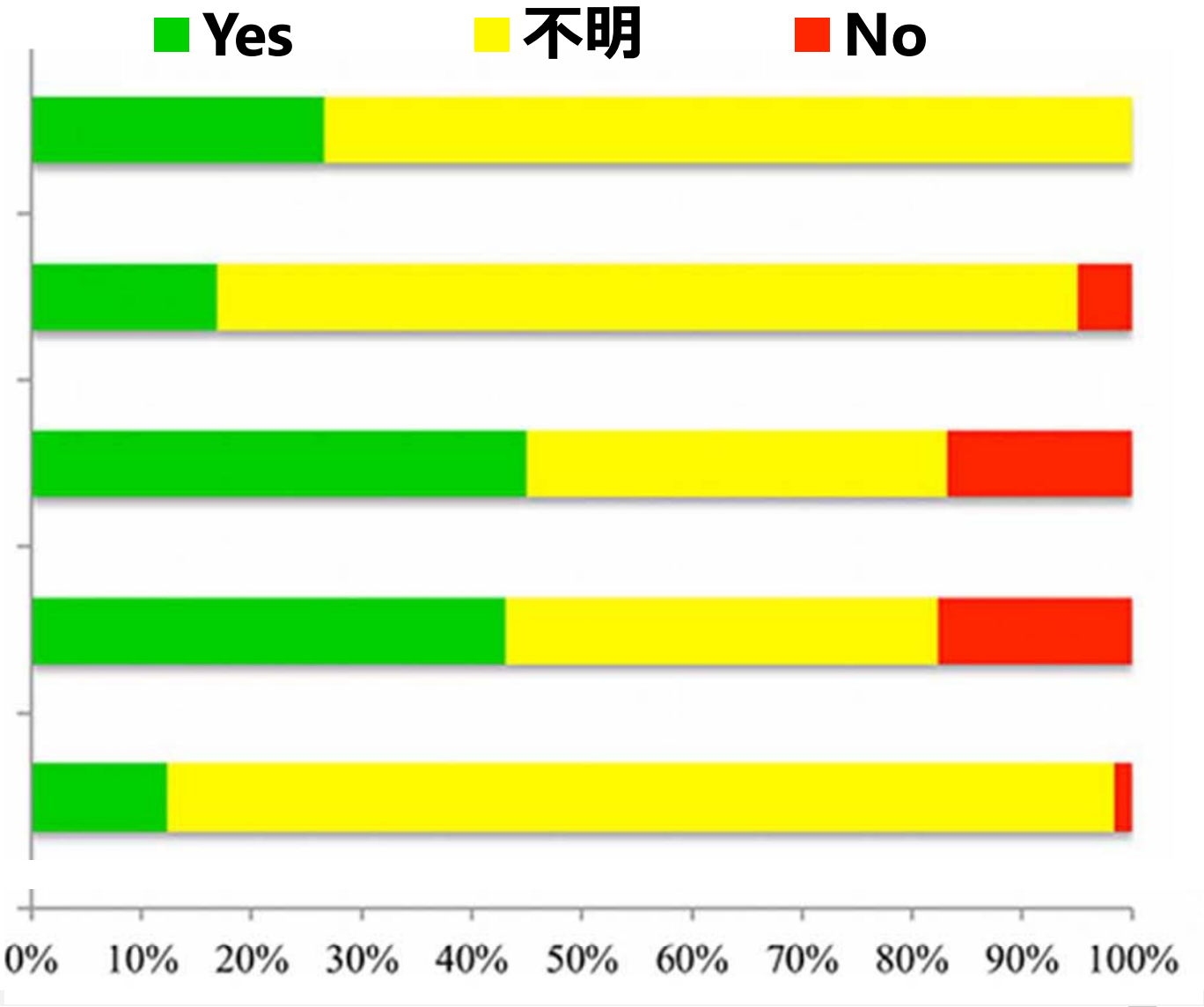
①無作為化の方法

②割付の隠蔽化

③患者への盲検

④治療者への盲検

⑤評価者への盲検



Yoneoka D et al: PLoS One. 2014 Mar 3;9(3):e90127.

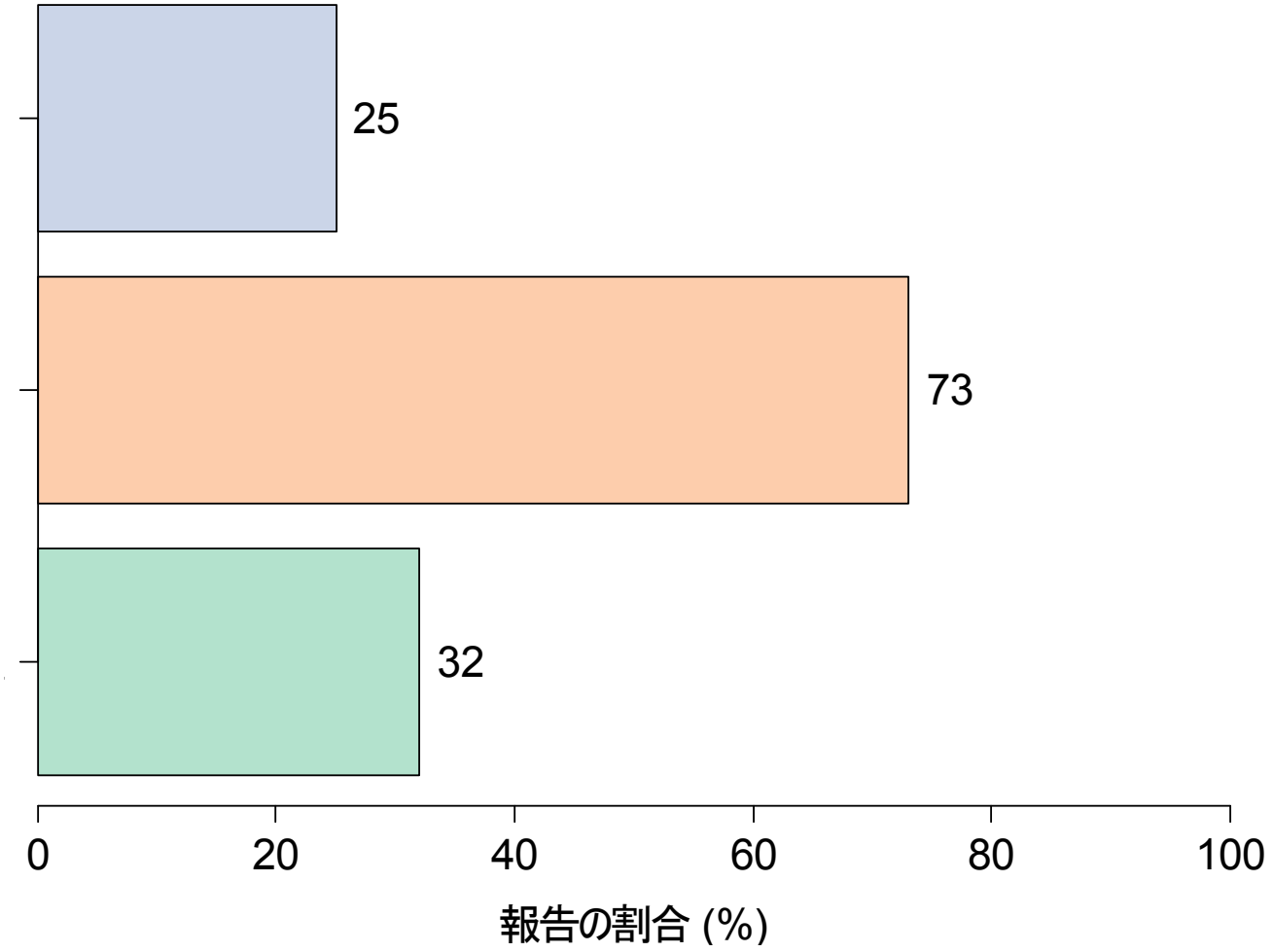
STROBE声明への**低い**遵守率

220研究，疫学・一般10誌，出版年2010~2012

①共変量の選択理由

②調整前後の効果推定値

③未測定の共変量による影響の方向性



Pouwels KB D et al: J Clin Epidemiol. 2016 Jan;69:217-24.

EQUATOR Network,
報告ガイドラインのポータルサイト

Online portal

academic writing tools and resources

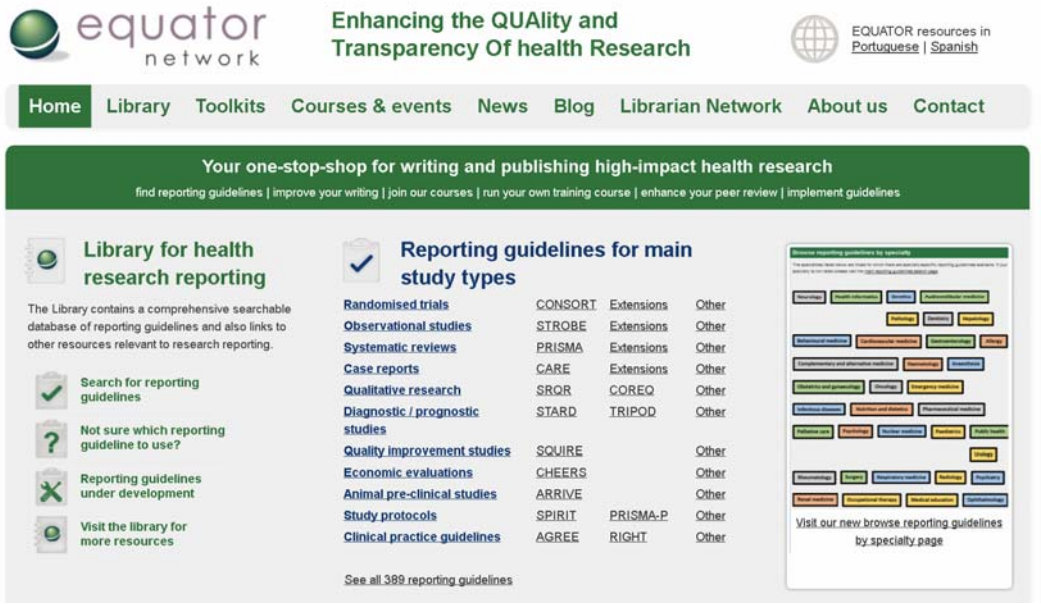
370+ reporting guidelines
translated into 17 languages

Key resources in &
adding & soon

38000 visits / month

1.5 million total visits

Linked by ICMJE Recommendations · COPE Recommendations · NIH Library · NIHR Journals · Wellcome Open Research · and many journals...



EQUATOR Network (http://www.equator-network.org/reporting-guidelines/)

EQUATOR Network, 報告ガイドラインの**教育**

Training

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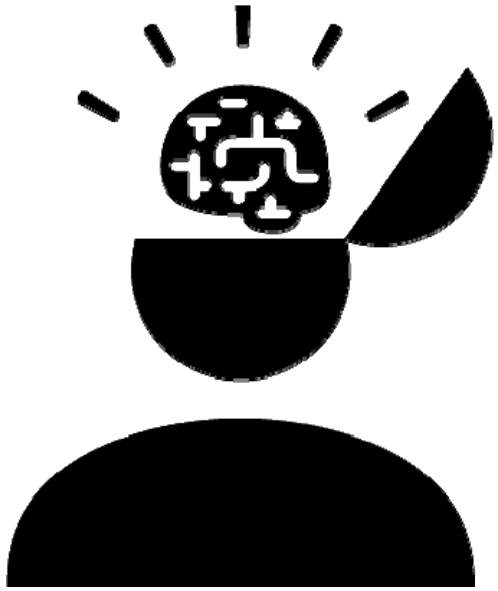
www.equator-network.org

EQUATOR Network (http://www.equator-network.org/reporting-guidelines/)

シンポジウムの主旨

- ✓観察研究における研究報告の質向上のためのガイドラインの普及啓発
- ✓疫学会の会員が頻用するデザイン・領域にフォーカス



横断研究,
相田潤先生 (東北大学)

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration

TITLE and ABSTRACT	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
INTRODUCTION		
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
METHODS		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants (b) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed

Vandenbroucke JP et al: PLoS Med. 2007 Oct 16;4(10):e297.

データベース研究,
康永秀生先生 (東京大学)

The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement

Title and Abstract			
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract. (b) Provide in the abstract an informative and balanced summary of what was done and what was found.	RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included. RECORD 1.2: If applicable, the geographic region and time frame within which the study took place should be reported in the title or abstract. RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.
Introduction			
Background rationale	2	Explain the scientific background and rationale for the investigation being reported.	
Objectives	3	State specific objectives, including any prespecified hypotheses.	
Methods			
Study Design	4	Present key elements of study design early in the paper.	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	
Participants	6	*(a) Cohort study*: Give the eligibility criteria and the sources and methods of selection of participants. Describe methods of follow-up. *Case-control study*: Give the eligibility criteria and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. *Cross-sectional study*: Give the eligibility criteria and the sources and methods of selection of participants. *(b) Cohort study*: For matched studies, give matching criteria and number of exposed and unexposed. *Case-control study*: For matched studies, give matching criteria and the number of controls per case.	RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided. RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided. RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.

Benchimol EI et al: PLoS Med. 2015 Oct 6;12(10):e1001885.

観察研究のメタアナリシス，後藤温先生 (国立がん研究センター)

Meta-analysis of Observational Studies in Epidemiology
A Proposal for Reporting

Reporting of background should include
- Problem definition
- Hypothesis statement
- Description of study outcome(s)
- Type of exposure or intervention used
- Type of study designs used
- Study population

Reporting of search strategy should include
- Qualifications of searchers (eg, librarians and investigators)
- Search strategy, including time period included in the synthesis and keywords
- Effort to include all available studies, including contact with authors
- Databases and registries searched
- Search software used, name and version, including special features used (eg, explosion)
- Use of hand searching (eg, reference lists of obtained articles)
- List of citations located and those excluded, including justification
- Method of addressing articles published in languages other than English
- Method of handling abstracts and unpublished studies
- Description of any contact with authors

Reporting of methods should include
- Description of relevance or appropriateness of studies assembled for assessing the hypothe to be tested
- Rationale for the selection and coding of data (eg, sound clinical principles or convenience)
- Documentation of how data were classified and coded (eg, multiple raters, blinding, and interrater reliability)
- Assessment of confounding (eg, comparability of cases and controls in studies where appropriate)
- Assessment of study quality, including blinding of quality assessors; stratification or regressi on possible predictors of study results
- Assessment of heterogeneity
- Description of statistical methods (eg, complete description of fixed or random effects mod justification of whether the chosen models account for predictors of study results, dose-response models, or cumulative meta-analysis) in sufficient detail to be replicated
- Provision of appropriate tables and graphics

Stroup DF et al: JAMA. 2000 Apr 19;283(15):2008-12.

発表の構成

- デザインと研究例の説明
- ガイドラインのスコープ
- 特に重要な項目の解説
- 良い報告例の紹介 (可能な限りJEから)
- Take Home Messages