How to Review a Research Manuscript?

Dominique Delbeke, MD, PhD
Editor-in-Chief of the Journal of Nuclear Medicine
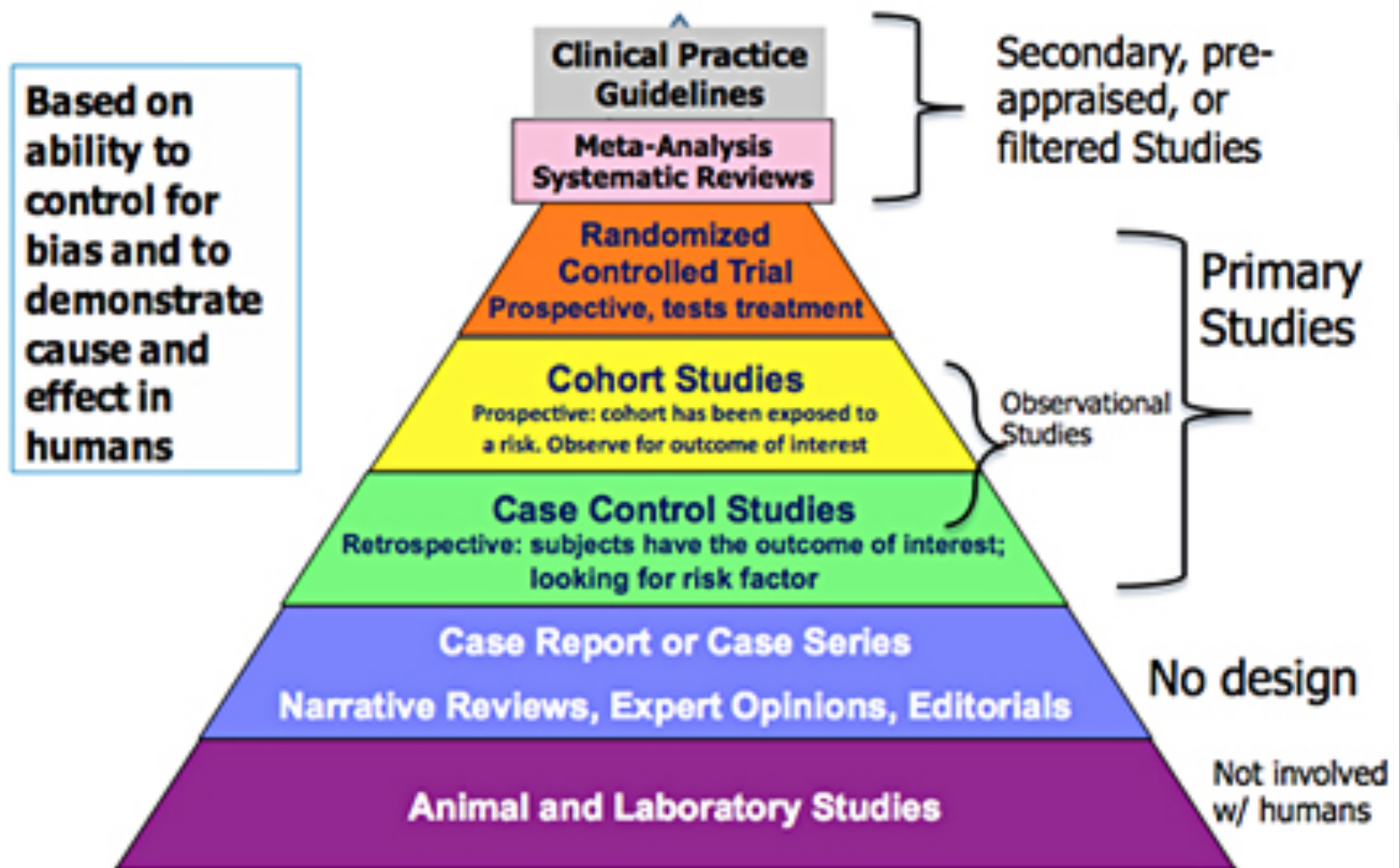Vanderbilt University Medical Center, Nashville, TN

VUMC Journal Club 2015

Hierarchic Model of Study Designs Based on Efficacy Outcome: Typical Measures of Analyses for the Efficacy of Diagnostic Imaging

◆ Level 1: Technical efficacy

◆ Level 2: Diagnostic accuracy efficacy

◆ Level 3: Diagnostic thinking efficacy

◆ Level 4: Therapeutic efficacy

◆ Level 5: Patient outcome efficacy

◆ Level 6: Societal efficacy

Pyramid for Levels of Evidence

Hierarchy of Research Designs & Levels of Scientific Evidence

Based on ability to control for bias and to demonstrate cause and effect in humans

Clinical Practice Guidelines

Meta-Analysis Systematic Reviews

Secondary, pre-appraised, or filtered Studies

Randomized Controlled Trial
Prospective, tests treatment

Cohort Studies
Prospective: cohort has been exposed to a risk. Observe for outcome of interest

Case Control Studies
Retrospective: subjects have the outcome of interest; looking for risk factor

Observational Studies

Primary Studies

Case Report or Case Series

Narrative Reviews, Expert Opinions, Editorials

No design

Animal and Laboratory Studies

Not involved w/ humans

Evidence Based Medicine
Incomplete or unusable reports of biomedical research

"At least 50% of research reports were sufficiently poor or incompletely as to make them unusable"

"Unless research is adequately reported, the time and resources invested in the conduct of research is wasted"

Glasziou P et al, Lancet 2014;383 (9913):267-76.

Abstract
Trials: missing effect size and confidence interval (38%); no mention of adverse effects (49%)[72]

Methods
Trials: 40–89% inadequate treatment descriptions[11, 13]
fMRI studies: 33% missing number of trials and durations[3]
Survey questions: 65% missing survey or core questions[25]
Figures: 31% graphs ambiguous[45]

Results
Clinical trials: outcomes missing: 50% efficacy and 65% harm outcomes per trial incompletely reported[6]
Animal studies: number of animals and raw data missing[17] (54%, 92%); age and weight missing (24%)
Diagnostic studies: missing age and sex (40%)[15]

Discussion
Trials: no systematic attempt to set new results in context of previous trials (50%)[69]

Data
Trials: most data never made available; author-held data lost at about 7% per year

Courtesy Paul Kinahan

Figures and tables are often incomplete or un-interpretable

◆ 31% of all graphs published in JAMA in 1999-2000 could not be interpreted unambiguously

Cooper RJ et al. Ann Emerg Med 2002; 40 (3):317-22

The Lack of Evidence for PET or PET/CT Surveillance of Patients with Treated Lymphoma, Colorectal Cancer, and Head and Neck Cancer: A Systematic Review

Kamal Patel[1], Nira Hadar[1], Jounghee Lee[1], Barry A. Siegel[2], Bruce E. Hillner[3], and Joseph Lau[1]
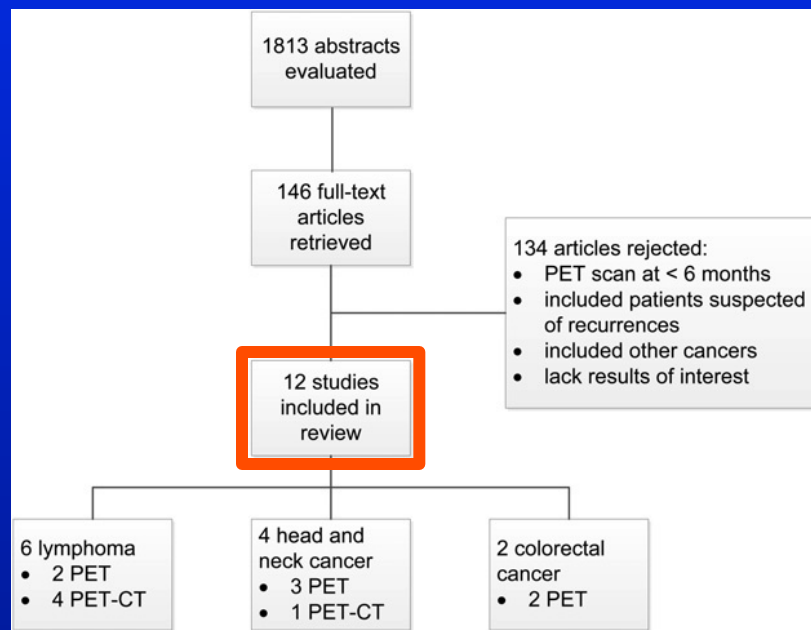
"Studies were generally of poor quality, with more than half being retrospective ... we were unable to use all available data because test accuracy was not consistently defined and reporting was incomplete."

Patel K et al. J Nucl Med 2013; 54:1518–1527

Study	Prospective study design?	Clear eligibility criteria?	Selection bias likely?	Index and reference tests adequately described?	Masked outcome assessment?	Clear reporting with no discrepancies?	Overall grade
PET/CT: lymphoma							
Crocchiolo (22)	No	Yes	No	Yes	No	Yes	B
El-Galaly (23)	No	Yes	No	Yes	No	Yes	B
Lee (21)	No	Yes	Yes	No	No	Yes	C
Rhodes (24)	No	Yes	No	Yes	No	Yes	B
PET/CT: head and neck cancer							
Abgral (25)	Yes	Yes	No	Yes	Yes	Yes	A
PET: lymphoma							
Hosein (27)	No	Yes	Yes	Yes	No	Yes	C
Zinzani (26)	Yes	Yes	No	Yes	No	No	B
PET: head and neck cancer							
Lowe (29)	Yes	Yes	Yes	Yes	Yes	No	B
Périé (30)	Yes	Yes	Yes	Yes	Yes	Yes	B
Salaun (31)	No	Yes	No	Yes	Yes	Yes	B
PET: colorectal cancer							
Selvaggi (28)	No	Yes	Yes	Yes	Yes	Yes	C
Sobhani (20)	Yes	Yes	No	Yes	Yes	No	B

Grade	Criteria
A	Adhered to recognized standards for diagnostic test studies Clear descriptions of design, population, test, reference standard, outcomes No major reporting omissions and no obvious source of bias
B	Some deficiencies, but considered unlikely to result in a major bias
C	Serious design or reporting deficiencies

146 papers

⬇

12 useable

⬇

1 grade A data

Patel K et al. J Nucl Med 2013; 54:1518–1527

Some Reporting Standards

STARD - STAndards for the Reporting of Diagnostic Accuracy studies
◈ Bossuyt et al. Clin Chem 2003;49:1–6

CONSORT - Reporting guideline for Parallel group Randomized Trials
◈ Moher et al. JAMA 2010:285: 1987–1991

PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses
◈ Moher et al. PLoS Med 6: e1000100, 2009

REMARK - REporting recommendations for tumour MARKer prognostic studies
◈ McShane et al. Br J Cancer 93: 387–391.

STROBE – Strengthening the Reporting of Observational Studies in Epidemiology
◈ Vandenbroucke et al. . PLoS Med 4: e297. 2007

BRISQ - Biospecimen Reporting for Improved Study Quality
◈ Moore et al. Cancer Cytopathol. 2011;119(2):92-101.

Patel K et al. J Nucl Med 2013; 54:1518–1527

STARD Statement

STAndards for the Reporting of Diagnostic accuracy studies

Home
News
Aim and history of STARD
STARD checklist
STARD flow diagram
STARD papers
Coordinators
Adopters of STARD
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Objective of the STARD initiative

The objective of the STARD initiative is to improve the accuracy and completeness of reporting of studies of diagnostic accuracy, to allow readers to assess the potential for bias in the study (internal validity) and to evaluate its generalisability (external validity).

The STARD statement consist of a checklist of 25 items and recommends the use of a flow diagram which describe the design of the study and the flow of patients.

News

April 2008
- More than 200 biomedical journals encourage the use of the STARD statement in their instructions for authors.

Accuracy is not "fixed"
> Accuracy varies with setting, prior tests, patient groups, and threats to validity such as bias.
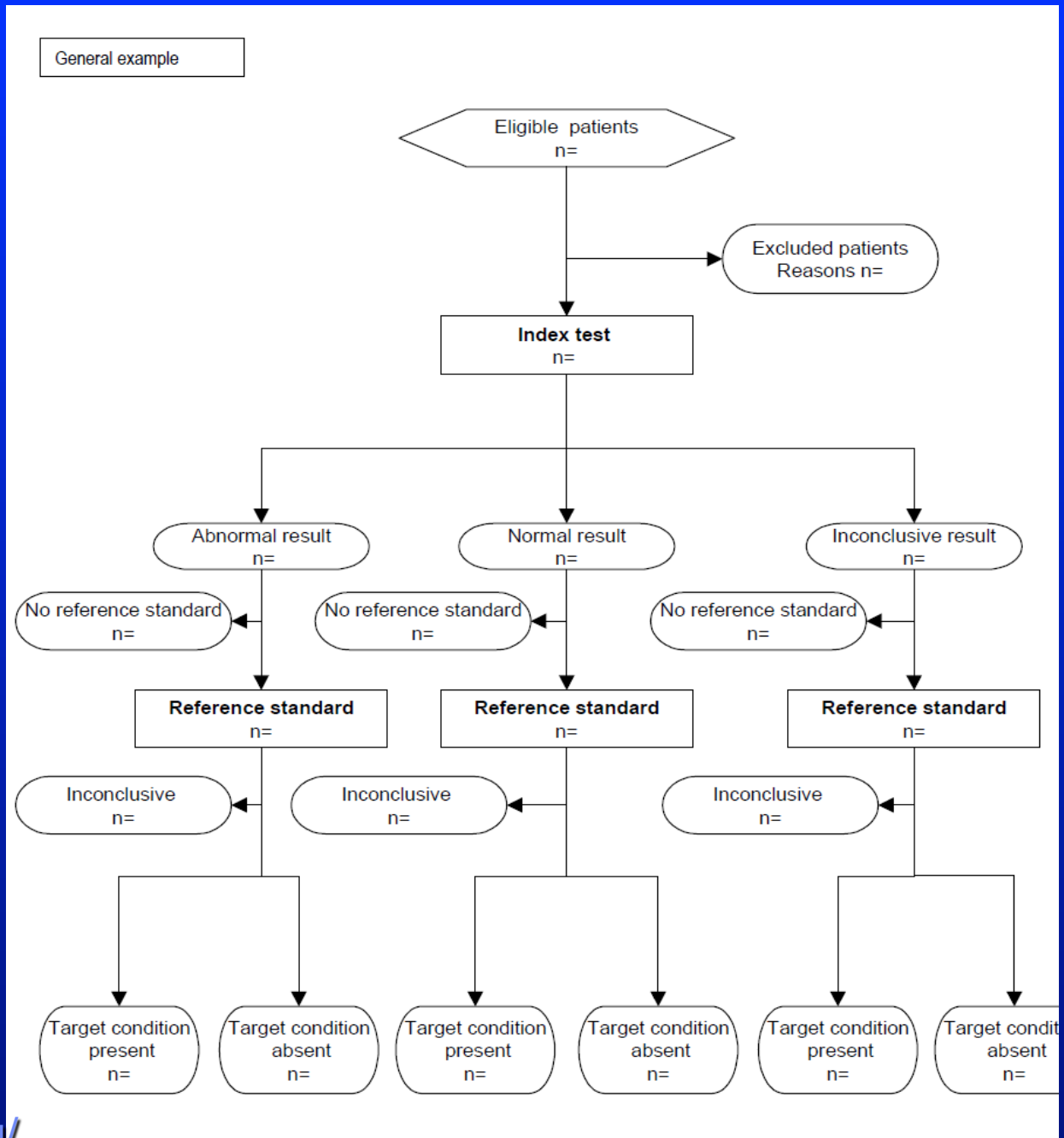
The initial STARD checklist (2003) is 25 items.

There have been improvements in reporting since the initial publication.

A STARD update process is in progress.

From Patrick MM Bossuyt, U. of Amsterdam. What is wrong with EBM criteria?, Editor Forum 2014

For Diagnostic Accuracy: The STARD Statement Flow Diagram

General example

For Diagnostic Accuracy: The STARD Statement Checklist

STARD checklist for the reporting of studies of diagnostic accuracy.
First official version, January 2003.

Section and Topic	Item #		On page #
TITLE/ABSTRACT/ KEYWORDS	1	Identify the article as a study of diagnostic accuracy (recommend MeSH heading 'sensitivity and specificity').	
INTRODUCTION	2	State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.	
METHODS			
Participants	3	Describe the study population: The inclusion and exclusion criteria, setting and locations where the data were collected.	
	4	Describe participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?	
	5	Describe participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in items 3 and 4? If not, specify how participants were further selected.	
	6	Describe data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	
Test methods	7	Describe the reference standard and its rationale.	
	8	Describe technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.	
	9	Describe definition of and rationale for the units, cutoffs and/or categories of the results of the index tests and the reference standard.	
	10	Describe the number, training and expertise of the persons executing and reading the index tests and the reference standard.	
	11	Describe whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.	

http://www.stard-statement.org/

For Diagnostic Accuracy: The STARD Statement Checklist

		available to the reader.	
Statistical methods	12	Describe methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).	
	13	Describe methods for calculating test reproducibility, if done.	
RESULTS			
Participants	14	Report when study was done, including beginning and ending dates of recruitment.	
	15	Report clinical and demographic characteristics of the study population (e.g. age, sex, spectrum of presenting symptoms, comorbidity, current treatments, recruitment centers).	
	16	Report the number of participants satisfying the criteria for inclusion that did or did not undergo the index tests and/or the reference standard; describe why participants failed to receive either test (a flow diagram is strongly recommended).	
Test results	17	Report time interval from the index tests to the reference standard, and any treatment administered between.	
	18	Report distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.	
	19	Report a cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.	
	20	Report any adverse events from performing the index tests or the reference standard.	
Estimates	21	Report estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).	
	22	Report how indeterminate results, missing responses and outliers of the index tests were handled.	
	23	Report estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.	
	24	Report estimates of test reproducibility, if done.	
DISCUSSION	25	Discuss the clinical applicability of the study findings.	

http://www.stard-statement.org/

For Randomized Trials: The CONSORT Statement Flow Diagram

CONSORT Statement 2010 Flow Diagram

Enrollment

Assessed for eligibility (n=)

Excluded (n=)
- Not meeting inclusion criteria (n=)
- Declined to participate (n=)
- Other reasons (n=)

Randomized (n=)

Allocation

Allocated to intervention (n=)
- Received allocated intervention (n=)
- Did not receive allocated intervention (give reasons) (n=)

Allocated to intervention (n=)
- Received allocated intervention (n=)
- Did not receive allocated intervention (give reasons) (n=)

Follow-Up

Lost to follow-up (give reasons) (n=)

Discontinued intervention (give reasons) (n=)

Lost to follow-up (give reasons) (n=)

Discontinued intervention (give reasons) (n=)

Analysis

Analyzed (n=)
- Excluded from analysis (give reasons) (n=)

Analyzed (n=)
- Excluded from analysis (give reasons) (n=)

From Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c332.

For more information, visit www.consort-statement.org.

http://www.consort-statement.org/consort-statement

For Randomized Trials: The CONSORT Statement Checklist

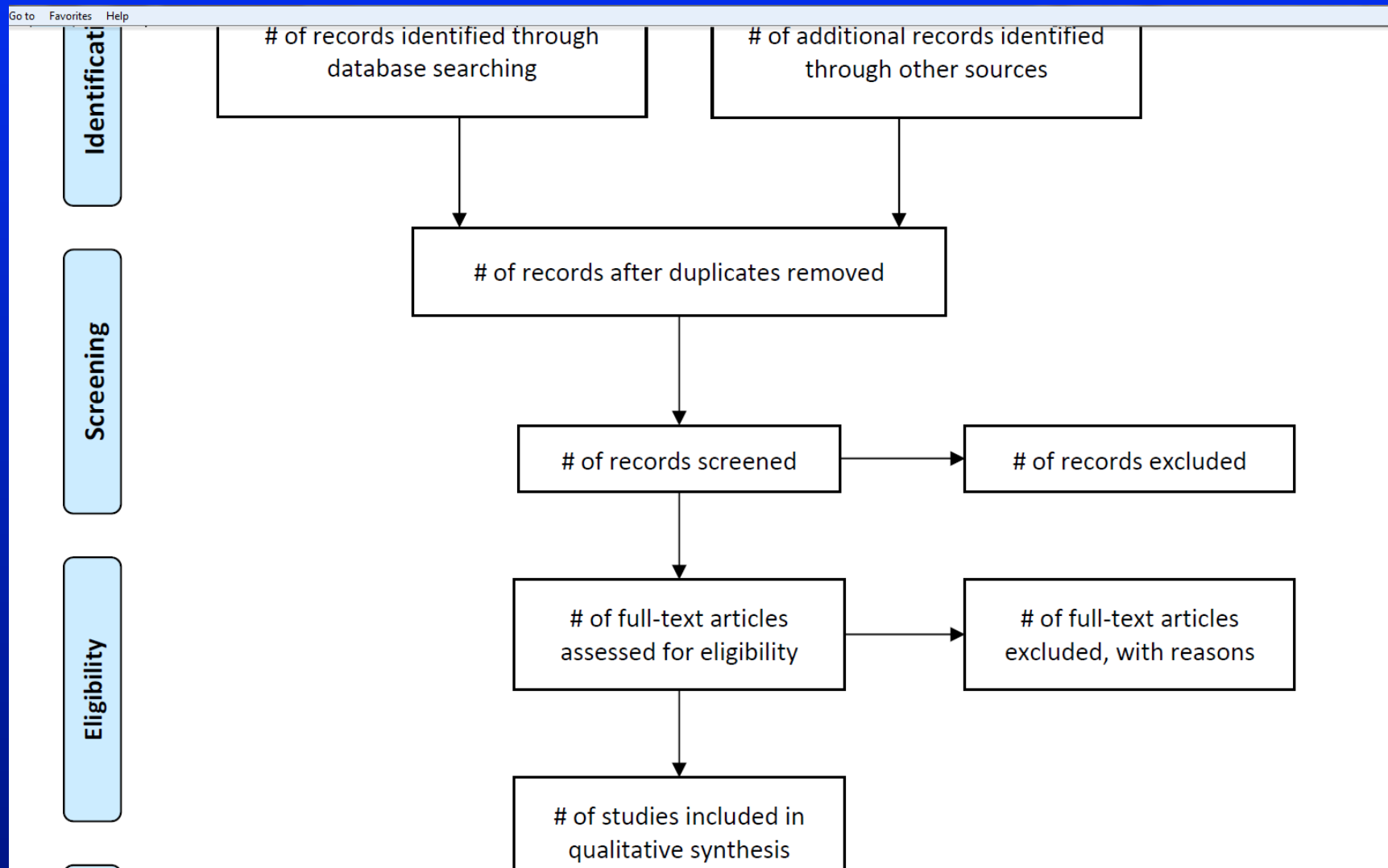## CONSORT 2010 checklist of information to include when reporting a randomised trial*

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	_____
	6b	Any changes to trial outcomes after the trial commenced, with reasons	_____
Sample size	7a	How sample size was determined	_____
	7b	When applicable, explanation of any interim analyses and stopping guidelines	_____
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	_____
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	_____
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	_____
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	_____
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	_____

http://www.consort-statement.org/consort-statement

For Randomized Trials: The CONSORT Statement Checklist

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	_____
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	_____
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	_____

Results

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	_____
	13b	For each group, losses and exclusions after randomisation, together with reasons	_____
Recruitment	14a	Dates defining the periods of recruitment and follow-up	_____
	14b	Why the trial ended or was stopped	_____
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	_____
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	_____
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	_____
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	_____
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	_____

Discussion

Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	_____
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	_____
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	_____

Other Information

Registration	23	Registration number and name of trial registry	_____
Protocol	24	Where the full trial protocol can be accessed, if available	_____
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

http://www.consort-statement.org/consort-statement

Meta-Analysis and Systematic Reviews: PRISMA Flow Diagram

PRISMA 2009 Checklist

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Page 1 of 2

http://www.prisma-statement.org/statement.htm

PRISMA 2009 Checklist

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

http://www.prisma-statement.org/statement.htm

REMARK: http://www.nature.com/nrclinonc/journal/v2/n8/full/ncponc0252.html

Table 1 REporting recommendations for tumor MARKer prognostic studies (REMARK).

Introduction

1   State the marker examined, the study objectives, and any prespecified hypotheses.

Materials and methods

Patients

2   Describe the characteristics (e.g. disease stage or comorbidities) of the study patients, including their source and inclusion and exclusion criteria.

3   Describe treatments received and how chosen (e.g. randomized or rule-based).

Specimen characteristics

4   Describe type of biological material used (including control samples) and methods of preservation and storage.

Assay methods

5   Specify the assay method used and provide (or reference) a detailed protocol, including specific reagents or kits used, quality control procedures, reproducibility assessments, quantitation methods, and scoring and reporting protocols. Specify whether and how assays were performed blinded to the study endpoint.

Study design

6   State the method of case selection, including whether prospective or retrospective and whether stratification or matching (e.g. by stage of disease or age) was used. Specify the time period from which cases were taken, the end of the follow-up period, and the median follow-up time.

7   Precisely define all clinical endpoints examined.

8   List all candidate variables initially examined or considered for inclusion in models.

9   Give rationale for sample size; if the study was designed to detect a specified effect size, give the target power and effect size.

Statistical analysis methods

10   Specify all statistical methods, including details of any variable selection procedures and other model-building issues, how model assumptions were verified, and how missing data were handled.

11   Clarify how marker values were handled in the analyses; if relevant, describe methods used for cutpoint determination.

Results

Data

12 Describe the flow of patients through the study, including the number of patients included in each stage of the analysis (a diagram may be helpful) and reasons for dropout. Specifically, both overall and for each subgroup extensively examined report the numbers of patients and the number of events.

13 Report distributions of basic demographic characteristics (at least age and sex), standard (disease-specific) prognostic variables, and tumor marker, including numbers of missing values.

Analysis and presentation

14 Show the relation of the marker to standard prognostic variables.

15 Present univariate analyses showing the relation between the marker and outcome, with the estimated effect (e.g. hazard ratio and survival probability). Preferably provide similar analyses for all other variables being analyzed. For the effect of a tumor marker on a time-to-event outcome, a Kaplan–Meier plot is recommended.

16 For key multivariable analyses, report estimated effects (e.g. hazard ratio) with confidence intervals for the marker and, at least for the final model, all other variables in the model.

17 Among reported results, provide estimated effects with confidence intervals from an analysis in which the marker and standard prognostic variables are included, regardless of their statistical significance.

18 If done, report results of further investigations, such as checking assumptions, sensitivity analyses, and internal validation.

Discussion

19 Interpret the results in the context of the prespecified hypotheses and other relevant studies; include a discussion of limitations of the study.

20 Discuss implications for future research and clinical value.

Guidance for Preclinical Imaging Papers

REVIEW

Guidance for Methods Descriptions Used in Preclinical Imaging Papers

David Stout, Stuart S. Berr, Amy LeBlanc, Joseph D. Kalen, Dustin Osborne, Julie Price, Wynne Schiffer, Claudia Kuntner, and Jonathan Wall

Abstract

Preclinical molecular imaging is a rapidly growing field, where new imaging systems, methods, and biological findings are constantly being developed or discovered. Imaging systems and the associated software usually have multiple options for generating data, which is often overlooked but is essential when reporting the methods used to create and analyze data. Similarly, the ways in which animals are housed, handled, and treated to create physiologically based data must be well described in order that the findings be relevant, useful, and reproducible. There are frequently new developments for metabolic imaging methods. Thus, specific reporting requirements are difficult to establish; however, it remains essential to adequately report how the data have been collected, processed, and analyzed. To assist with future manuscript submissions, this article aims to provide guidelines of what details to report for several of the most common imaging modalities. Examples are provided in an attempt to give comprehensive, succinct descriptions of the essential items to report about the experimental process.

The Era of Evidence-Based Medicine: What Are the Implications for *JNM* and Other Imaging Journals?

Dominique Delbeke

Vanderbilt University Medical Center, Nashville, Tennessee

The population is aging, and the cost of health care is increasing rapidly to unsustainable levels. High-technology molecular imaging procedures such as PET/CT and SPECT/CT have developed rapidly in the past decade, and new radiopharmaceuticals have been approved by regulatory agencies (e.g., radiopharmaceuticals for imaging amyloid and dopamine transporters). These advances in medical imaging have greatly increased the need for evidence-based data to facilitate comprehensive reimbursement decisions.

The national coverage policy of Medicare reads, "Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury. National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation." In the hierarchic model of study designs based on efficacy outcome described by Fryback and Thornbury in 1991, imaging studies are often at the level of "technical efficacy or diagnostic accuracy efficacy" and sometimes at the level of "therapeutic efficacy" (impact on management). Rarely, however, are they at the level of "patient outcome" or "societal efficacy" (cost-effectiveness).

ment and checklist for reporting randomized trials, the PRISMA flow diagram and checklist for reporting metaanalyses and systematic reviews, and the REporting recommendations for tumor MARKers prognostic studies (REMARK). There is also the QUADAS tool (questions) to assess the quality of studies evaluating diagnostic tests.

In an effort to improve the quality and level of evidence of the articles published in *The Journal of Nuclear Medicine*, we encourage authors to follow the reporting standards that apply to their studies. The submission checklist for the authors has been revised to include definitions of the reporting standards and a link to the different checklists. Authors have the opportunity to submit the checklist related to their manuscript as supplemental material online. The availability of the completed checklist related to a submitted manuscript will facilitate the review process and

Dominique Delbeke

Properties of adequate reporting
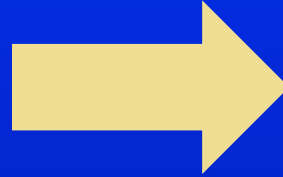
Reproduce	→	**Confirmation**
Assess	→	**Quality**
Combine	→	**Meta-analysis for evidence-based practice**
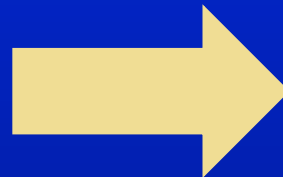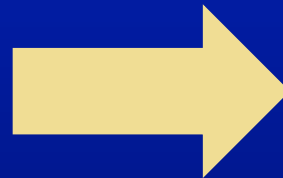
Courtesy Paul Kinahan

JNM Submissions and Acceptances 2001-2014
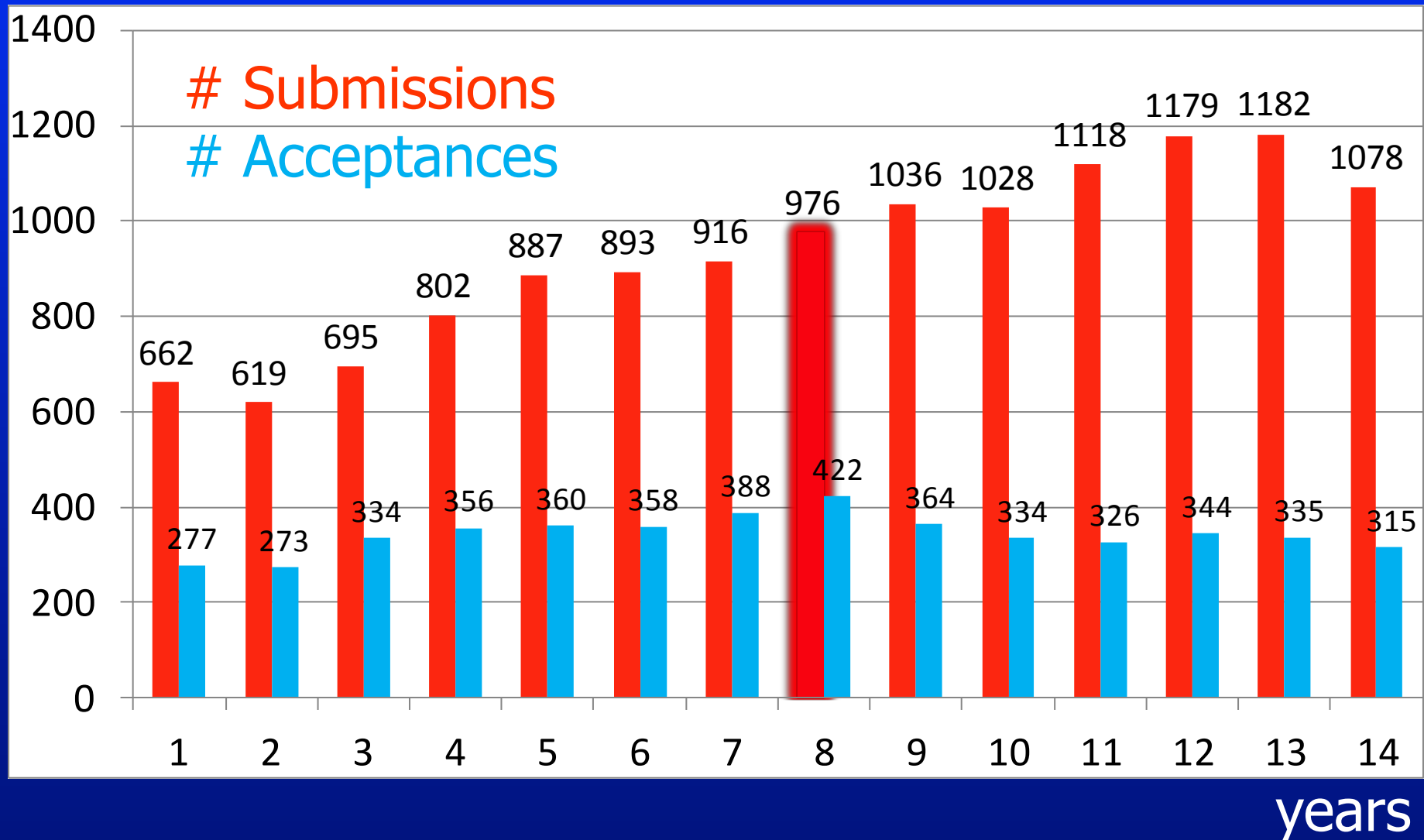
JNM Acceptance Rate
2001-2014

% Manuscripts
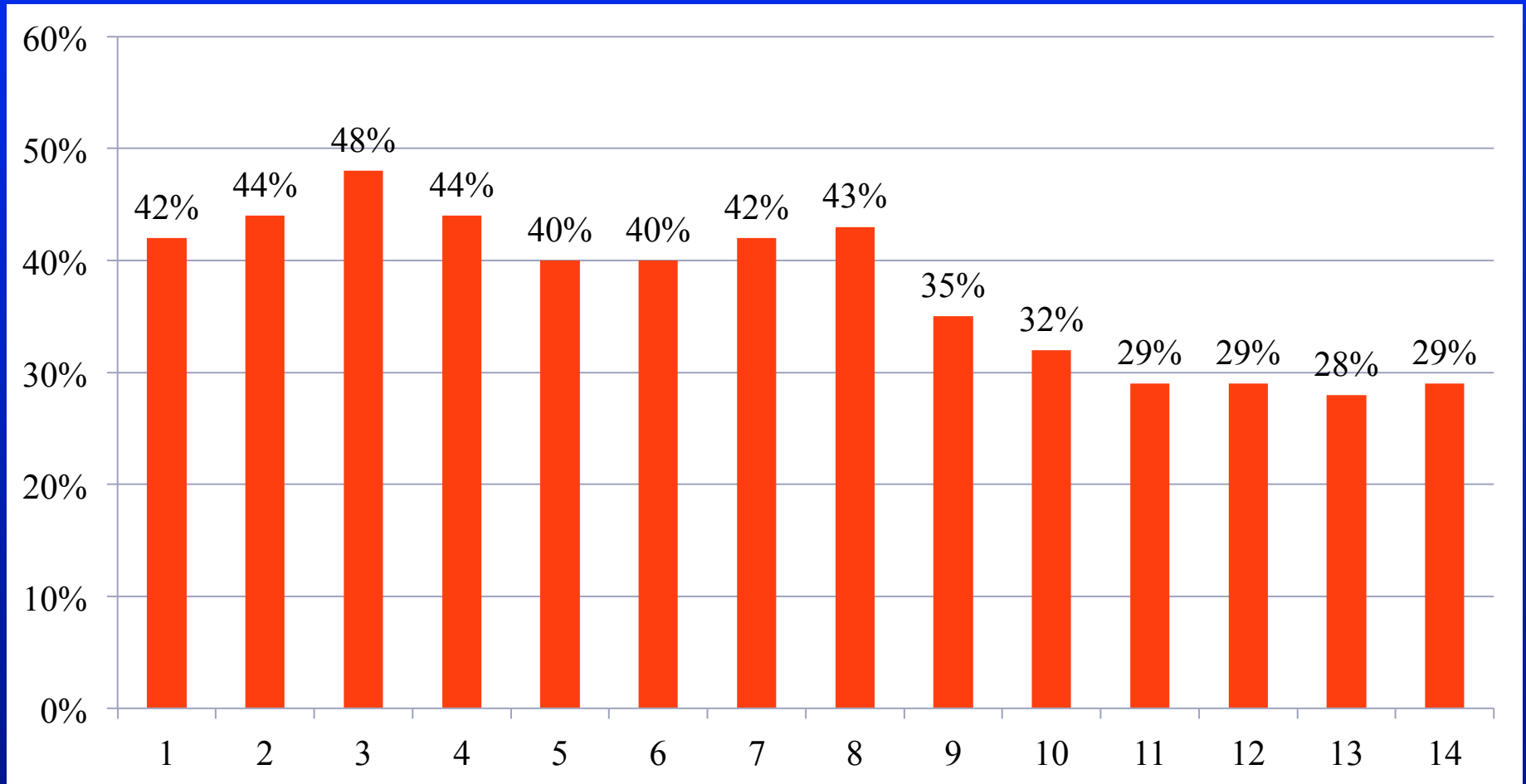
EJNMMI: 1,300 submissions, acceptance rate 19%   years

Decision process for acceptance/rejection

- According to reviews: Choice of recommendations are the following:
  - Accept as is
  - Minor revisions
  - Standard revisions
  - Major revisions
  - Reject-Resubmission allowed
  - Reject-Resubmission NOT allowed

Decision process for acceptance/rejection

Reviews	Accept	Minor revisions	Standard revisions	Major revisions	Reject – Resub. allowed	Reject
Accept	Accept	Minor	Standard	Arbitrator	Arbitrator	Arbitrator
Minor revisions	Minor	Minor	Standard	Major/ arbitrator	Arbitrator	Arbitrator
Standard revisions	Standard	Standard	Standard	Major/ Reject	Major/ Reject	Major/ Reject
Major revisions	Arbitrator	Major/ arbitrator	Major/ Reject	Major/ Reject	Reject	Reject
Reject-Resub. allowed	Arbitrator	Arbitrator	Major/ Reject	Reject	Reject	Reject
Reject	Arbitrator	Arbitrator	Major/ Reject	Reject	Reject	Reject

Acceptance is expected
Look at scores!

Peer-review process: Timeline

◆ Submission to publication: goal 6 months/24 weeks
- 2013: 29 weeks due to backlog
- 2014: 20.6 weeks
- Peer-review process: goal 3 months/12 weeks
- Production : goal 3 months/12 weeks
- Turnaround time for rejected manuscripts: 1 month

◆ Rejection without review: goal 20%
- 2013: 134/1182 = 11%
- 2014: 112/1,064 = 10.6%

Peer-review process: Timeline

- Week 1:
    - JNM office: send to EIC (1-2 days)
    - EIC and/or designee office: 2-5 days (Tom Ebers checks English)
        - Reject
        - Identify reviewers
- Week 2-3: Reviewer turnaround time (2 weeks)
- Week 4:
    - SNM office notify EIC or designee: reviews are in (1 day)
    - EIC or designee office:
        - Reject/accept
        - Additional reviewer or arbitrator needed
        - Sent to authors for minor, standard or major revisions
- Week 5-8:   Authors completion of revisions (4 weeks)
- Week 9-11: EIC or designee office:
    - Reject/Accept
    - Need additional reviewer/arbitration
    - Needs additional revisions by authors

Reviewers Timelines

◈ Week 2-3: Reviewer turnaround time (2 weeks)

- # of reviews: 2,442
- # of declined review requests: 428
- Average days to complete: 13 days
- % returned on time: 61%
- % returned less than one week late: 23%
- % returned one to two weeks late: 8%
- % returned more than two weeks: 5%
- % never returned: 1.6%

Instructions to authors (revised 2012)

- **<u>Manuscript submission: Cover letter</u>**
  - The Cover letter should have statements about:
    - Approval by all authors
    - Partially published content
    - Conflict of interest of authors
  - The copyright transfer agreement must be signed and include a statement about:
    - Originality of the content
    - Conflict of interest
    - Compliance with the institution regulations

We also warrant that **any** human and/or animal studies undertaken as part of the research from which this manuscript was derived are in compliance with regulations of our institution(s) and with generally accepted guidelines governing such work.

Instructions to authors (revised 2013)

◈ **Manuscript submission:**

■ **In the Materials and Methods: Statements to include**

- ◆ Approval by IRB or equivalent
- ◆ *Signed written informed* consent or waiver
- ◆ Compliance with HIPPA: *is rarely included*
- ◆ Clinical trial registration number must be provided

> For human studies, approval must be obtained from the institutional review board or equivalent ethic committee and signed informed consent must be obtained from research subjects, unless this requirement is waived by the institutional review board or equivalent. For studies in the United States, compliance with the Health Insurance Portability and Accountability Act is also required. Authors must also comply with the clinical trial registration statement from the International Committee of Medical Journal Editors, and the clinical trial registration number must be provided.

Instructions to authors (revised 2012)

- **Manuscript submission:** Authorship, Rights, Permission
  - **In the Materials and Methods:**
    - The language for first-in-man radiopharmaceutical must be included, allowing future RDRC supervision instead of IND.
      - Administered mass (mean +/- SD)
      - Administered activity (mean +/- SD)
      - No adverse or clinically detectable pharmacologic effects

ry investigational new drug: "The mean and standard deviation of the administered mass of [drug] was XX ± YY µg (range, AA–ZZ µg). The mean administered activity was XX ± YY MBq (range, AA–ZZ MBq). There were no adverse or clinically detectable pharmacologic effects in any of the [##] subjects. No significant changes in vital signs or the results of laboratory studies or electrocardiograms were observed [if true]."

Instructions to authors (revised 2012)

◈ **<u>Manuscript submission</u>: In the Materials and Methods: Statement about:**

- ◆ Approval by Animal care committee

> For animal studies, approval must be obtained from the appropriate animal care committee for compliance with the National Institutes of Health for use of laboratory animals or equivalent.
>
> In compliance with the Copyright Revision Act of 1976, effective January, 1, 1978, the following copyright transfer agreement must be faxed, e-mailed, or mailed to the *JNM* office. (A printable version is available at http://jnm.snmjournals.org/site/misc/ifora.xhtml).

Instructions to authors

◈ **Format requirements**

  ▪ General requirements

  ▪ Title page

  ▪ Abstract

  ▪ Text

      ◆ Introduction

      ◆ Materials and Methods

      ◆ Results

      ◆ Discussion

      ◆ Conclusions

  ▪ Letters

  ▪ References

  ▪ Units of measurements

  ▪ Abbreviations and symbols

  ▪ Tables

  ▪ Figures

  ▪ Figure legends

  ▪ Acknowledgement and Conflict of Interest

  ▪ Supplemental data

Instructions to Reviewers (revised 2012)

- **Comments to the editor**: Confidential
  - Brief summary of the article
  - Overall assessment of the manuscript with
  - List the manuscript strength and weaknesses
  - Recommendation with regard to revision/publication/rejection
  - Priority: potential clinical importance
  - Is the manuscript better suited for another journal
- **Comments to the authors**: the reviewer identity is anonymous to the authors:
  - Constructive comments for improvements by sections
- **Manuscript scoring and recommendation**
- Process for CE accreditation for reviewers
- Process for evaluation of the quality of reviews

Instructions to Reviewers

- General comment
  - Is the objective of the study important for the field of molecular imaging?
  - Are the experimental methods described adequately?
  - Are the study design and methods appropriate
  - Overall organization and accuracy
- Title: Is the title appropriate and clear?
- Abstract:
  - Is it specific and representative of the article?
  - Can the abstract be understood without reading the manuscript?
  - Any discrepancies between abstract and remainder of the manuscript?
- Key words:
- Have key words been provided?
  - Are key words representative of the articles?
  - Are some key words irrelevant?

Instructions to Reviewers (revised 2012)

- Introduction:
  - Is the purpose of the article made clear?
  - Does the introduction summarizes previous work?
  - Does it states the purpose of the article?
- Materials and Methods:
  - Statements about approval from IRB or equivalent, signed written consent or waiver, animal care, trial registry number, first in human study…

    Standard language for IRB/consent:

    "The study was approved by the Institutional Review Board (or equivalent) and all subjects signed a written informed consent (or there was a waiver)"
  - Is the hypothesis clearly stated?
  - Is the design of the study appropriate to test the hypothesis?
  - Number and selection of subjects
  - Prospective or retrospective
  - Procedure description should be detailed enough to be reproduced by others.

JNM Authors Checklist on-line

- **IRB:** Was the study approved by IRB or equivalent?

- <u>**Consent :**</u> Did all subjects sign a written informed consent or did the IRB approve a waiver of consent?

- **Animal Care:** Was the study approved by the animal care committee or equivalent?

- Is the **Clinical Trial Registration number** provided**?**

- Is the **First-in-human radiopharmaceutical language** included**?**

- Did you follow checklist and flow diagram from the **STARD statement:** http://www.stard-statement.org

- Did you follow checklist and flow diagram from the **CONSORT statement:** http://www.consort-statement.org/

- Did you follow checklist and flow diagram from the **PRISMA statement:** http://www.prisma-statement.org/statement.htm

- Did you follow checklist and flow diagram from the **REMARK statement:** http://www.nature.com/nrclinonc/journal/v2/n8/full/ncponc0252.html

- Did you follow the guidance for preclinical papers:

- Did you submit a checklist from one of the Evidence-Based Statement as supplemental material

Statistical methods

- Was the population appropriate and representative?
- Are there important difference between subgroups that are explainable or predictable
- Are covariate effects and confounding variable controlled?
- Are study design and statistical methods references to standard work?
- Are treatment assignment systematic and randomized?
- Is blinding described in enough details?
- Are findings quantified and presented with indicators of uncertainty?

Instructions to Reviewers

- Results:
  - Are there error of facts or interpretation?
  - Are there error in calculations (scan and spot-check)?
  - Is the content repeated or duplicated (text and figures)?
- Discussion:
  - Comparison with literature
  - Are limitations stated?
  - Is there a clear conclusion?
  - Is all discussion relevant?
- References:
  - Have authors omitted references?
  - Are all references current and relevant?
- Tables and figures:
  - Are they all necessary or some duplication with text?
  - Are they too crowded?
  - Can some be combined?
  - Can they be improved?

Decision process for acceptance/rejection

- Overall acceptance rate should be 20-25%:
  - Goal: 50% clinical/50% basic sciences
- The reviewers score (scale 1-5) each of 4 categories
  - Originality: can usually NOT be improved with revisions
  - Methodology
  - Presentation: can usually be improved with revisions
  - Priority: MOST IMPORTANT
- Implication of scores:
  - Score of 3 or less leads to rejection
  - Score of 4 or more leads to acceptance
    - ~ 20% of manuscripts have an average score of 4

Decision process for acceptance/rejection Definition of reviewers scores (scale 1-5)

- ◈ Originality: Is it new?
  - ◆ Score 1: Partially published by the authors
  - ◆ Score 2: Similar data published by others
  - ◆ Score 3: Confirmatory with additional data
  - ◆ Score 4: New or confirmatory and definitive evidence
  - ◆ Score 5: Groundbreaking/Newsworthy
- ◈ Methodology: Is it true?
  - ◆ Score 1: Not appropriate
  - ◆ Score 2: Need more experiments or subjects
  - ◆ Score 3: Need additional or re-analysis
  - ◆ Score 4: Appropriate/need more info
  - ◆ Score 5: Most appropriate

Decision process for acceptance/rejection Definition of reviewers score (scale 1-5)

- Presentation: Is it clear?
  - Score 1: Not appropriate
  - Score 2: Weak/confusing/need major rewriting
  - Score 3: Appropriate/minor re-writing/adjust illustrations
  - Score 4: Appropriate/minor re-writing
  - Score 5: Most appropriate
- Priority: Is it significant? (change patient care or future research?)
  - Score 1: No impact on patient care/future research
  - Score 2: Minimal impact on patient care/future research
  - Score 3: Impact is difficult to evaluate
  - Score 4: Probable impact on patient care/future research
  - Score 5: Definite impact on patient care/future research

Decision process for acceptance/rejection

◆ According to reviews: Choice of recommendations are the following:

- ◆ Accept as is
- ◆ Minor revisions
- ◆ Standard revisions
- ◆ Major revisions
- ◆ Reject-Resubmission allowed
- ◆ Reject-Resubmission NOT allowed

Decision process for acceptance/rejection

◆ **<u>Response to reviewer's comments</u>**

- Standard and Major revisions
  - ◆ The recommendation is to send back to one or both reviewers
  - ◆ Reviewer can revise their recommendations and scores up or down (revise e-mail to reviewers)

Process for Evaluation of the Reviewers

◆ EIC and AE grade the reviews for the manuscripts assigned to them:

- Grade 1: Not useful
- Grade 2: Format is addressed but not scientific methods
- Grade 3: Scientific methods are addressed
- Grade 4: Strengths and weaknesses are addressed
- Grade 5: Accept/reject/revise/priority and rationale are provided

CME for Review of Journal Manuscripts

- EIC and AE give CME to the reviewers for the manuscripts assigned to them:

- CME Effective July 1, 2011: Each acceptable review can be given up to three (3) AMA PRA Category 1 Credits^{TM} toward the AMA Physician's Recognition Award.

- Usually: 2 CE for first review and 1 CE for re-review

- No CE credit will be given if the review is not provided within 2 weeks of the request

Thank you!

Grand Bahama 2004