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4 Guide to the contents of a Cochrane review and protocol

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4.1 Format of a review of diagnostic test accuracy

All systematic reviews of diagnostic test accuracy published in the *Cochrane Database of Systematic Reviews* have the same format. There are several reasons for this. It helps readers to find the results of research quickly and to assess the validity, applicability and implications of those results. It guides authors to report their work explicitly and concisely, and minimises the effort required to do this. The format is also suited to electronic publication and updating, and facilitates the production of statistical summary figures and tables, which are informative and readable when viewed on a computer monitor or printed.

The Review Manager software (RevMan5) is designed to help authors construct reviews in the appropriate format and to prepare files required to transfer reviews electronically. Standard headings and tables embedded in RevMan5 guide review authors when preparing their report and are used by the publisher to structure the publication and link readers to the sections which are of particular interest to them. The content that should follow each heading is described in this chapter.

Each protocol consists of:

- Title;
- Protocol information – details of authors, contact person, important dates, ‘What’s new’ and ‘History’;
- Main text of the protocol – consisting of the background, objectives, methods, acknowledgements and declaration of interests;
- Tables – relevant to the background or methods;
- Studies and references – other references relevant for the background or methods;
- Sources of support – split into internal and external sources of support;
- Appendices – relevant to the background or methods.

Each review consists of:

- Title;
- Review information – details of authors, contact person, important dates, ‘What’s new’ and ‘History’;
- Structured abstract;
- Plain language summary;

- Text of the review – consisting of the background, objectives, methods, results, discussion, authors’ conclusions, acknowledgements, contribution of authors, declaration of interests, differences between protocol and review, and published notes;
- Tables – showing characteristics and methodological quality of the included studies, a summary of results table, a log of the studies that were excluded and reasons why, and additional tables relevant to the review;
- Studies and references – presenting the references of the included studies, excluded studies and other references;
- Data and analyses – presenting the data (2x2 table) by test or by study;
- Figures – summarizing the methodological quality of the included studies, forest plots of sensitivity and specificity, figures of summary receiver operating characteristic (ROC) plots, and any additional imported figures;
- Sources of support – split into internal and external sources of support;
- Feedback;
- Appendices.

4.2 Protocol and review information

This section of a review includes information about the title of the review, details of the contact person and co-authors, and key dates relating to the production and publication of the review and protocol.

4.2.1 Title of the review

The essence of the objective should be captured in the review’s title. Typically this involves stating the diagnostic technology together with the key characteristics of the people to whom it is applied and the purpose for which it is used. The key components of the title are therefore:

- the patients (how they present, where they present to, what tests have been done before);
- the target condition (disease, disease stage, or sub-type of a disease eligible for a specific treatment);
- the test or tests being evaluated.

The test that is being evaluated is known as the index test. A review may evaluate and compare the diagnostic accuracy of several index tests, and may elect one as a comparator test with which the diagnostic accuracy of the other index tests is compared, particularly if this test is currently standard diagnostic practice. The target condition is the condition of interest that the index and comparator test(s) are attempting to detect. The clinical reference standard is usually the test or tests representing the best available method of detecting the target condition. Reference standards, which give results with very little error, are known as ‘gold standards’. Please note the difference between the reference standard and the comparator test: the reference standard is the best test available to detect the target condition (and may not routinely be used in clinical practice) while the comparator test is a routinely used test, the diagnostic accuracy of which we wish to compare with other index tests to decide which is the best for detecting the target condition.

The review title in RevMan5 is structured to ensure that the correct information is reported to reflect the objective of the review for example, “What is the diagnostic accuracy of ‘index

test' for diagnosing 'target condition' in 'patient description'?" Four title options are possible (Table 4.2.a). These vary in the number of tests being evaluated (options 1 and 2 are for two tests, options 3 and 4 work for either a single test or several tests), and whether the patient description is required (options 1 and 3). Options 2 and 4, which do not include the patient description, should only be used where the target condition clearly implies a particular patient group.

Table 4.2.a: Structure for titles of Cochrane systematic reviews of diagnostic test accuracy

Option 1	Format	<Index test 1> <i>versus</i> <index test 2†> <i>for</i> <target condition(s)> <i>in</i> <patient description>
	Example	<Chlamydia antibody titre testing> <i>versus</i> <hysterosalpingography> <i>for diagnosing</i> <tubal pathology> <i>in</i> <subfertile women>
Option 2	Format	<Index test 1> <i>versus</i> <index test 2†> <i>for</i> <target condition(s)>
	Example	<MRI> <i>versus</i> <ultrasound> <i>for diagnosing</i> <ischaemic stroke>
Option 3	Format	<Index test(s)> <i>for</i> <target condition(s)> <i>in</i> <patient description>
	Example	<Physical examination> <i>for the diagnosis of</i> <lumbar radiculopathy due to disc herniation> <i>in</i> <patients with low back pain>
Option 4	Format	<Index test(s)> <i>for</i> <target condition(s)>
	Example	<Physical tests> <i>for</i> <detection of shoulder impingements>

† if the comparison is with current diagnostic practice, the second index test will be the comparator test

4.2.2 Authors

Authorship of all scientific papers (including Cochrane protocols and reviews) establishes accountability, responsibility and credit (Rennie 1997, Flanagan 1998, Rennie 1998). When deciding who should go in the by-line for Cochrane reviews, it is important to distinguish individuals who have made a substantial contribution to the review (and who should be listed) and those who have made other contributions, which should be noted in the acknowledgements section. Ideally, the order of authors should relate to their relative contributions to the review. The person who contributed most should be listed first. Authorship should be based on substantial contributions to all of the following three steps, based on the requirements for submitting papers to biomedical journals, developed by the International Committee of Medical Journal Editors (ICMJE 2006):

- Conception and design of study, or analysis and interpretation of data;
- Drafting the review or revising it critically for important intellectual content;
- Final approval of the version to be published;

Affiliations of authors will be published within the completed protocol or review, so authors should ensure that these fields are completed and up to date in 'Archie', the web interface of

The Cochrane Collaboration's Information Management System (IMS). The fields that must be completed are the First name(s) and Last name(s) of the author, Organisation and Country. If a co-author does not have a publishable address, but should still appear in the by-line for the citation, then the Organisation and Country should be those of the Review Group (for example Smith J. c/o Cochrane Pregnancy and Childbirth Group, UK). Group authorship is possible but requires an entry to be created in 'Archie' in the name of the group (see [Chapter 2](#)).

4.2.3 Contact Person

Contact details (i.e. name, address, e-mail, telephone and fax number) for the person to whom correspondence about the review should be addressed, and who has agreed to take responsibility for maintaining and developing the review, are automatically taken from 'Archie', the web interface of The Cochrane Collaboration's Information Management System (IMS). This person usually takes responsibility for developing and organising the review, communicates with the editorial base, ensures that the review is prepared within agreed timescales, submits it to the editorial base, communicates feedback to co-authors and ensures that the updates are prepared.

The contact author does not need to be the first author, and the choice of contact author will not affect the citation for the review. If the contact author no longer wishes to be responsible for a published review and another member of the review team does not wish to take responsibility for it, then the Review Group Co-ordinator (RGC) should be listed as the contact author, and the former contact author listed as a co-author. The RGC need not be listed as a co-author.

4.2.4 Dates

There are several dates associated with a Cochrane review. Some of these are automatically generated by RevMan, and some need to be entered by the review author. These dates are important both to inform readers of the review and to facilitate management of review publication. It is essential that authors apply these definitions when entering dates into relevant fields during an update or amendment to a review.

For considerations to make when updating a review please see [Chapter 11](#) 'Updating and maintaining reviews'.

4.2.4.1 Assessed as Up-to-date

This date is entered by review authors for full reviews only (not protocols). On publication, this date is reproduced in a prominent place in the review to inform readers of how recently the review has been assessed as up to date. The criteria for assessing a review as up to date are listed in Box 4.2.a.

A review might be considered to be up to date even if it has received only minimal edits for many years, for example if a recent search for studies identifies no new evidence since the review was published. All reviews submitted for publication must include a date on which the review was last assessed as being up to date. The date should be entered by the authors, and will often coincide with the date on which the authors submit the review for consideration to be published in the *Cochrane Database of Systematic Reviews*. It may be appropriate to amend the date on approval of the review for publication.

Box 4.2. a: Guidance for declaring a review as being up to date

The date a review is assessed as being up to date must be chosen so that the review (new, updated or amended) meets the following key criterion:

1. The evidence is up to date on the performance of the test(s)

The list of included studies should include all available evidence, and should result from a most recent search typically being within six months of the date on which the review is assessed as being up to date;

In addition, it is highly desirable, but not mandatory, that

2. The methods of the review are up to date

All mandatory methods for Cochrane reviews (as described in the current version of the *Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy*) should be incorporated;

3. Factual statements are correct

Factual statements, for example, in the Background and Discussion, should not be unreasonably out-dated.

4.2.4.2 Date of search

This date is entered by review authors for full reviews only (i.e. not protocols). ‘Search’ here refers to the searches of all the databases searched for the review. If different databases were searched on different dates, the most recent date of the search for each database should be given within the text of the review and the earliest of the dates should be put in this field. For example, if the most recent searches of the following databases were on the following dates (MEDLINE 5 June 2007, EMBASE 12 June 2007 and CENTRAL 28 June 2007) the ‘Date of search’ would be 5 June 2007. For further details on how to document your searches please see [Chapter 7](#).

4.2.4.3 Next stage expected

This is entered by review authors as:

- For protocols: the date on which the full review is expected (e.g. in 1 year);
- For full reviews: the date on which the next update is expected (e.g. in 2 years).

4.2.4.4 Protocol first published, Review first published, Last citation issue

These dates are automatically recorded in RevMan and generated at the time of publication of the protocol or full review.

4.2.5 What’s new and History

This should describe the changes to the protocol or review since it was last published in the *Cochrane Database of Systematic Reviews*. At each update of a review, substantive or not, the ‘What’s new’ field should contain the calendar date of the change, the event and a description of what was changed. The following options for the events in the protocol are: feedback incorporated, amendment, declare new citation version (major change or minor

change). In the full review examples of events to note include: Update (new search for studies), feedback incorporated, amendment, declare new citation version (conclusions changed or not changed) and declare review as no longer being updated. In the description, the authors should give a brief summary of how much new information has been added to the review (for example, number of studies, participants or extra analyses) and any important changes to the conclusions, results or methods of the review.

Changes which are made between versions prior to the penultimate version should be listed as events under 'History'. The 'What's New' section should only indicate changes made between the previous version and the current version.

4.3 Abstract

All full reviews must include an abstract of not more than 400 words. It should be kept as brief as possible without sacrificing important content. Abstracts to Cochrane reviews are published in MEDLINE and the Science Citation Index, and are made freely accessible on the Internet, so will often be read as stand-alone documents. They should, therefore, summarize the key methods and results of the review and not contain any material that is not in the review. The content must be consistent with the text, data and conclusions of the review and not include references to any information outside the review. Links to other parts of the review (such as references, studies, additional tables and additional figures) may not be inserted in the abstract. An example is included in Box 4.3.a.

Abstracts should be made as readable as possible without compromising scientific integrity. They should primarily be targeted at healthcare decision makers (clinicians, consumers and policy makers) rather than just researchers. Terminology should be reasonably comprehensible to a general rather than a specialist healthcare audience. Abbreviations should be avoided, except where they are widely understood (for example, HIV). Where essential, other abbreviations should be spelt out (with the abbreviations in brackets) on first use.

It is important that Cochrane reviews of diagnostic test accuracy are identifiable in MEDLINE and other electronic bibliographic databases from their titles, abstracts and keywords. Indexing of diagnostic terms is currently poor, and the guidelines for the titles of Cochrane reviews rule out the use of phrases such as 'systematic review' or 'diagnostic test accuracy'. Their titles may therefore be difficult to distinguish from reviews of interventions. "Screening for type 2 diabetes mellitus", for example, may refer to an intervention review investigating the effectiveness of screening for type 2 diabetes mellitus in reducing morbidity and mortality associated with diabetes, but it could also describe a diagnostic test accuracy review investigating the accuracy of screening tests for type 2 diabetes mellitus. Diagnostic test accuracy reviews will be clearly identifiable by 'flags' within *The Cochrane Library*, but these will be lost when the abstracts are transferred to bibliographic databases.

To overcome this problem it is recommended that the phrase 'diagnostic accuracy' be included somewhere in the abstract – the 'objectives' section may provide a natural home for this phrase. This is a key phrase that is highly likely to be used in searching by researchers who want to identify reviews of diagnostic tests. Combining this phrase with the phrase for the *Cochrane Database of Systematic Reviews* as a journal title (for example, 'Cochrane Database of Syst Rev' in PubMed) will retrieve Cochrane reviews of diagnostic test accuracy. Ultimately, the introduction of specific database indexing terms into MEDLINE (such as Publication Types 'diagnostic test accuracy review' and 'diagnostic test accuracy study') should improve the efficiency of searching.

The content under each heading in the abstract should be as follows:

Background

One or two sentences explaining the context, the purpose and rationale for the review.

Objectives

A precise statement of the primary objective of the review, ideally in a single sentence. Where possible the style should be of the form 'To determine the diagnostic accuracy of [Index test] for diagnosing [target condition] in [patient description]'. The exact phrase 'diagnostic accuracy' is important as this can then be used as a search term to retrieve Cochrane systematic reviews of diagnostic test accuracy from MEDLINE and the Science Citation Index, and other publications of these reviews in other electronic bibliographic databases.

Search methods

List the sources and the dates of the search for each source, using the active form 'We searched...'. For example 'We searched MEDLINE from January 1950 to December 2006'. Search terms should not be listed here, and if a large number of databases have been searched only key databases and the number of databases should be stated. The date range of the search for each database should be given. For most databases such as MEDLINE, it should be in the form 'MEDLINE (January 1950 to December 2006)'. Searching of bibliographies for relevant citations can be covered in a generic phrase 'reference lists of articles'. If there were any constraints based on language or publication status, these should be listed. If individuals or organisations were contacted to locate studies this should be noted and it is preferable to use, 'We contacted pharmaceutical companies' rather than a listing of all the pharmaceutical companies contacted. If journals were specifically handsearched for the review, this should be noted.

Selection criteria

Briefly list the main criteria used to select studies for inclusion in the review. Please include; type of study design (for example consecutive patient series and /or case-control studies); index and /or comparator tests; target condition; eligible reference standards, and key characteristics of the study population.

Data collection and analysis

Describe how data extraction and quality assessment of studies were done, whether by more than one person, and whether multiple assessments were done independently. The description should be restricted to how data were extracted and assessed, and not include details of what data were extracted. It should be stated whether a meta-analysis was done and if so the statistical methods used should be named, and the summary statistics estimated stated. If comparisons are made between index and/or comparator tests it should be stated whether comparisons were direct (made within studies) or indirect (made between studies).

Results

This section should begin with the total number of studies and participants included in the analysis, and brief details pertinent to the interpretation of the results, such as a summary of study quality, diversity in study characteristics and heterogeneity in study results. It should address the primary objective and be restricted to the main results. Wherever possible, accuracy should be expressed using summary statistics most likely to help someone make a decision about whether or not to use a particular test. Any summary statistics in the abstract

should be the same as those presented in the review and in the summary of results table. Summary statistics should be stated together with confidence intervals.

Authors' conclusions

The primary purpose of the review should be to present information, rather than to offer advice. The authors' conclusions should be succinct, address the review question and draw directly from the findings of the review so that they directly and obviously reflect the main results. Assumptions should not be made about practice circumstances, values, preferences and tradeoffs, and the giving of advice or recommendations should generally be avoided. Any important limitations of data and analyses should be noted. Important conclusions about the implications for research should also be included.

Box 4.3.a: Example of an abstract for a Cochrane Systematic Review of Diagnostic Test Accuracy: Magnetic resonance imaging for provisional diagnosis of multiple sclerosis in patients with suspected disease.

Background

Detection of clinically silent brain lesions on magnetic resonance imaging (MRI) in patients with a single episode of neurological dysfunction may allow earlier diagnosis of multiple sclerosis (MS) if MRI lesions accurately predict the occurrence of a second episode required for a definitive MS diagnosis.

Objective

To determine the diagnostic accuracy of MRI for the provisional diagnosis of MS in patients with suspected disease.

Search methods

We searched MEDLINE (January 1950 to November 2004) and 11 other electronic databases (from inception to November 2004). We conducted citation searches, and screened reference lists of included studies.

Selection criteria

Diagnostic accuracy studies that compared MRI (or diagnostic criteria incorporating MRI) with standard clinical diagnosis of MS.

Data collection and analysis

Two authors independently screened titles and abstracts for relevance. Screening for inclusion, data extraction, and quality assessment were carried out by one author and checked by a second. Studies were assessed for methodological quality using QUADAS. HSROC meta-analytical methods were used to estimate summary ROC curves and diagnostic odds ratios, and to investigate the impact of study design and length of follow up on diagnostic accuracy.

Results

29 studies (18 cohort studies, 11 other designs) recruiting 2714 patients were included. Test accuracy depended on both study design and length of follow-up, hence we focused on the results of the two higher quality studies with cohort designs and clinical follow-up of 10 years or more. The presence of many lesions on MRI (>8 or > 10), could not accurately rule in MS (positive likelihood ratios of 3.6; 95% CI 0.9 to 14.4 and 1.9; 95% CI 1.0 to 3.7). The absence of lesions had limited ability to rule out a diagnosis of MS (negative likelihood ratios of 0.1; 95% CI 0.04 to 0.3 and 0.5; 95% CI 0.4 to 0.6).

Conclusions

Use of MRI to confirm MS after a single attack of neurological dysfunction has poor accuracy, and may lead to both misdiagnosis and inappropriate treatment.

4.4 Writing a plain language summary

The format and structure of plain language summaries for systematic reviews of diagnostic test accuracy are currently the subject of discussion with the Cochrane Steering Group. This section will be updated once these discussions are completed.

4.5 Main text

The text of the review should be as succinct and readable as possible. Although there is no formal word limit on Cochrane reviews, review authors should consider 10,000 words an absolute maximum unless there is a special reason to write a longer review (for example, where a large number of index tests are evaluated). The majority of reviews should be substantially shorter than this. A review should be written so that someone who is not an expert in the area can understand it, in light of the following policy statement, reported in Cochrane News 1999; 15: 14:

“The target audience for Cochrane reviews is people making decisions about health-care. This includes health-care professionals, consumers and policy makers with a basic understanding of the underlying disease or problem.

It is a part of the mission and a basic principle of The Cochrane Collaboration to promote the accessibility of systematic reviews of the effects of healthcare interventions to anyone wanting to make a decision about healthcare. However, this does not mean that Cochrane reviews must be understandable to anyone, regardless of their background. This is not possible, any more than it would be possible for Cochrane reviews to be written in a single language that is understandable to everyone in the world. It is important to translate the content, or elements of the content, of reviews into different languages and formats targeted at different audiences including healthcare professionals, consumers and policy makers in a variety of circumstances.

Cochrane reviews should be written so that they are easy to read and understand by someone with a basic sense of the topic who may not necessarily be an expert in the area. Some explanation of terms and concepts is likely to be helpful, and perhaps even essential. However, too much explanation can detract from the readability of a review. Simplicity and clarity are also vital to readability. The readability of Cochrane reviews should be comparable to that of a well-written article in a general medical journal.”

The text of a Cochrane review contains a number of fixed headings and subheadings that are available in the RevMan5 document structure. Additional optional subheadings are also included in the structure, but authors should not be limited by these and should add their own subheadings where appropriate. Authors are encouraged to use the optional subheadings included in the structure where possible, but not if they make individual sections needlessly short.

Text cannot be placed immediately under the following Level 1 headings: ‘Abstract’, ‘Methods’, ‘Criteria for considering studies for this review’, ‘Results’, or ‘Authors conclusions’. Text for these sections starts below the first subsequent subheading.

Background

[fixed, level 1 heading]

Well-formulated review questions do not appear out of thin air. They occur in the context of an existing body of knowledge. This context should be explained in the background section of

the review. The background helps set the rationale for the review, and should explain why the questions being asked are important and why closely related questions are not being covered. The background section of the review should inform the readers of the review about why the review is being done, particularly where there are existing systematic reviews published outside The Cochrane Collaboration. This can generally be done within 1 to 1.5 printed pages.

The background section contains 4 optional subheadings which can be used to help structure the text:

Target condition being diagnosed [optional, level 2 heading]

A description of the target condition of interest (frequency, severity, prognosis and possible treatments). If there are Cochrane reviews of interventions for the target condition they should be cross-referenced here.

Index test(s) [optional, level 2 heading]

A description of the index tests that are being evaluated in this review, whether they are currently used in clinical practice, and the roles being considered for the tests (for example, as replacement for a comparator test because of lower cost and invasiveness).

Alternative test(s) [optional, level 2 heading]

A description of the possible diagnostic tests and strategies that could (and are) used in clinical practice, irrespective of whether they are evaluated in this review. This will help place the review in context of all available diagnostic options.

Rationale [optional, level 2 heading]

The background helps set the rationale for the review, and should explain why the questions being asked are important. It might also mention why this review was undertaken and how it might relate to a wider review of a general problem.

Objectives [fixed, level 1 heading]

The review question should be clearly stated. The primary objective should be described and include the index test(s), the target condition verified by the reference standard ('gold standard') and the study population. Where possible the style should be 'To determine the diagnostic accuracy of [index test] for detecting [target condition] in [patient description]'. It should also be clear from the objective whether the authors want to investigate the accuracy of an index test as triage for the current normal test regime, as a replacement for it, or in combination with it (see [Chapter 5](#)). The term 'comparator' is specifically used to refer to what is thought to be the most commonly used current normal test regime. Where the aim of the review is to make comparisons between tests these should be clearly stated.

Secondary objectives [optional, level 2 heading]

Complex reviews that investigate multiple questions may categorise their objectives as 'Primary Objectives' and 'Secondary Objectives'. For example, the primary objectives may be to compare test accuracy between two tests; the secondary objectives may estimate test accuracy for each test at pre-specified thresholds. However, secondary objectives related to investigating heterogeneity between study results should not be listed under this subheading but under the next subheading.

Investigation of sources of heterogeneity [optional, level 2 heading]

Heterogeneity investigations explore factors which may affect diagnostic accuracy, and are essential because they may provide a framework by which the expected heterogeneity may be explained a priori and to provide a more clinically useful review. For example, the test accuracy of troponin may vary depending upon when the test is done after the start of symptoms. Providing a primary objective only, for example a comparison of troponin against Creatine Kinase-MB for patients with chest pain to detect myocardial infarction, is not sufficient for clinical decision making when patients present at different time points after the onset of chest pain, and the test performance of troponin may vary accordingly. Alternative subgroups can be aspects of study design and execution, age groups, setting, differences in the presence or degree of clinical characteristics or differences in the operation of either the index test or the reference test.

Methods

[fixed, level 1 heading]

The Methods section in a protocol should be written in the future tense. Cochrane reviews are updated as new evidence accumulates, therefore methods outlined in the protocol should generally anticipate a sufficiently large number of studies to address the review's objectives (even if it is known this is not the case).

The Methods section in a full review should be written in the past tense, and should describe what was done to obtain the results and conclusions of the current version of the review. Often a review is unable to implement all of the methods outlined in the protocol, usually because there is insufficient evidence. In such circumstances, it is recommended that the methods that were not implemented still be outlined in the review, so that it serves as a protocol for future updates of the review. Some Cochrane review groups (CRGs) have policies on this issue, and these should be available from the Review Group Co-ordinator (RGC). Examples include adding an additional subsection at the end of 'Methods of the review', or including the methods for future updates in an additional table.

In the methods section, the authors should clearly describe the selection criteria for considering studies for the review (Chapter 5 and Chapter 6), the methods used to identify relevant studies (Chapter 7), the process used for selection of studies and collecting data (Chapter 8) and how the methodological quality of the included studies is assessed (Chapter 9). A statistician may best write the section for describing the statistical analysis and data synthesis (Chapter 10). In addition, information about how to investigate sources of heterogeneity and any pre-planned sensitivity analyses should be described clearly here (Chapter 10).

Criteria for considering studies for this review

[fixed, level 2 heading]

The eligibility criteria required for studies to be included in the review must be clearly stated.

Types of studies

[fixed, level 3 heading]

Eligible study designs should be stated here, along with any thresholds for inclusion based on the conduct or quality of the studies. For example, 'All consecutive series of patients and case-control studies' or 'All study designs'. Exclusion of particular types of studies (for example, case-control studies, retrospective studies) should briefly be justified. Restrictions based on the use of particular reference standards should not be listed here.

Participants

[fixed, level 3 heading]

Specify the participants for whom the test would be applicable, including any restrictions on diagnoses, age groups and settings. Planned subgroup analyses related to participant characteristics should not be listed here.

Index tests

[fixed, level 3 heading]

Specify the test or tests under evaluation.

Comparator tests

[optional, level 3 heading]

This subheading is optional. The comparator test is the testing regime used in practice, which the index test may be seeking to replace. Not all reviews will have a comparator test, hence it is an optional subheading. If a comparator is stated in the review question it should be stated here. There is potential to confuse the comparator with the reference standard. However the reference standard used in the context of research to establish test accuracy will not usually be the same as the test or test combination used in day-to-day practice.

Target conditions

[fixed, level 3 heading]

The target condition is a particular disease or disease stage that the index test is intended to identify. Tests may occasionally be used to differentiate between several target conditions – if this is the case they should all be listed here.

Reference standards

[fixed, level 3 heading]

Describe the clinical reference standards ('gold standard') that are considered appropriate to establish the presence or absence of the target condition in the tested population. If particular reference standards are commonly used but considered inadequate they should be stated here as exclusion criteria.

Search methods for identification of studies

[fixed, level 2 heading]

Electronic searches

[fixed, level 3 heading]

The methods used to identify studies should be summarized. Further details of the content of these sections are discussed in [Chapter 7](#). The bibliographic databases searched, the dates and periods searched and any constraints, such as language, should be stated. The full search strategies for each database should be listed in an appendix to the review.

Searching other resources

[optional, level 3 heading]

List grey literature sources, such as reports and conference proceedings. If journals are specifically handsearched for the review, this should also be noted. List people (for example, researchers, experts) and/or organisations who were contacted. List any other sources, which may include, for example, reference lists, the World Wide Web or personal collections of articles.

This text may be organised under the following four subheadings:

- Grey literature,
- Handsearching,
- References lists and
- Correspondence.

These subheadings are not included in the RevMan5 structure, so if required an author will need to create them. They can be used either in place of 'Searching other resources' or as subheadings to it.

Data collection and analysis [fixed, level 2 heading]

Selection of studies [fixed, level 3 heading]

The method used to apply the selection criteria should be described stating whether the criteria were applied independently by more than one author, and how any disagreements were resolved (see [Chapter 8](#)).

Data extraction and management [fixed, level 3 heading]

State the method used to extract or obtain data from published reports or from primary authors of the included studies (for example, using a data extraction/data collection form). Any reanalysis of individual patient data should be described. Whether data are extracted independently by more than one author should be stated, along with how any disagreements are resolved. If relevant, methods for processing data in preparation for analysis should be described (see [Chapter 8](#)).

Assessment of methodological quality [fixed, level 3 heading]

Assessment of methodological quality involves describing both the tool, and the method by which it was applied. The tool(s) used (i.e. QUADAS) should be described or referenced, with an indication of how quality assessments were incorporated into the interpretation of the results (see [Chapter 9](#)). Operational definitions of items within the quality assessment tool should be stated (possibly using an additional table). For example, the QUADAS scale requires authors to explicitly state what they consider to be ‘appropriate spectrum’ and an ‘appropriate reference standard’ before applying the tool. The method used to assess methodological quality should be described, stating whether the tool was applied independently by more than one author and how any disagreements were resolved.

Statistical analysis and data synthesis [fixed, level 3 heading]

In this section, the descriptive and inferential statistical methods should be described. Descriptive methods consist of tabulation, graphical displays of estimates of diagnostic accuracy (for example sensitivities and specificities), and plotting the study results in ROC space (see [Chapter 10](#)). Inferential statistical methods are used for the estimation of summary ROC curves and average operating points, testing of differences between tests, and investigations of heterogeneity. Details should be given of the statistical method and model used, what parameters were estimated, whether random effects were estimated, and the software used.

Investigations of heterogeneity [optional, level 3 heading]

Indicate how the sources of heterogeneity listed in the objectives were investigated (see [Chapter 10](#)).

Sensitivity analyses [optional, level 3 heading]

Pre-planned sensitivity analyses should be stated here. These could include restricting analyses to a particular subgroup of patients, or to studies without a particular methodological shortcoming for example verification bias or review bias (see [Chapter 10](#)).

Assessment of reporting bias [optional, level 3 heading]

If any tests or investigations were undertaken to detect reporting biases the methods used should be explained here (see [Chapter 10](#)).

Results

[fixed, level 1 heading]

Results of the search

[fixed, level 2 heading]

The results section of the full review should start with a summary of the results of the search, reporting the number of citations identified by the electronic searches, the number for which full reports were retrieved, the number of citations that were finally included in the review, and the number of unique studies that they report. Brief details should be given of the occurrence of duplicate reports citations of the same studies. Similar details should be given for the results of searching other sources where possible (for example handsearching, correspondence and reference lists).

An overview of the selection process should be given. This can be summarized using a flow diagram, and it is recommended that authors consider including one as an additional Figure (see [Chapter 7](#)).

The number of included studies should be clearly stated, together with the numbers of participants and the number who have the target condition. If a review evaluates more than one test these numbers should be given per test. Where pairwise comparisons are based on direct (within study) comparisons, the number of studies and patients available for each comparison should be stated.

Individual details of the studies are tabulated in the ‘Characteristics of included studies’ table. A succinct summary of the key characteristics of the design, participants, index tests and other methodological issues presented in this table should be given. In some circumstances an additional table may be useful to give a tabular summary of the different index tests that were encountered, or other aspects of the study. If such a table is produced a link to it must be created at an appropriate place in this section.

The number of excluded studies should be mentioned here and refer to the information contained in the ‘Characteristics of Excluded Studies’ table, providing a succinct summary of why studies were excluded from the review.

Methodological quality of included studies

[fixed, level 2 heading]

A figure summarising overall methodological quality, and a table of the methodological quality ratings for individual studies can be produced automatically in RevMan5 (see Figures below), and should be linked to the text in this section. The text should summarize the general quality of the included studies, its variability across studies and any important flaws in individual studies which will threaten the validity of the results. The criteria that were used to assess the methodological quality bias should be described in the ‘Methods’ and not here. For reviews that evaluate several tests in separate studies, reporting of methodological quality by test should be considered if there are important differences.

Findings

[fixed, level 2 heading]

The main findings on the diagnostic accuracy of the index tests studied in the review should be presented, together with the results of the planned comparisons between the index tests, or between the index tests and the comparator tests. The section should directly address the objectives of the review rather than list the findings of the included studies in turn. The focus should be on reporting the pattern of results across all the included studies. Numerical summaries and results of statistical analyses may best be summarized in additional tables and a link to the table placed in the text where they are discussed. Links to relevant forest plots and summary ROC plots may also be placed in the text.

Subheadings are encouraged if they make reading easier (for example, for each index test if a review addresses more than one). Any exploration of heterogeneity, sensitivity analyses and investigations of possible biases that were undertaken should be reported.

Inferences should be avoided in the results section.

Discussion **[fixed, level 1 heading]**

A structured discussion can aid the systematic consideration of the implications of the review (Docherty 1999).

Summary of main results **[fixed, level 2 heading]**

The authors should summarize the main findings of the diagnostic accuracy of the index test(s). This description should mirror the summary of results table (it may be easiest to create this table before writing this section). The authors should summarize the relevance of the findings of investigations of heterogeneity. There should also be comment on the homogeneity and methodological quality of the evidence, and the completeness of the evidence in terms of whether it has been possible to address all the objectives of the review and the degree to which uncertainties remain. Consideration should be given to the amount of data available to address the primary hypotheses.

Strengths and weaknesses of the review **[fixed, level 2 heading]**

The author should state the strengths and limitations of the review with regard to preventing bias. These may be factors within, or outside, the control of the review authors. The discussion might include whether all relevant studies were identified, whether all relevant data could be obtained, or whether the review methods used (for example, searching, study selection, data extraction, and analysis) could have introduced bias. The degree to which robust conclusions can be drawn if the study results are notably heterogeneous should be discussed.

Comments on how the included studies fit into the context of other published reviews might be included, stating clearly whether the other evidence was systematically reviewed.

Applicability of findings to clinical practice and policy **[fixed, level 2 heading]**

To assess the applicability of their findings authors consider whether the studies that were identified were sufficient to address all of the objectives of the review. They should consider the relevance of the patients, tests and settings that were included in the review to the review objectives, and identify the limits of the situations to which the evidence from the included studies definitely applies. For example, studies from secondary care may have limited relevance to primary care, or the evaluations located may have only evaluated an outmoded version of the test technology. Comments on how the results of the review fit into the context of current practice should also be included here, although authors should bear in mind that current practice might vary internationally.

Authors' conclusions **[fixed, level 1 heading]**

The primary purpose of the review should be to present information, rather than to offer advice. Conclusions of the authors are divided into two sections:

Implications for practice **[fixed, level 2 heading]**

The implications for practice should be as practical and unambiguous as possible. They should not go beyond the evidence that was reviewed and be justifiable by the data presented in the review.

Implications for research

[fixed, level 2 heading]

This section of Cochrane reviews is used increasingly by people making decisions about future research, and authors should try to write something that will be useful for this purpose. As with the 'Implications for Practice', the content should be based on the available evidence and should avoid the use of information that was not included or discussed within the review.

In preparing this section, authors should consider the different aspects of research, perhaps using types of studies, index tests, study population and target condition verified by the reference standard as a framework. Implications for *how* research might be done and reported should be distinguished from *what* future research should be done. It is important that this section is as clear and explicit as possible. General statements that contain little or no specific information, such as "Future research should be better conducted" or "More research is needed" are of little use to people making decisions, and should be avoided.

Acknowledgements

[fixed, level 1 heading]

This section should be used to acknowledge any individuals or organisations who have contributed but who are not listed among the authors. This would include any previous authors of the Cochrane review and might include the contributions of the editorial team of the CRG. Permission should be obtained from persons acknowledged.

Contribution of authors

[fixed, level 1 heading]

The names and contribution of the present co-authors should be described in this section. One author, usually the contact author, should be identified as the guarantor of the review. All authors should discuss and agree on their respective descriptions of contribution before the review is submitted for publication in the *Cochrane Database of Systematic Reviews*. When the review is updated, this section should be checked and revised as necessary to ensure that it is accurate and up to date.

The following potential contributions have been adapted from Yank et al (Yank 1999). This is a suggested scheme and the section should describe what people did, rather than attempt to identify within which of these categories someone's contribution falls. Ideally, the contributors should describe their contribution in their own words:

- Conceiving the review;
- Designing the review;
- Co-ordinating the review;
- Data collection for the review
- Designing search strategies;
- Undertaking searches;
- Screening search results;
- Organising retrieval of papers;
- Screening retrieved papers against inclusion criteria;
- Appraising quality of papers;

- Extracting data from papers;
- Writing to authors of papers for additional information;
- Providing additional data about papers;
- Obtaining and screening data on unpublished studies;
- Data management for the review;
- Entering data into RevMan5;
- Analysis of data;
- Interpretation of data;
- Providing a methodological perspective;
- Providing a clinical perspective;
- Providing a policy perspective;
- Providing a consumer perspective;
- Writing the review;
- Providing general advice on the review;
- Securing funding for the review;
- Performing previous work that was the foundation of the current study.

Declarations of interest

[fixed, level 1 heading]

Authors should report any conflict of interest that might be perceived by others as being capable of influencing their judgements, including personal, political, academic and other possible conflicts, as well as financial conflicts. Authors must state if they have been involved in a study included in the review. Details of The Cochrane Collaboration's policy on conflicts of interest appear in [Chapter 2](#) of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2006a).

Financial conflicts of interest cause the most concern, and should be avoided, but must be reported if there are any. Any secondary interest (such as personal conflicts) that might unduly influence judgements made in a review (concerning, for example, the inclusion or exclusion of studies, assessments of the validity of included studies or the interpretation of results) should be reported.

If there are no conflicts of interest, this should be stated explicitly, for example, by writing 'None known'.

Differences between protocol and review

[fixed, level 1 heading]

Authors should report and clearly explain why the differences between the methods reported in the protocol and the full review exist.

Published notes

[fixed, level 1 heading]

These will be published in the *Cochrane Database of Systematic Reviews*. They may include:

- Editorial notes and comments from the CRG and the Diagnostic Test Accuracy Editorial Board, for example where issues highlighted by editors or referees are believed worthy of publication alongside the review;

- A summary of previous changes to the review. Changes since the previous published version must be stated under ‘What’s new’.

The published notes must be completed for all withdrawn publications to give the reason for withdrawal. Only the cover sheet and published notes are published for withdrawn protocols and reviews.

4.6 Tables

4.6.1 Characteristics of included studies

This is a standard table with eight entries for each study including the following fixed items: (1) Study ID, (2) Clinical features and settings, (3) Participants, (4) Study design, (5) Target condition and reference standard(s), (6) Index and comparator test(s), (7) Follow up and (8) Notes. Footnotes should be used for explanations of any abbreviations used (these will be published in the *Cochrane Database of Systematic Reviews*).

Table 4.6.a: Guide to the contents of the ‘Characteristics of included studies table’.

Heading	Content
Study ID	First author, year of publication
Clinical features and settings	Report the presenting clinical signs and symptoms, and previous test results, clinical setting, and referral routes.
Participants	Report the sample size, socio-demographic items (age, gender, ethnic group etc), co-morbidities, geographic region.
Study design	Was the sample selected as a single group, or as separate groups with and without the target condition? Were participants consecutively enrolled in the study? How was comparability of the groups ensured? Were participants identified retrospectively or prospectively? If studies evaluated more than one test, how were tests allocated to individuals, or did each individual receive all tests?
Target condition and reference standard(s)	State the target condition, the definition and description of reference standard(s), and the criteria used to define an individual to have the target condition. Give details of test operators (who performed the reference standard). If applicable, report the timing, manufacturer, technical characteristics, etc. of the reference standard. Report the prevalence of the target condition in the sample.
Index and comparator tests	For all index and comparator tests, report the test(s) definition and description, criteria for positive test results, and details of test operators. If applicable, report the timing, manufacturer and technical characteristics.
Follow up	How much of the sample was lost, or has missing or uninterpretable test

	results? Were adverse events noted that could be caused by the test?
Notes	Other information that the author considers relevant to report, for example sources of funding, abbreviations, and other issues not covered elsewhere.

4.6.2 Assessment of methodological quality table

This table is used to record the methodological quality of each study. The table contains eleven predefined quality assessment items from the QUADAS tool (see Table 4.6.b). These items are strongly recommended, but can be deleted in exceptional circumstances when not relevant. In addition it is possible to enter custom quality items by creating ‘user defined’ fields. Details of how to edit the table can be found in [RevMan5 Help](#). Full details of how to assess quality and how to decide which quality items to assess can be found in [Chapter 9](#).

For each item in the quality assessment the author must enter both a description of how the study addressed the issue, and a classification as to whether this was adequate (‘yes’), inadequate (‘no’), or whether not enough detail was presented for a judgement to be made (‘unclear’). For both the standard and the user defined items details of the criteria for classifying studies as ‘yes’, ‘no’ and ‘unclear’ must be stated in the review protocol, probably using an additional table (see [Section 4.6.1.7](#)).

It is possible to attribute quality assessments either to a study, or to each test within each study. In the former, all tests within a study are classified the same way, in the latter, tests within the same study can have different quality assessments. In RevMan5 this is described as ‘by test’ or ‘by study’. It is possible to specify a mixture of ‘by test’ and ‘by study’ quality assessment items within a review. For details of how to define the quality assessment table please refer to [RevMan5 Help](#).

Table 4.6.b: Guide to the contents of the Assessment of methodological quality table

Representative spectrum?	Was the spectrum of patients representative of the patients who will receive the test in practice?
Acceptable reference standard?	Is the reference standard likely to correctly classify the target condition?
Acceptable delay between tests?	Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?
Partial verification avoided?	Did the whole sample or a random selection of the sample, receive verification using a reference standard of diagnosis?
Differential verification avoided?	Did patients receive the same reference standard regardless of the index test result?
Incorporation avoided?	Was the reference standard independent of the index test? (i.e. the index test did not form part of the reference standard).
Reference standard results blinded?	Were the reference standard results interpreted without knowledge of the results of the index test?
Index test results blinded?	Were the index test results interpreted without knowledge of the results of the reference standard?

Relevant clinical information?	Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?
Uninterpretable results reported?	Were uninterpretable/ intermediate test results reported?
Withdrawals explained?	Were withdrawals from the study explained?

4.6.3 Characteristics of excluded studies

Studies for which reports were retrieved based on the abstract and title, but finally excluded based on the content of the report, should be listed and the key reason for exclusion should be given. This should be kept brief, and a single reason for exclusion is usually sufficient.

4.6.4 Characteristics of studies awaiting classification

Details of studies for which insufficient information is available to include them or exclude them from the review should be reported in this table, using the same structure as the included studies table. For example, translations may be awaited, or confirmation of details required from authors, which mean some studies cannot be included when the review is first published. Studies which are discovered just before publication could also be listed here, but all attempts should be made to include all available literature in the review.

4.6.5 Characteristics of ongoing studies

Studies that may be eligible but are still ongoing are reported here. Please record principal investigator and/or contact person, location and country, web site address (if provided), start date, target condition, reference standard and tests which are being evaluated.

4.6.6 Summary of results tables

In order to make Cochrane systematic reviews of diagnostic test accuracy informative and as accessible as possible for readers, they must contain a summary of results table (see [Chapter 11](#)) as well as a summary in the text. It is essential however that the two are consistent with each other.

4.6.7 Additional tables

Additional tables may be used for information that cannot be conveniently placed in the text or in fixed tables. Examples include:

- information to support the background for example details about the index test, comparator test or reference standard;
- explicit details of the methodological quality criteria assessed;
- numerical statistical summaries.

4.7 Studies and references

Authors should check all references for accuracy (Dickersin 1986, Eichorn 1987).

4.7.1 References to studies

Studies are organized under four fixed headings:

Included studies

Studies that specifically meet the inclusion criteria and are included in the review should be listed here.

Excluded studies

Studies for which reports were retrieved but were found not to meet the inclusion criteria should be listed here.

Studies awaiting assessment

Relevant studies that have been identified, but cannot be assessed for inclusion until additional data or information are obtained, should be listed here. These need not be cited in the text of the review.

Ongoing studies

Studies that are ongoing but meet (or appear to meet) the inclusion criteria should be listed here.

Each of these headings can include multiple studies (or no studies). A study is identified by a 'Study ID'. A year can be associated with each study (usually the year of completion, or the publication year of the primary reference to that study). In addition, each study should be assigned a category of 'Data source' from among the following.

- Published data only;
- Published and unpublished data;
- Unpublished data only;
- Unpublished data sought but not used.

Each study can have multiple references. Each reference has its own 'Reference ID'. A single reference for each study should be awarded the status of 'Primary reference', usually the reference that most completely reports the study.

4.7.2 Other references

References other than those to studies are divided into three categories:

Additional references

Other references cited in the text should be listed here, including those cited in the background and methods sections. If a report of a study is cited in the text for some reason other than referring to the study (for example, because of some background or methodological information in the report), it should be listed here as well as under the relevant study.

Other published versions of this review

References to other published versions of the review in a journal, textbook or the *Cochrane Database of Systematic Reviews* should be listed here.

Classification pending references

RevMan5 also includes an optional subheading ‘Classification pending references’ category to facilitate **organisation** of references while preparing a review. Any references remaining in this category when the review is submitted are not published.

4.8 Data and analyses

4.8.1 Study results

Results of the studies included in a review can be organised either by entering all data from a single study together even when it includes several tests (data tables by study), or by entering all data for a single test from several studies together (data tables by test). Each test requires entry of the number of true positives, false positives, false negatives and true negatives. Where results are available for a test at several thresholds these can either be added as separate results with a covariate (see below) specifying the threshold, or several tests defined each with a specific threshold. When the review is published all of the data entered will be displayed in paired sensitivity-specificity forest plots, even if these are not included in the review. This flexible approach to organise and enter data differs from that for Cochrane reviews of interventions where the data structure (comparisons, outcomes, subgroups) defines the analyses which will be undertaken. In reviews of test accuracy all data are entered before the structure of the analyses is specified.

4.8.2 Covariates

For each test and study, authors can define one or more covariates for example setting, age, severity of disease, or specific features of the test such as threshold. These covariates can be used for identifying subgroups that may have different test accuracy results.

4.8.3 Analyses

In RevMan5, authors can select analyses from a list of five options:

- a simple analysis of a single test;
- a simple analysis of a single test that investigates heterogeneity (subgroups);
- an analysis comparing several tests;
- an analysis comparing several tests that investigates heterogeneity (subgroups);
- an analysis of two tests restricted to paired data.

For each analysis paired forest plots of sensitivity and specificity can be created and summary ROC plots produced. In addition, plots of the summary ROC curve, based on the Littenberg and Moses (Littenberg 1993) linear regression model can be presented. However, summary ROC curves, average operating points including 95% confidence intervals and 95% prediction regions can also be produced in RevMan5 using estimates from more valid statistical models: the hierarchical summary ROC (HSROC) model and the bivariate model.

4.9 Figures

RevMan5 can create four types of figures for automatic inclusion in reviews:

- a methodological quality graph (a bar chart showing overall compliance with the methodological criteria);
- a methodological quality summary (an indication of whether individual studies meet the methodological criteria);

- paired forest plots of sensitivity and specificity (which can be ordered and grouped by covariates);
- summary ROC plots (with variations for including lines, operating points, confidence and prediction regions, and indicating different tests and subgroups using colours).

Authors can also import their own additional figures. All figures need to be created within Figures, and captions specified. To be published with the review the Figures need to be linked to from the text.

Review authors can also include additional figures created by other software. Additional figures should never be used for content that can be included in other ways in RevMan5, for example as standard RevMan5 graphs, tables or created as additional tables. Guidance on technical aspects of preparing additional figures, including appropriate file size, guidance on labelling and captions is available in RevMan5 help files. The images authors upload as additional figures will not be edited or otherwise improved by others, but will be published 'as is'. It is therefore important that images are fully fit for publication. Important results from all additional figures should be summarized in the Results section of the review text. Wherever numerical results taken from a figure are reported in the text of the review their meaning and derivation should be clear, and a reference to the relevant figure should be provided.

If permission to publish a copyrighted figure is granted, the final phrase of the figure caption must be: "Copyright © [Year] [Name of copyright holder, or other required wording]: reproduced with permission." Warning! Large images take up lots of disk space. A single large image can easily take up ten times the total space used for the text and tables of the review. This leads to very large export files. Scanned images can be especially space-consuming because the resolution may be much higher than needed. Always use images with a good balance between resolution and detail, and include as few images as possible.

4.10 Sources of support to the review

Authors should give details of grants that supported the review and other forms of support, such as support from their university or institution in the form of a salary. Sources of support are divided into 'internal' (provided by the institutions at which the review was produced) and 'external' (provided by other institutions or funding agencies).

4.11 Feedback

This section is used to present feedback and comments from people who have read the published protocol or review. There are three subheadings: **Summary**, **Reply** and **Contributors**. The summary should be prepared by the feedback editor for the CRG in consultation, if necessary, with the person submitting the comment. A reply to this should then be prepared by the author(s) of the review. Details of the people who contributed to this process should be given. Further information on the comments and feedback and the updating of reviews is given in [Chapter 10](#) of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2006b).

4.12 Appendices

Appendices provide a place to publish additional material that might be of interest to readers of the review. Appendices should be considered as supplementary information, as they may not appear in some reduced formats of the published review. Examples of the types of material that authors may wish to present in Appendices include:

- Details of the search strategies used to identify studies for the review in each of the databases searched (the recommended place to put these);
- Detailed statistical methods;
- Data extraction forms;
- Correspondence with authors of studies.

4.13 Contributions to this chapter

Editors: Nynke Smidt, Jonathan Deeks, Theresa Moore.

Contributors: This chapter was based on:

Higgins JPT, Green S (editors). Chapter 4: Guide to the contents of a Cochrane protocol and review. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.0 (updated February 2008). The Cochrane Collaboration, 2008. Available from <http://www.cochrane.org/resources/handbook>.

And

Schünemann HJ, Oxman AD, Higgins JPT, Vist GE, Glasziou P, Guyatt GH. Chapter 11: Presenting results and 'Summary of findings tables'. In: Higgins JPT, Green S (editors), *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.0 (updated February 2008). The Cochrane Collaboration, 2008. Available from <http://www.cochrane.org/resources/handbook>.

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4.14 References

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