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Comparison of conference abstracts and presentations with full-text articles in the health technology assessments of rapidly evolving technologies

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The research reported in this monograph was commissioned and funded by the HTA Programme on behalf of NICE as project number 04/05/01. The protocol was agreed in May 2004. The assessment report began editorial review in July 2005 and was accepted for publication in August 2005. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Comparison of conference abstracts and presentations with full-text articles in the health technology assessments of rapidly evolving technologies

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Objectives: To assess the extent of use of data from conference abstracts and presentations in health technology assessments (HTAs) provided as part of the National Institute for Health and Clinical Excellence (NICE) appraisal process. Also to assess the methodological quality of trials from conference abstracts and presentations, the consistency of reporting major outcomes between these sources and subsequent full-length publications, the effect of inclusion or exclusion of data from these sources on the meta-analysis pooled effect estimates, and the timeliness of availability of data from these sources and full articles in relation to the development of technology assessment reviews (TARs).

Data sources: A survey of seven TAR groups. An audit of published TARs: included all NICE TARs published between January 2000 and October 2004. Case studies of selected TARs.

Review methods: Analyses of the results of the survey and audit were presented as a descriptive summary and in a tabular format. Sensitivity analyses were carried out to compare the effect of inclusion of data from abstracts and presentations on the meta-analysis pooled effect estimates by including data from both abstracts/presentations and full papers, and data from only full publications, included in the original TAR. These analyses were then compared with meta-analysis of data from trials that have subsequently been published in full.

Results: All seven TAR groups completed and returned the survey. Five out of seven groups reported a general policy that included searching for and including studies available as conference abstracts/presentations. Five groups responded that if they included data from these sources they would carry out methodological quality assessment of studies from these sources using the same assessment tools as for full publications, and manage the data from these sources in the same way as fully published reports. All groups reported that if relevant outcome data were reported in both an abstract/presentation and a full publication, they would only consider the data in the full publication. Conversely, if data were only available in conference abstract/presentation, all but two groups reported that they would extract and use the data from the abstract/presentation. In total, 63 HTA reports for NICE were identified. In 20 of 63 TARs (32%) explicit statements were made with regards to inclusion and assessment of data from abstracts/presentations. Thirty-eight (60%) identified at least one randomised controlled trial (RCT) available as a conference abstract or presentation. Of these, 26 (68%) included trials available as abstracts/presentations. About 80% (20/26) of the 26 TARs that included RCTs in abstract/presentation form carried out an assessment of the methodological quality of such trials. In 16 TARs full reports of these trials were used for quality assessment where both abstracts/presentations and subsequent full publications were available. Twenty-three of 63 TARs (37%) carried out a quantitative analysis of results. Of these, ten (43%) included trials that were available as abstracts/presentations in the review; however, only 60% (6/10) of these included data from abstracts/presentations in the data analysis of results. Thirteen TARs evaluated rapidly evolving technologies and only three of these identified and included trial data from conference abstracts/presentations and carried out a quantitative analysis where abstract/presentation data were used. These three TARs were used as case studies. In all three case studies the overall quality of reporting in abstracts/presentations was generally poor. In all case studies abstracts and presentations failed to describe the method of randomisation or allocation concealment. Overall, there was no mention of blinding in 66% (25/38) of the abstracts and in 26% (7/27) of

the presentations included in case studies, and one presentation (4%) explicitly stated use of intention-to-treat analysis. Results from one case study demonstrated discrepancies in data made available in abstracts or online conference presentations. Not only were discrepancies evident between these sources, but also comparison of conference abstracts/presentations with subsequently published full-length articles demonstrates data discrepancies in reporting of results. Sensitivity analyses based on one case study indicated a change in significance of effect in two outcome measures when only full papers published to date were included.

Conclusions: There are variations in policy and practice across TAR groups regarding searching for and inclusion of studies available as conference abstracts/presentations. There is also variation in the level of detail reported in TARs regarding the use of abstracts/presentations. Therefore, TAR teams should be encouraged to state explicitly their search strategies for identifying conference abstracts and presentations, their methods for assessing these for inclusion, and where appropriate how the data were used and their effect on the results. Comprehensive searching for trials available as conference abstracts/presentations is time consuming and may be of questionable value. However, there may be a case for searching for and including abstract/presentation data if, for example, other sources of data are limited. If conference abstracts/presentations are to be included, the TAR teams need to allocate additional time for searching and managing data from these sources. Incomplete reporting in conference abstracts and presentations limits the ability of reviewers to assess confidently the methodological quality of trials. Where conference abstracts and presentations are considered for inclusion in the review, the TAR teams should increase their efforts to obtain further study details by contacting trialists. Where abstract/presentation data are included, reviewers should discuss the effect of including data from these sources. Any data discrepancies identified across sources in TARs should be highlighted and their impact discussed in the review. In addition, there is a need to carry out, for example, a sensitivity analysis with and without abstract/presentation data in the analysis. There is a need for research into the development of search strategies specific to identification of studies available as conference abstracts and presentations in TARs. Such strategies may include guidance with regard to identification of relevant electronic databases and appropriate conference sites relevant to certain clinical areas. As there are limited case studies included in this report, analyses should be repeated as more TARs accrue, or include the work of other international HTA groups.

Contents

Glossary and list of abbreviations

Glossary

Conference abstract and presentations Reports of research studies initially presented at scientific conferences, meetings, workshops or symposia and usually published in conference proceedings or journal supplements in non-peer-reviewed form, or available after the conference from or through Internet-based conference sites.

Full report Reports of research studies published in full in a journal or journal supplement.

Grey literature Study reports that have not been formally published or are not widely distributed.

List of abbreviations

ACR	American College of Rheumatology
AE	adverse event
ATTRACT	Anti-TNF Trial in Rheumatoid Arthritis with Concomitant Therapy
BLIC	British Library Inside Conferences (Datastar)
CCTR	Cochrane Controlled Trials Register
CDSR	Cochrane Database of Systematic Reviews
CI	confidence interval
CPI	Conference Papers Index
CRD	Centre for Reviews and Dissemination
CRF	Cardiovascular Research Foundation
DARE	Database of Abstracts of Reviews of Effectiveness
DES	drug-eluting stents
DMARD	disease-modifying antirheumatic drug
EIGS	European Investigators Study Group
EMEA	European Agency for the Evaluation of Medicinal Products
ERA	Etanercept Early Rheumatoid Arthritis
FDA	Food and Drug Administration
HAQ	Health Assessment Questionnaire
HTA	health technology assessment
IDEA	Internet Database of Evidence-based Abstracts
IL-1Ra	interleukin-1 receptor antagonist

continued

List of abbreviations *continued*

InterTASC	Technology Assessment Services Collaboration
IPA	International Pharmaceutical Abstracts (Dialog)
ISTP	Index to Scientific and Technical Proceedings
ITT	intention-to-treat
IVUS	intravascular ultrasound
MA	meta-analysis
MACE	major adverse cardiac events
MHA	Mental Health Abstracts (Dialog)
MI	myocardial infarction
MR	moderate release
NA	not applicable
NCCHTA	National Coordinating Centre for Health Technology Assessment
NICE	National Institute for Health and Clinical Excellence
NIH	National Institutes of Health
NS	not stated
OR	odds ratio
RA	rheumatoid arthritis
RCT	randomised controlled trial
RET	rapidly evolving technology
SCI	Science Citation Index
SR	slow release
TAR	technology assessment report
TAR group	technology assessment review group
TarNice	National Institute for Health and Clinical Excellence technology assessment report
WOS	Web of Science

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

The evaluation of rapidly evolving health technologies to inform policy decisions is a challenge for those conducting systematic reviews. There is debate as to whether data from unpublished studies available only as conference abstracts and presentations should be included in high-quality systematic reviews of evidence.

Inclusion of unpublished data from conference abstracts and presentations could assist in the generation of a more comprehensive data set. However, conference abstracts and presentations are difficult to locate as they are poorly or not indexed in standard bibliographic databases typically searched when conducting systematic reviews. In addition, overall quality of reporting in conference abstracts and presentations may be inadequate, and data reported in these sources may not be complete and may be inconsistent with those reported in subsequent full publications.

Objectives

The objectives of this research were to assess:

- the extent of use of data from conference abstracts and presentations in health technology assessments (HTAs) provided as part of the National Institute for Health and Clinical Excellence (NICE) appraisal process
- the ability to judge the methodological quality of trials from conference abstracts and presentations
- the consistency of reporting major outcomes between conference abstracts and presentations and subsequent full-length publications
- the effect of inclusion or exclusion of data from conference abstracts/presentations on the meta-analysis pooled effect estimates
- the timeliness of availability of data from abstracts/presentations and full articles in relation to the development of technology assessment reports (TARs).

Methods

Evidence for this research was obtained from:

- a survey of *technology assessment review groups* (*TAR groups*): conducted of all seven TAR groups in the UK to identify current policy and practice regarding identification, inclusion and assessment of conference abstracts and presentations for TAR reports
- an *audit of published TARs*: included all NICE TARs published between January 2000 and October 2004 to identify the extent of use of conference abstracts and presentations
- *case studies of selected TARs*: included TARs of rapidly evolving technologies that identified and included trial data from conference abstracts and presentations and included a quantitative analysis.

Analyses of the results of the survey and audit are presented as a descriptive summary and in a tabular format. Data extracted from abstracts and presentations and subsequent full publications included in the case studies are presented descriptively and quantitatively. Sensitivity analyses were carried out to compare the effect of inclusion of data from abstracts and presentations on the meta-analysis pooled effect estimates by including data from both abstracts/presentations and full papers, and data from only full publications, included in the original TAR. These analyses were then compared with meta-analysis of data from trials that have subsequently been published in full.

Results

Survey

All seven TAR groups completed and returned the survey. Five out of seven groups reported a general policy that included searching for and including studies available as conference abstracts and presentations. Five groups responded that if they included data from abstracts/presentations they would carry out methodological quality assessment of studies from abstracts/presentations using the same assessment tools as for full publications, and would manage the data from these sources in the same way as fully published reports. All groups reported that if relevant outcome data were reported in both an abstract/presentation and a full publication, they would only consider the data in the full publication. Conversely, if data were

only available in a conference abstract/presentation, all but two groups reported that they would extract and use the data from the abstract/presentation.

Audit

In total, 63 HTA reports for NICE were identified. In 20 of 63 TARs (32%) explicit statements were made with regards to inclusion and assessment of data from abstracts/presentations. Thirty-eight (60%) identified at least one randomised controlled trial (RCT) available as a conference abstract or presentation. Of these, 26 (68%) included trials available as abstracts/presentations.

About 80% (20/26) of the 26 TARs that included RCTs in abstract/presentation form carried out an assessment of the methodological quality of such trials. In 16 TARs full reports of these trials were used for quality assessment where both abstracts/presentations and subsequent full publications were available. In four TARs it was clearly stated that formal quality assessment was not possible for the trials that were available only as abstracts/presentations, and in one TAR trial quality could not be fully assessed; however, trials were not excluded from the review on the basis of methodological quality.

Twenty-three of 63 TARs (37%) carried out a quantitative analysis of results. Of these, ten (43%) included trials available as abstracts/presentations in the review; however, only 60% (6/10) of these included data from abstracts/presentations in the data analysis of results.

Case studies

Thirteen TARs evaluated rapidly evolving technologies and only three of these identified and included trial data from conference abstracts/presentations and carried out a quantitative analysis where abstract/presentation data were used. These three TARs were used as case studies.

In all three case studies, the overall quality of reporting in abstracts and presentations was generally poor. In one case study, this was more apparent in the conference abstracts compared with the online conference presentations, possibly because of limited space available in abstracts. In all case studies abstracts and presentations failed to describe the method of randomisation or allocation concealment. Overall, there was no mention of blinding in 66% (25/38) of the abstracts and in 26% (7/27) of the presentations included in case studies, and one presentation (4%) explicitly stated use of intention-to-treat analysis.

Results from one case study [drug-eluting stents (DES) review] demonstrate discrepancies in data made available in abstracts or online conference presentations. Not only are discrepancies evident between these sources, but also comparison of conference abstracts and presentations with subsequently published full-length articles demonstrates data discrepancies in reporting of results.

Sensitivity analyses based on one case study (DES review) indicated a change in significance of effect in two outcome measures when only full papers published to date were included. In terms of direction of effect, only using data from full papers published to date would not have altered the direction of any of the results when compared with those published in the original review. If conference abstracts and presentations were excluded from data available at the time of the original review, the direction of effect, and hence the conclusions of the review, would not have changed substantially, except in one of the ten results.

Conclusions

There are variations in policy and practice across TAR groups regarding searching for and inclusion of studies available as conference abstracts and presentations. There is also variation in the level of detail reported in TARs regarding the use of abstracts/presentations. Therefore, TAR teams should be encouraged to state explicitly their search strategies for identifying conference abstracts and presentations, their methods for assessing these for inclusion, and where appropriate how the data were used and their effect on the results.

Comprehensive searching for trials available as conference abstracts/presentations is time consuming and may be of questionable value. However, there may be a case for searching for and including abstract/presentation data if, for example, other sources of data are limited. If conference abstracts/presentations are to be included, the TAR teams need to allocate additional time for searching and managing data from these sources.

Incomplete reporting in conference abstracts and presentations limits the ability of reviewers to assess confidently the methodological quality of trials. Where conference abstracts and presentations are considered for inclusion in the review, the TAR teams should increase their efforts to obtain further study details by contacting trialists.

Where abstract/presentation data are included, reviewers should discuss the effect of including data from these sources. Any data discrepancies identified across sources in TARs should be highlighted and their impact discussed in the review. In addition, there is a need to carry out, for example, a sensitivity analysis with and without abstract/presentation data in the analysis.

Recommendations for research

There is a need for research into the development of search strategies specific to identification of studies available as conference abstracts and presentations in TARs. Such strategies may include guidance with regard to identification of relevant electronic databases and appropriate conference sites relevant to certain clinical areas.

As there are limited case studies included in this report, analyses should be repeated as more TARs accrue, or include the work of other international HTA groups (e.g. the Canadian Coordinating Office for Health Technology Assessment, the Blue Cross Blue Shield Association, the Swedish Council for Technology Assessment in Health Care and Australian HTA) to support the findings.

Chapter 1

Research aims

The objectives of this research are to assess:

- the extent of use of data from conference abstracts and presentations in health technology assessments (HTAs) provided as part of the National Institute for Health and Clinical Excellence (NICE) appraisal process
- the ability to judge the methodological quality of trials from conference abstracts and presentations
- the consistency of reporting major outcomes between conference abstracts/presentations and subsequent full-length publications
- the effect of inclusion or exclusion of data from abstracts/presentations on the meta-analysis pooled effect estimates
- the timeliness of availability of data from abstracts/presentations and full articles in relation to the development of technology assessment reports (TARs).

Evidence for this research was obtained from:

- a survey of technology assessment review groups (TAR groups)
- an audit of published NICE TARs
- case studies of selected TARs.

Chapter 2
Background

Definition

In this study, conference abstracts and presentations (oral or poster presentations) are:

- initial, interim or final reports of research studies presented at scientific conferences, meetings, workshops or symposia, and
- usually published in conference proceedings or journal supplements in non-peer-reviewed form, or available after the conference through Internet-based sites.

Full-text articles are defined as reports of research studies published in full in a journal or journal supplement.

Use of abstracts in systematic reviews

There is debate as to whether data from unpublished studies available only as conference abstracts and presentations should be included in high-quality systematic reviews.[1] In systematic reviews, accepted gold-standard data sources traditionally have required that the reviewer be able to judge the quality of research process and extract data from the final analysis of the results. Within this standard, therefore, data from conference abstracts, presentations or interim reports of studies have not routinely been considered for inclusion in the review. It is, however, argued that inclusion of unpublished data from grey literature, in particular from conference abstracts, could assist in the generation of a more comprehensive data set.[2] One large survey carried out by Cook and co-workers showed that most meta-analysts (78%) believe that unpublished data should definitely or probably be included as long as the studies can be subjected to the same scrutiny as published data. However, only 47% of journal editors agreed with this.[1]

Grey literature generally refers to study reports that have not been formally published or are not widely distributed. It covers conference proceedings, research reports, theses/dissertations, book chapters, personal communications and other types of unpublished reports. It has been reported that approximately 31% of published meta-analyses include grey literature in their primary analysis.[1]

A systematic review of eight research studies that examined the effect of inclusion and exclusion of grey literature on the results of meta-analyses of randomised controlled trials (RCTs) of healthcare interventions showed that for all included studies the most common source of grey literature was conference abstracts (49%).[3]

Unpublished data and conference abstracts and presentations are also the main sources of grey literature in Cochrane systematic reviews. Results of an analysis of the first 1000 Cochrane reviews indicate that 56% of Cochrane reviews include grey literature and nearly half of these refer to conference abstracts as sources of data.[4] More recently, a study of 57 Cochrane reviews that included at least one RCT found that 21% of the trials in Cochrane reviews were from the grey literature, of which 80% were conference abstracts.[5]

Publication bias and selective reporting

Publication bias

Empirical evidence suggests that published work is more than twice as likely to be statistically significant ($p < 0.05$) than unpublished research.[6–8] It is therefore argued that limiting systematic reviews to only full publications could possibly introduce the risk of publication bias, which has been recognised as a potential threat to the validity of any subsequent meta-analysis.

It has been estimated that only half of the conference abstracts are subsequently published in full.[9] Similar findings were reported in a Cochrane methodology review of 79 research studies. Scherer and colleagues[10] found that only 45% (60% for those that only presented the results of RCTs) of studies initially presented as abstracts subsequently appeared in full within 2 years following presentation at the meeting. Studies primarily available as abstracts were more likely to be subsequently published in full if their results were statistically significant.

Selective reporting

Within-study selective reporting, which can occur in both abstracts and full-text reports, has been defined as "the selection of a subset of the original variables recorded for inclusion in publication of trials".[11] Direct empirical evidence for the existence of such bias is now accumulating.[12,13] Examples have been identified in which an outcome reaching statistical significance has been reported in an abstract relating to an interim analysis, but no data on the same outcome are presented in the final publication.[14] The effect in a meta-analysis of selection of results has been investigated theoretically under particular assumptions and shown to be substantial when the proportion of overall variance contributed by the selectively reported trial is high, the number of variables selected from is high and the correlation between variables is low.[11] The difficulty of allowing for such bias in a meta-analysis has been recognised.[15] Sensitivity analysis has been proposed for adjusting for selectively reported effect sizes,[11] selectively unreported subgroup results[13] and selectively unreported binary outcomes.[14]

Impact of inclusion or exclusion of abstracts in systematic reviews

Several studies have investigated the potential impact of inclusion of grey literature in systematic reviews. Hopewell and colleagues' Cochrane methodology review[3] included eight research studies (containing four multiple and four single meta-analyses) and examined the impact of grey literature in meta-analyses of RCTs of healthcare interventions. In nearly half of the included studies, the most common type of grey literature was abstracts. All four of the studies containing multiple meta-analyses and three containing single meta-analyses found that published trials showed an overall greater treatment effect than trials reported in grey literature, but this difference was significant in only two of the four multiple meta-analyses, and none of the single analyses. One study containing a single meta-analysis indicated that published trials showed no effect of treatment, whereas grey literature showed a negative treatment effect (not statistically significant).

Literature focusing specifically on the impact of use of abstracts in systematic reviews is limited. The present group identified only one study (included in Hopewell's review[3]), carried out by McAuley and colleagues,[2] which included data from 41 randomly selected meta-analyses containing 467 RCTs. The study investigated the sources of grey literature and explored the impact of different types of grey literature on the overall results of the meta-analyses. It found that published trials, when compared with grey literature, showed significantly larger estimates of the intervention effect by 15%. In this study, conference abstracts were the main source of the grey literature (61%), and their exclusion from analysis (20 meta-analyses) resulted in an overestimate of the effectiveness by 33%.

Difficulties with including abstracts in systematic reviews

Identification of abstracts

Identification, selection and retrieval of studies for inclusion in analysis make up one of the most important steps in carrying out a systematic review.

Bias can be potentially introduced into the process of locating and selecting studies for inclusion in a systematic review. Studies are not always published as peer-reviewed journal articles, and may remain unpublished or may be published only as abstracts in non-peer-reviewed form. It is acknowledged that attempts should be made to search for an unbiased and complete set of relevant studies, both published and unpublished, for inclusion in the review to ensure that the reports of studies identified are not a biased sample of the existing evidence.[16]

Conference abstracts and presentations are difficult to locate as they are poorly or not indexed in standard bibliographic databases typically searched in systematic reviews (e.g. MEDLINE, EMBASE). These databases rarely index journal supplements in which conference abstracts often appear. Extended search strategies including additional sources are therefore required to identify these sources (e.g. handsearching of journal supplements, meeting abstract books and conference sites).[17,18] However, it is acknowledged that such strategies are time-consuming and difficult to design, and may increase the resources required to complete a systematic review.[19]

There is much empirical evidence on the use of extensive search strategies to identify all existing studies for inclusion with the intention of reducing bias in systematic reviews.[20–22] However, an analysis of sources searched in Cochrane reviews indicates that extended database

searching beyond major databases (Cochrane, MEDLINE and EMBASE) retrieved only a small percentage of extra trials, which were generally of poorer quality than those trials that were easily found.[5]

Similarly, results from a methodology review for the National Coordinating Centre for Health Technology Assessment (NCCHTA) carried out by Royle and Waugh[18] indicate that database searching beyond the four major electronic databases [e.g. MEDLINE, EMBASE, Cochrane Controlled Trials Register (CCTR) and Science Citation Index (SCI)] provides limited additional benefit. Of these, only CCTR contains a considerable number of trials reported in conference abstracts. Only 8% of studies (published or available as abstracts) from a sample of 20 TARs included in this methodology review identified a study report that was not found in these major databases.

Even when every attempt is made to identify unpublished sources, the studies identified through exhaustive searches may not be representative of all unpublished studies. A study by Cook and colleagues examining the usefulness of grey literature searching in the area of palliative care reported that exhaustive searches were generally not successful in retrieving unpublished studies: only one of the 25 reports identified through grey literature search met the inclusion criteria for the review. The authors concluded that this represented an unjustifiable use of resources when conducting a systematic review in palliative care.[23]

Methodological quality of trials from conference abstracts

The limited availability of information about a study in a conference abstract/presentation is a challenge routinely experienced by systematic reviewers. It is argued that the overall quality of reporting in conference abstracts and presentations may be insufficient and therefore it is difficult to assess the quality of the trial.

A recent review of 500 abstracts of RCTs included in the Proceedings of American Society of Clinical Oncology (ASCO) meetings revealed that many of the abstracts were missing information on fundamental elements of a clinical trial, particularly those relating to study design and analysis of data.[24] These findings are consistent with the results from another review of 465 abstracts (presented at the annual meeting of the American Academy of Orthopaedic Surgeons) in which the authors found that less than half of the abstracts reported key methodological issues and less than 15% of abstracts provided information on data analysis (e.g. measures of precision including standard error, or confidence intervals).[25]

Another study by Hopewell assessing the impact of abstracts included in Cochrane reviews (presented at the Thoracic Society of Australia and New Zealand) found that the methods of allocation concealment could be determined in only four of the 183 (2%) included abstracts.[26]

The peer-review process for conference abstracts and presentations may be different to that of full publications as they do not contain the same methodological detail of a study as a full-length journal article owing to the limited space available in an abstract. However, this problem may also be present in reports of studies published in full. Research investigating the effect of peer review and quality of reports suggests that peer review has its limitations and may not necessarily ensure quality of research.[27]

A study comparing conference abstracts of surgical RCTs to their subsequent full publication found that overall quality of reporting was poorer in abstracts than in full publications. Method of blinding was only reported in 16% of abstracts (38% in full publications) and method of concealment was not reported in any of the abstracts (43% in full papers).[28]

Consistency of reporting of outcomes between abstracts and subsequent full publications

Data reported in abstracts or presentations may not be complete: conference abstracts/presentations may only include interim analysis (planned or unplanned) or may report short-term follow-up data or relative treatment effect estimates rather than actual numbers of events. In addition, there is evidence that inconsistencies regarding results, as well as the reporting of the primary outcome measures, may occur between conference abstracts/presentations and subsequent full reports.[25,28–31]

Weintraub compared surgical meeting abstracts of 33 RCTs with their subsequent full reports.[29] He found that only 30% of the final publications had the same authors and title as the abstract, only 33% had the same number of patients as reported in the abstract, 45% included data that were inconsistent with their conference abstracts, and in 30% of papers the conclusions were not only

different but routinely weaker than in the abstract. These discrepancies may be partly explained by the stage of the study when the abstract was submitted (the author did not split the results by whether the abstract reported interim analysis).

Bhandari and colleagues[25] retrieved 465 orthopaedic abstracts presented at the Annual Meeting of the American Academy of Orthopaedic Surgeons and examined the consistency of reporting between abstracts and subsequent full publications. They found that two-thirds (66%) of the abstracts were not subsequently published in full and the number of patients initially reported in conference abstracts was decreased in the subsequent full publication nearly 9% of the time (the absolute difference ranged from <1% to 73%). Their results also indicate that the primary outcome measure reported in abstracts and subsequent full publications changed 14% of the time, and study results reported for the primary outcome measure were inconsistent between the abstract and the final publication 19% of the time.

One study by Chokkalingham and colleagues[30] examined the disagreements between data in 62 conference abstracts of RCTs (using 1988 and 1989 abstract volumes of the Association of Vision and Ophthalmology and the American Academy of Ophthalmology) and their subsequent full reports of RCTs. They found that data reported on the number of patients randomised in abstracts were inconsistent with the full publications 35% (14/40) of the time, and the direction of outcome disagreed between abstracts and full reports 9% (4/44) of the time. Reasons for discrepancies in data included misinterpretation in the abstract of the number of patients analysed as the number randomised (43%) and presentation of interim results in the abstract (36%).

Reporting and analysis of data may be incomplete in the abstract, particularly if it reports interim or preliminary results.[31] Tooher and colleagues[28] examined the inconsistencies in 37 trials initially presented at the conference proceedings of four surgical speciality conferences with their subsequent full publications. They found that more participants were randomised in full publications (median 81) than in abstracts (median 60), with nine abstracts reporting interim results. Results reported were the same for only 45% of abstracts and full publications, and the direction of results was the same in 79% of studies. However, the authors did not compare the statistical or clinical significance of results in this study.

NICE appraisal process

NICE was set up as a Special Health Authority for England and Wales in 1999. It is the independent organisation responsible for producing national guidance on the use of selected new and established health technologies (e.g. medicines, medical devices, diagnostic techniques and procedures) for the NHS.

The guidance issued about the use of technology is based on an appraisal of that technology. The purpose of the appraisal is to consider health benefits and the costs of a health technology and to make recommendations that form the guidance on the use of the technology that is issued to the NHS in England and Wales.[32,33]

The appraisal is based on a number of sources, which include a TAR, information by the consultees (including pharmaceutical manufacturer submissions) to the appraisal process, and the involvement of clinical specialists and patient experts. Technology assessments are carried out by an independent academic group (assessment group) commissioned by the NHS Research and Development Health Technology Assessment Programme (HTA Programme) through the NCCHTA. The purpose of this programme is to ensure that high-quality research information on the effectiveness, costs and broader impact of health technologies is provided for those who use, manage and provide care in the NHS.

The assessment group prepares a TAR within a limited and predetermined time-frame. The TAR is based on a critical review of the clinical and cost-effectiveness of the technology (the time available from the allocation of the research topic to the submission of finalised report is approximately 28 weeks) and involves a systematic review of the available evidence concerning the technology under appraisal. It also involves a review of submissions to NICE from manufacturers and sponsors, which include published or unpublished studies sponsored by them or known to them, and study evidence to which they have access and that is not in the public domain.[32,33]

The type of evidence used in preparation of a TAR is pragmatically determined by the quantity and quality of evidence for each indication under assessment, and the outcome measures under consideration. Evidence from various types of source may be relevant to the appraisal considerations. This includes evidence from

published and unpublished clinical trials and additional evidence from trials that have only been published in abstract form or for which only selected information has been reported.[32,33] Royle and Waugh's methodology review of literature searching for clinical and cost-effectiveness studies indicates that these sources are commonly used in TARs.[18] Of the 424 studies included in the clinical effectiveness section of the review, 11.3% were meeting abstracts and 60% of TARs included at least one abstract in the review.

Rapidly evolving technologies (RETs) (e.g. pharmaceutical interventions, procedures or devices) are those that have not previously been widely used within the NHS (e.g. those that have recently gained a licence) and where there is limited or rapid evolution of evidence. Decisions regarding effectiveness need to be made before the integration of RETs into clinical practice. Where there are limited or no full-text articles available, especially in the case of RETs, the TAR teams may rely on evidence from studies that may be available only in conference abstract or presentations.

The overall aims of this research were to examine the current practice and extent of the identification and use of data from conference abstracts and presentations in TARs by (1) carrying out a survey of TAR groups, (2) conducting an audit of published TARs, and (3) identifying cases of RETs to compare and contrast data from abstracts/presentations with their subsequent full reports, and to assess the effect of inclusion or exclusion of these sources in the analysis of data.

Plan of report

The rest of this report consists of five chapters. Chapter 3 reports on a survey of the TAR groups to identify general policy and experience related to the identification and use of abstract/presentation data. Chapter 4 includes an audit of published NICE TARs and investigates the extent of use of conference abstracts and presentations. Chapter 5 contains three case studies of RETs, selected from the audit, and examines the comparability of reporting major outcomes, and the ability to judge the methodological quality of RCTs, from conference abstracts and presentations. Finally, Chapter 6 presents a general discussion and Chapter 7 conclusions of the report.

Chapter 3
Survey of TAR groups

Purpose of the survey

This survey was developed to provide information on whether the TAR groups have a policy regarding:

- identification of studies available only as meeting abstracts/presentations
- inclusion of data from abstracts/presentations
- assessment of data from abstracts/presentations.

A further aim was to determine whether inclusion or exclusion of conference abstracts and presentations created challenges for the groups in terms of quality assessment or analysis of results, particularly in the case of systematic reviews of RETs.

Methods

In August 2004, a survey was conducted of all seven TAR groups in the UK. All directors of the TAR groups were contacted through Technology Assessment Services Collaboration (InterTASC).

The TAR group questionnaire asked questions regarding the identification and extent of use of data from conference abstracts and presentations within their organisation. The questionnaire consisted of 16 questions and was presented in two parts. The first contained four questions relating to identification of conference abstracts and presentations in TARs. The second included 12 questions relating to inclusion and assessment of data from conference abstracts and presentations in TARs. The questionnaire is shown in Appendix 1.

Non-responders were contacted by e-mail in October 2004 and sent a reminder with a further questionnaire attached. The process of recontact was continued until the completed questionnaires were obtained.

Responses are tabulated and discussed narratively.

The term 'abstract' in this section refers to conference abstracts and presentations (oral or poster) given at conferences, meetings, workshops and symposiums.

Results

All seven TAR groups completed and returned the survey.

Results have been grouped and summarised according to questions relating to:

- searching for abstracts
- inclusion and assessment of abstracts in TARs where at least one study is *only* available as abstracts
- inclusion and assessment of abstracts in TARs where *both* abstracts *and* subsequent full publications are available
- the effect of inclusion of abstracts on data analysis and conclusions and difficulties experienced by TAR groups.

Further details of the results of the survey are provided in the summary tables of responses in *Tables 1–4*.

Searching for abstracts

Policy

Five out of seven TAR groups reported a general policy to search for abstracts. One of these groups responded that the policy was contingent on the type of technology evaluated.

Search strategies

Identification of studies available only as abstracts was achieved by developing both general and explicit search strategies (i.e. where the objective is to search for abstracts) in four groups and general searches in one group. Databases and sources routinely searched by groups to identify such studies are listed in *Table 1*. All four groups included the electronic database of ISI proceedings (Web of Knowledge) in their explicit searches for abstracts.

Experiences

Comments from three groups identified problems related to inadequate indexing of abstracts, difficulties in finding appropriate sites to search for studies available only as abstracts and costs involved in obtaining such studies.

Details of the results are given in *Table 1*.

TABLE 1 *Questions relating to searching for abstracts*

TAR groups	General policy (identification of abstracts)	Search strategies (general or explicit)	Databases and sources searched	Comments (e.g. examples of difficulties/experiences)
1	Yes[a]	General and explicit	*General search:* CENTRAL *Explicit search:* SCI (limit to meeting abstracts) BIOSIS (limit to meeting abstracts) ZETOC (limit to conference search) Professional societies ISI Proceedings CPI General Internet search (e.g. Dogpile) Handsearching journals or supplements	Obtaining abstracts published in obscure journals can be time-consuming and/or expensive
2	No	Not stated	Not stated	No comments
3	No	Not stated	Not stated	No comments
4	Yes[b]	General and explicit	*General search:* CENTRAL *Explicit search:* SCI Professional societies Conference sites ISI Proceedings General Internet search Handsearching journals or supplements	• Published conference proceedings; poorly or not indexed • Time-consuming (e.g. finding appropriate site, searching site content) • Lack of study detail (e.g. quality factors)
5	Yes	General	Not stated	No comments
6	Yes	General and explicit	*General search (not specified)* *Explicit search:* ISI Proceedings Current controlled trials NIH Cancer Trials (if relevant) BIOSIS reviews (meetings) NRR General Internet searches	
7	Yes	General and explicit	*General search (not specified)* *Explicit search:* CPI (used previously) ISI Proceedings: Social Science and Humanities ISI Proceedings: Science and Technology BIOSIS Inside conferences (occasionally)	Grey literature is generally the more problematic material (particularly non-UK)

[a] With considerable reservations: cannot judge quality of study from abstracts, problems with acquiring abstracts (e.g. cost), most do not contain useful information.
[b] Depending on the technology, abstracts are not excluded from the search.
CPI, Conference Papers Index; NIH, National Institutes of Health; NRR, National Research Register; SCI, Science Citation Index; ZETOC, Z39.50-compliant access to the British Library's Electronic Table of Contents.

Inclusion of abstracts in TARs where at least one included study is *only* available as abstracts

Number of TARs

The number of TARs where at least one study included in the review was available only as an abstract varied from two to eight in four TAR groups. The remaining three groups did not specify the number of such TARs.

Policy

Five out of seven groups reported that they had a policy for inclusion of studies available only as abstracts. Four groups' policies were contingent on the availability of data. Three of these groups stated that they would exclude abstracts unless there was adequate information included regarding the trial (e.g. information on the methods, characteristics and results of the studies); the other group would always include abstracts if any data on study results were available. One group referred to abstracts only as a guide to forthcoming research.

Two groups said that they had no policy, but one would include abstracts if otherwise there was limited evidence.

Routine assessment

One group reported that they would not consider studies available as abstracts for assessment unless there was no other evidence available, and another group stated that they would assess abstracts if there was a limited number of studies included. All other groups reported that whether they included abstracts depended on the availability of data in the abstracts.

Inclusion criteria

All groups, including the group that would not consider abstracts for assessment in the review, responded that where abstracts were included in the review, the same inclusion criteria would be applied to both abstracts and full publications. One group stated that inclusion of abstracts would be contingent on sufficient detail in reporting.

Quality assessment

Five groups responded that if they included data from abstracts they would carry out methodological quality assessment of studies obtainable only as abstracts using the same assessment tools [e.g. Centre for Reviews and Dissemination (CRD) Report 4 or Jadad checklist criteria] as for full publications.

Data extraction

One group reported that they would not normally extract data from abstracts unless no other evidence was available, and one group only extracts data if there is sufficient information to assess the methodological quality of the trial. All other groups stated that data from abstracts were managed in the same way as full publications.

Details of the results are provided in *Table 2*.

Inclusion of abstracts in TARs where *both* abstracts and subsequent full reports are available

Number of TARs

All groups have completed TARs that included both abstracts and subsequent full reports. The number of TARs conducted where both abstracts and subsequent full reports were available varied from one to five in four groups. The remaining groups did not quantify this, with two groups stating that many TARs in which they were involved had both abstracts and full reports available.

Policy

When asked what the approach would be if relevant outcome data were reported in

- abstract alone: all but two groups reported that they would extract and use the data from the abstract. Of these, two reported that they would state the source of data as abstract in the report and one reported that they would also compare the study details with those of the full paper to identify any differences and for the results of the abstract to be considered in context
- full report alone: six groups would extract and use the data. One group made no statement
- both abstract and full publication: all groups would consider the data reported in the full publication. Four reported they would compare data between abstract and full report and, if identified, highlight any discrepancies.

Involvement in a TAR where data discrepancies were identified between abstracts and subsequent full papers

Five groups identified discrepancies between abstracts and full publications, but three were unable to report exact numbers of TARs involved. Two groups had not found discrepancies between abstracts and full publications.

Details of the results are given in *Table 3*.

TABLE 2 *Inclusion of abstracts: TARs where at least one study is only available as an abstract*

TAR groups	No. of TARs	Policy for inclusion of data from abstracts	Routine assessment	Same inclusion criteria applied as for full papers?	Quality assessment	Data extraction for presentation in tables or use in analyses
1	3	Yes Abstracts listed in appendices and referred in the clinical section only as a guide to forthcoming research	No Unless there is no other evidence. Data not usually extracted	Yes	No Usually not possible because of lack of detail	No Unless there is no other evidence available; data managed same way as full papers
2	8	No Depends on the TAR (e.g. abstracts would be considered if there is a limited number of studies)	Yes If appropriate (see policy)	Yes PICO where possible	Yes Same tools used as for full papers where possible	Yes Studies are clearly labelled as abstracts
3	Several	Yes There must be a sufficiently detailed account of the methods to permit critical appraisal	Yes If appropriate (see policy)	Yes Inclusion is contingent on sufficient detail in reporting	Yes Same tools used as for full papers (CRD Report 4)	Yes If they meet the inclusion criteria (i.e. detail and relevance)
4	2	Yes Abstract data on study results included if available; same criteria applied as stated in the protocol	Yes	Yes	Yes Same as for full papers	Yes
5	Unsure	No	Yes	Yes	No Only if enough data available, or state it was impossible owing to insufficient data	Yes Extract all data available
6	2	Yes Abstracts are searched and considered for inclusion using the same criteria stated in the protocol as for all studies, but included and data extracted only if they include adequate information. If not, they are excluded and used as a source to identify studies that may be later published in full	Yes See policy	Yes Same inclusion criteria for all studies as stated in the protocol	Yes Same tools used as specified in the protocol	Yes See policy. Same extraction process as specified in the protocol
7	Several	Yes Trials are excluded if there are insufficient data (most abstracts are excluded unless more information is available about the trial through additional publications)	Yes	Yes	Yes Depends on the topic. Mostly, new tools are developed for NICE reviews based on the items from the Jadad scale	Yes If there is sufficient information to assess the quality of the trial

Impact assessment of inclusion of abstracts, difficulties related to inclusion of data from abstracts and TARs involving RETs

Impact assessment

Two groups would assess the effect of including data from abstracts that differed from subsequent full publications or include a discussion of the effect of inclusion of abstracts. One group reported that they would explicitly state the source of data.

Where the group policy was to exclude abstracts, three groups stated that they would make an exception and include abstracts if no other evidence was available or sufficient details were reported in the source.

Experiences

All TAR groups responded that they experienced difficulties related to inclusion of data available only from abstracts. These included the inability to carry out a methodological quality assessment of the study owing to insufficient data, and lack of details in the abstract for the results to be included in the analysis.

Number of TARs involving RETs

The number of TARs involving RETs conducted by six groups varied from one to four, while two groups did not specify a number.

Details of the results are shown in *Table 4*.

Summary

This survey aimed to identify and collate information on the approach of HTA TAR groups to the identification, inclusion and assessment of studies published as conference abstracts.

This survey demonstrates that the majority of TAR groups (five out of seven) have a policy concerning the identification of studies published as abstracts. This is achieved either by devising both general and explicit search strategies (where the objective is to search for abstracts) (reported by four groups) or by using general search strategies (one group).

Search strategies in TARs are dependent on the TAR assessed, scoping searches and advice from experts from the area. This task involves the use of extended search strategies when attempts are made to identify unpublished studies, in particular conference abstracts. Such strategies often include electronic databases, individual conference sites, general Internet searches and handsearching journals or journal supplements. In this survey, the TAR teams consistently reported SCI, ISI Proceedings and BIOSIS as their source of abstract evidence.

Development of extensive search strategies to identify abstracts requires additional time and resources, and this can be difficult for TAR teams to achieve in a strict, predefined and limited period. Furthermore, as one group commented, obtaining these sources can be expensive, especially if found in obscure journals.

This survey found that policies regarding assessment and inclusion of data from abstracts in the different TAR groups vary considerably. One group would exclude data from abstracts if other data sources were available, three would include data depending on the quality of reporting and one would include data regardless. This indicates that there is no standardised practice across groups and therefore there is a need for transparency from TAR groups regarding how abstract data are managed.

Most TAR groups (five out of seven) indicated that they apply the same quality assessment criteria (e.g. CRD criteria for RCTs) to the studies available as abstracts as they would to other fully published papers. However, as reported by the TAR groups in this survey, conference abstracts and presentations often do not contain the same methodological details as a full journal article and therefore it is not always possible to judge the validity of their results. Furthermore, the reporting of outcome data is often poor or incomplete, which limits the extractable data from reports. This may be because the data were not yet available or were withheld for commercial reasons at the time when the abstract was submitted.

Studies may be available as both abstracts and full publications, and relevant outcomes may be reported either in the abstract or in the full publication alone, or in both. If data are reported in abstracts alone, most TAR teams (five out of seven) would extract and use these data. Where data are reported in both sources, most groups (five out of seven) would use the data only from full publications. However, one may argue that data should be extracted from both sources and if there are discrepancies in reporting, they should be highlighted and further information should be sought from the authors. It would also be useful, as indicated by three groups, to explore and discuss the effect of inclusion of abstracts in each review.

To the authors' knowledge this is the first survey of TAR groups that has looked specifically at the

TABLE 3 *Inclusion of data from abstracts: TARs where* both *abstracts and subsequent full publications are available*

TAR groups	No. of TARs	Policy where data reported in abstract alone	Policy where data reported in full paper alone	Policy where data reported in abstract and full paper	Involvement in a TAR where data discrepancies between abstracts and full reports were found
1	Most TARs Abstracts discarded, only full papers used	Abstract not considered if full paper is available	?	Abstract not considered if full paper is available	Don't know; abstract not considered if full paper is available
2	5	Reported but also state that data are from abstract	Report data	Full paper is reported. If abstract different, it is reported as a duplicate trial report and noted as an abstract	2 publications where the latter is a trial update 1 (number of patients treated: the most recent version is reported)
3	At least 4 Full papers used where both are available	Full publication is used	Full publication is used	Full publication used	Unsure
4	1	Use data	Use data	Full paper used Compare and contrast data	1
5	Don't know Often full papers are published around the time of an assessment	Extract relevant data and state that it is an abstract	Treat as an ordinary publication	Full paper reported	No
6	1	Extract relevant data Compare study details with those of the full paper; this would allow any differences to be identified and for the results of the abstract to be considered in context	Extract data Any differences between the abstract and full report would be highlighted	Data extracted from both Any differences compared, if evident, these are highlighted and discussed in TAR	No
7	Several There are too many to list	Extract data Data are presented in tables and used in the report	Extract data	Extract data from both If the abstract is end-of-trial, but still different from the main publication, data from full paper used and mentioned in the data extraction table that other results were also reported	A few; can't recall On several occasions where interim data reported in abstracts, only end-of-trial data used and abstracts ignored

TABLE 4 *Inclusion of abstracts: impact assessment and difficulties*

TAR groups	Impact assessment on data analysis and conclusions	Any exceptions made if the policy is to exclude studies available only as abstracts	Difficulties (e.g. data management, quality assessment or analysis)	No. of TARs involving RETs
1	No Would only apply if no full papers	Yes If nothing else	Yes Quality assessment and scanty details	1
2	Yes The impact is usually discussed in the discussion	No Not if stated in inclusion/exclusion criteria	Yes Quality assessment difficult owing to lack of details	2
3	No If there is sufficient detail for inclusion then they are treated the same	Yes If sufficient details are reported	Yes Generally, details are limited	3
4	No	Abstracts are not excluded	Yes Lack of study detail, e.g. quality factors	1
5	Yes It is clearly stated that the source of data is from abstracts and not peer-reviewed papers	–	Yes Often insufficient data for quality assessment, study details	Not specified
6	Yes As part of the synthesis of evidence, the effect of differences in such evidence to other studies published in full is examined	No Studies available only as abstracts would be noted as indication of evidence that may be published	Yes Adequacy of information provided (usually sparse). Abstracts would be excluded if the information is inadequate to judge the methods or results, or on some occasions the information may be adequate but lack details to allow meta-analysis	None stated
7	No	Yes Group policy is not to exclude abstracts completely, but mostly they are excluded owing to a lack of information about study methods. An exception is made if the methods are properly reported in the abstracts	Yes Quality assessment	4

extent of identification and use of data from studies available only as abstracts. The majority of TAR groups in this survey indicate that they have a group policy involving searching for and use of data from studies available as abstracts. However, the specific policies employed by the TAR groups identified in this survey varied considerably. It appears that the TAR teams are pragmatic in the way they conduct TARs. For example, if they have good evidence, they are not likely to include data from abstracts but if evidence is limited, they would.

Identification, retrieval and use of data from studies available as conference abstracts or presentations can be challenging, expensive and time-consuming. The decision on whether or not to include such data is particularly significant when data from other sources are limited. Given that, in TARs, decisions need to be made on the basis of best available evidence but on a limited and predetermined timescale, it is important for TAR teams to make appropriate decisions and to judge the added value of including these sources in the review process.

Chapter 4

Audit of completed TARs

Introduction

Conference abstracts in this section include conference, meeting, workshop and symposium abstracts, and presentations include oral (e.g. PowerPoint slide presentations) and poster presentations.

The audit was designed to collect information on the identification and extent of use of data from conference abstracts/presentations in published NICE TARs and to identify TARs that evaluated RETs. Specifically, the objectives of this audit were to:

- identify reviews of RETs
- determine the number of TARs that identified, included or analysed data from meeting abstracts or presentations.

Methods

Inclusion and exclusion criteria

The audit included all of the NICE technology assessment reports (TarNice) commissioned by the HTA Programme on behalf of NICE and published between January 2000 and October 2004. TARs were obtained from the NCCHTA website.

TARs that were not associated with the NICE process (e.g. methodology TARs, other HTA reports) were excluded from the audit.

Only data involving the clinical effectiveness component of the review were considered.

Data extraction

One reviewer carried out data extraction (YD). Individual TAR data relating to (1) types of interventions evaluated, (2) identification, (3) inclusion, (4) quality assessment and (5) analysis of trial data from conference abstracts/presentations were extracted using pretested data extraction forms. Data were cross-checked by a second reviewer (SD).

Types of interventions evaluated in TARs were classified into six different categories:

- pharmaceutical agents
- devices
- surgical procedures
- therapeutic procedures
- patient education
- prevention and treatment.

Search strategies were defined as explicit if a decision to search for conference abstracts/presentations to inform TARs was clearly stated in the review methods and/or reported separately in the search strategy. Search strategies were described as not explicit if an intention to search for abstracts/presentations (e.g. by handsearching journal supplements or searching for conference sites) was not clearly stated in the methods but the search strategy included a search for abstracts/presentations indexed by electronic databases.

Results

Characteristics of included TARs

In total, 63 completed NICE TARs were identified. These involved assessments of pharmaceutical agents (n = 43), devices (n = 7), therapeutic procedures (n = 6), surgical procedures (n = 5), patient education (n = 1) and prevention and treatment (n = 1) (*Table 5*, *Table 28* in Appendix 2).

Cancer was the disease area with the largest number of TARs (n = 18), followed by coronary heart disease (n = 8), rheumatology (n = 5), diabetes mellitus (n = 4) and obesity (n = 3). The remaining TARs (n = 25) involved a wide range of disease topics or areas (e.g. Alzheimer's disease, asthma, renal disease, smoking cessation and indications for use of growth hormones) (*Table 28* in Appendix 2).

Fifty-eight out of 63 (92%) TARs included at least one RCT: the total number of RCTs ranged from one to 171 (median 9.5). Twenty-five of the 63 TARs (40%) included evidence only from RCTs for the clinical effectiveness part of the review (*Table 28* in Appendix 2).

Forty TARs (63%) carried out a narrative synthesis of the results, whereas 23 (37%) included a meta-

TABLE 5 *Identification and inclusion of conference abstracts/presentations in TARs by type of technology assessed*

Technology (*n*)	No. of TARs that identified abstracts/ No. of TARs (%)	No. of TARs that included abstracts in the review (%)	No. of TARs that included data from abstracts in MA (%)
Pharmaceutical agent (*n* = 43)	27/43 (63%)	18/43 (42%)	4/43 (9%)
Device (*n* = 7)	5/7 (71%)	4/7 (57%)	2/7 (29%)
Therapeutic procedure (*n* = 6)	2/6 (33%)	1/6 (17%)	0/6
Surgical procedure (*n* = 5)	3/5 (60%)	2/5 (40%)	0/5
Other (*n* = 2)	1/2 (50%)	1/2 (50%)	0/2
Total (*n* = 63)	38/63 (60%)	26/63 (41%)	6/63 (10%)

MA, meta-analysis.

TABLE 6 *Identification and inclusion of conference abstracts/presentations in TARs by search strategies*

Search strategy for abstracts	*n*/*N* (%)	No. of TARs that identified abstracts (%)	No. of TARs that included abstracts in the review (%)	No. of TARs that included data from abstracts in MA (%)
Explicit[a]	17/63 (27%)	13/63 (21%)	11/63 (17%)	4/63 (6%)
Not explicit	38/63 (60%)	24/63 (38%)	16/63 (25%)	2/63 (3%)
Total searched	47/63 (75%)	30/63 (48%)	21/63 (33%)	5/63 (8%)
Not searched	16/63 (25%)	8/63 (13%)	5/63 (8%)	1/63 (2%)
Total		38/63 (60%)	26/63 (41%)	6/63 (10%)

[a] Eight TARs (13%) also searched electronic databases to identify abstracts as part of the general search strategy.

TABLE 7 *Number of RCTs included and number of TARs that identified and included abstracts/presentations*

No. of RCTs included in TARs	No. of TARs (%)	No. of TARs that identified abstracts in the review (%)	No. of TARs that included abstracts in the review (%)	No. of TARs that included abstracts of those that identified abstracts (%)
0	5 (8%)	1/5 (20%)	0/5	0/1 (0%)
1–4	18 (29%)	6/18 (33%)	4/18 (22%)	4/6 (67%)
5–10	12 (19%)	9/12 (75%)	6/12 (50%)	6/9 (67%)
11–20	18 (29%)	13/18 (72%)	10/18 (56%)	10/13 (77%)
>20	10 (16%)	9/10 (90%)	6/10 (60%)	6/9 (67%)
Total	63	38/63 (60%)	26/63 (41%)	26/38 (68%)

analysis for all or some of the included outcomes (*Table 28* in Appendix 2).

Twenty TARs (32%) made explicit statements regarding the identification and inclusion of abstracts/presentations in the methods section of the review. These are tabulated in *Table 29*, Appendix 2.

Searching for and identification of conference abstracts in TARs

Overall, a total of 38 TARs (60%) identified at least one trial available as an abstract/presentation (i.e. available only as an abstract/presentation or as both abstracts/presentations and subsequent full publications). Results are presented by the type of technology in the review in *Table 5*, and by search strategies used in the review *Table 6*. The total number of RCTs identified in abstract/presentation form varied from one to 19 (*Table 7* and in *Table 28* in Appendix 2).

In total, 47 of TARs (75%) included a search to identify abstracts/presentations. Seventeen out of 63 TARs (27%) carried out an explicit search for trials published as conference abstracts and presentations and reported the sources searched to identify such studies. This was generally achieved by searching and listing conference websites or professional societies, or handsearching online or print copies of journals or supplements. Thirty-eight TARs (60%) searched electronic databases

for abstracts as part of the general search strategy. Out of those that included an explicit search, seven (41%) also searched electronic databases to identify abstracts as part of the general search strategy. The following electronic databases which index abstracts were most commonly searched: Index to Scientific and Technical Proceedings (ISTP) (Web of Science), CPI, BIOSIS, Inside Conferences (DIALOG) and Internet Database of Evidence-based Abstracts (IDEA).

The remaining 16 TARs (25%) did not include a search strategy for abstracts/presentations in the review.

Overall, approximately two-thirds (26/38) of the TARs that identified abstracts/presentations actually included data from these sources in the review. This proportion remained virtually constant regardless of the number of RCTs included (*Table 7*)

Inclusion of trials available as abstracts in TARs

Of the 38 TARs that identified at least one trial in abstract/presentation form only, 26 (68%) included trials that were available as abstracts/presentations.

Of the 23 TARs that carried out a meta-analysis of results, ten (43%) included trials that were available only as abstracts/presentations in the review. However, only six of these (60%) included data from these sources in the meta-analysis (*Tables 5* and *6* and *Table 28* in Appendix 2).

Table 5 presents the results by the type of technology assessed in the review.

Quality assessment of included trials available as abstracts

Of the 26 TARs that included RCTs in abstract/presentation form, 20 (77%) carried out an assessment of the methodological quality of such studies either using Jadad scoring checklist or criteria based on CRD Report November 4.[34] In four of the 26 TARs, it was stated that an assessment of the methodological quality of RCTs in abstract/presentation form was not carried out and in one TAR trial quality from abstracts/presentations could not be fully assessed owing to insufficient data. (*Table 29* in Appendix 2). In 16 (25%) TARs, full reports of these studies (published or unpublished) were used for quality assessment where both abstracts/presentations and subsequent full publications were available (*Table 28* in Appendix 2).

Summary

A total of 38 (60%) TARs identified abstracts/presentations using general search strategies (e.g. searching electronic databases that index conference proceedings) and/or thorough explicit searches (e.g. handsearching journal supplements or specific conference sites).

As discussed in the previous chapter, extensive search strategies including handsearching of conference abstracts/presentations (published or available online) can be time-consuming within the review process. In two TARs authors explicitly stated that although reported in the review protocol, searching for an abstract was not possible in the time available.

Contrary to policies stated in the survey, TARs with no or few trials did not appear more likely to include studies available as abstracts/presentations. This may be because of identification and inclusion of studies other than RCTs (e.g. case–control or uncontrolled study designs) in the reviews.

Of the 38 TARs that identified at least one trial in abstract/presentation form only, 26 (68%) included trials that were available as abstracts/presentations. In 20 of 63 TARs (32%) explicit statements were made with regard to inclusion and assessment of data from abstracts/presentations. Nine of these clearly stated in the methods section of the report that conference abstracts and poster presentations were excluded from the review. Five TARs reported that where data were available in different publications, the fully published report would be used. In one TAR it was stated that conference abstracts could be used with caution for purposes such as sensitivity analysis, but this was not carried out in the review.

About 80% of the TARs (20/26) that included RCTs in abstract/presentation form carried out an assessment of the methodological quality of such studies. In 16 TARs full reports of these studies were used for quality assessment where both abstracts/presentations and subsequent full publications were available. In four TARs it was clearly stated that formal quality assessment was not possible for the trials that were available only as abstracts/presentations, and in one TAR trial quality from abstracts/presentations could not be fully assessed; however, trials were not excluded from the review on the basis of methodological quality.

Of the TARs that carried out a quantitative analysis of results (23/63), ten (43%) included trials that were available as abstracts/presentations in the review; however, only 60% (6/10) of these included data from abstracts/presentations in analysis of results. In the remaining TARs, it was difficult to determine confidently the source of data used in the reviews because TAR groups also made use of the confidential data provided in the pharmaceutical company submissions to NICE. Thus, data from abstracts/presentations are being used for analyses, but it is not always clear whether they are being supported by other sources.

The results of this audit show that conference abstracts/presentations were identified in a substantial number of TARs (about two-thirds). Inclusion of conference abstracts and presentations was consistent (60–70%) across TARs regardless of the availability of RCTs. However, data from abstracts/presentations were used in less then 30% of the 23 TARs (6/23) that included a quantitative analysis.

Extensive variability across TAR groups and between individual TARs means that there is a need for TARs to be explicit regarding searching for abstracts/presentations and reporting of data sources. This would allow readers to judge the quality of the results of the review and determine the degree to which review methods minimised potential biases.

Chapter 5

Case studies

Introduction

This section reports on three cases selected from NICE TARs evaluating RETs published up to October 2004. The purpose of this research was to assess:

- the consistency of reporting major outcome data between abstracts/presentations and subsequent full publications
- the ability to judge methodological quality of trials from abstracts/presentations
- the statistical and clinical significance of inclusion or exclusion of data from RCTs available only in abstracts/presentations
- the timeliness of availability of abstracts/presentations and subsequent full reports.

Methods

Selection of case studies

Two researchers (YD and TW) assessed the eligibility of case studies resulting from the audit of published TARs on a case-by-case basis. TARs had to meet the following criteria:

- association with a NICE guidance and published as an HTA monograph by the end of October 2004
- evaluation of RETs (e.g. pharmaceutical interventions, procedures or devices)
- identification and inclusion of RCT data from conference abstracts/presentations
- inclusion of quantitative analysis where data from abstracts/presentations were used.

It was planned that one researcher (PW) would randomly select the case studies to be included in this report. However, only three TARs met the inclusion criteria and these were all used as case studies.

There is no straightforward definition of what constitutes an RET. For the purpose of this report, RETs (e.g. pharmaceutical interventions, procedures or devices) included those that had not previously been used within the NHS, particularly those that have recently gained a regulatory approval and/or for which there is rapid evolution of publication of evidence.

Search strategy for subsequent full publications

The RCTs published as abstracts/presentations that were included in the case studies were identified and retrieved. Further literature searching was carried out to identify any subsequent publications of each abstract/presentation in a journal by searching electronic databases for the first author (and other authors if this was not successful) as listed in the abstract/presentation. Subsequent full reports identified were then examined to ascertain whether they corresponded with the trials reported in the conference abstracts and presentations. The principal investigator of the trial was contacted when necessary for information with regard to any further publication of the trial.

The following electronic databases were searched to identify relevant published literature for the period up to February 2005:

- MEDLINE
- EMBASE
- Cochrane Central Register of Controlled Trials (Issue 1, 2005)
- ISI Web of Knowledge: SCI Expanded.

All references were exported to EndNote reference database (Version 8, ISI Research Soft, California, USA).

Data extraction

Data extraction was carried out by one researcher (YD) and checked by a second (SD) using a pretested data extraction form. Any disagreements were resolved through discussion.

Data were extracted from the clinical effectiveness component of the review relating to:

- number of trials identified, number of trials available as abstracts/presentations and number of subsequent full reports
- whether and how meeting abstracts/presentations had been assessed for inclusion

- whether and how quality of RCTs available as abstracts/presentations had been assessed
- whether and how data from abstracts/presentations had been used in the analysis.

The following data were extracted from both abstracts/presentations and subsequent reports of the individual RCTs published in a peer-reviewed journal:

- numbers of participants
- interventions evaluated
- major outcome data.

The timeliness of availability of abstracts/presentations and full articles in relation to the development of TARs was also considered and data were extracted on the following:

- when the abstract/presentation appeared
- when the full article was published
- when the TAR would have been completed if delayed until all sources of evidence were published.

Methodological quality

Methodological quality of the RCTs included in the case studies, which were available as conference abstracts and presentations and subsequent full articles, is presented separately for each trial. Individual trial data from abstracts, presentations and subsequent full-text articles are presented separately in structured tables for all the studies included in the original TAR.

The quality assessment of trials was carried out independently by two researchers (YD and SD) for all included trials by extracting information from each abstract/presentation and newly identified subsequent full publication. For consistency, the methodological quality assessment criteria based on CRD Report 4[34] were used for all case studies.

Analysis of data from case studies

The degree of discrepancy between results obtained from conference abstracts, presentations and published reports included in three case studies was assessed. Data extracted were descriptively and quantitatively compared. Individual trial data are summarised in structured tables and as a narrative description. In addition, information is included regarding the availability and consistency of data to assess adequately the trial quality based on an abstract or conference presentation compared with subsequent full reporting of the trial.

To assess the impact of these data discrepancies on meta-analysis, sensitivity analyses of the key outcomes included in the TAR were carried out, comparing the following three scenarios by including data from:

- only full publications available at the time of the review (i.e. excluding abstracts/presentations)
- all sources included in the original meta-analysis in the review (i.e. including both abstracts/presentations and full publications)
- all full papers published to date (i.e. excluding abstracts/presentations).

Results

Thirteen TARs[35–47] evaluating RETs were identifed. Of these, only three cases[35,39,41] had identified and included RCT data from conference abstracts/presentations and carried out a quantitative analysis that included data from these sources. These three TARs were used as case studies.

The three case studies are:

- Anakinra in rheumatoid arthritis.[35]
- Infliximab and etanercept in rheumatoid arthritis.[41]
- Systematic review of coronary artery stents.[39]

Case study 1: Systematic review of anakinra for the treatment of rheumatoid arthritis in adults

This review was published in May 2004, and was conducted to assess the clinical and cost-effectiveness of anakinra, an interleukin-1 receptor antagonist (IL-1 Ra), for the treatment of rheumatoid arthritis (RA) in adults.[35]

Methods for reviewing clinical effectiveness reported in the review

Search strategy

Sensitive (i.e. comprehensive) rather then specific (i.e. aiming to exclude irrelevant records) search strategies were used. Electronic searches included MEDLINE, EMBASE, SCI, NRR, Database of Abstracts of Reviews of Effectiveness (DARE) and ISTP, and covered the period from 1966 to November 2002. No language or age restrictions were applied.

Explicit searches to identify other relevant studies available as abstracts included electronic searching

of proceedings from rheumatology meetings, and use of a meta-search engine to search the Internet. In addition, handsearching of Food and Drug Administration (FDA) submissions for new drug applications, European Agency for the Evaluation of Medicinal Products (EMEA) reports and pharmacological company submissions to NICE was carried out.

Inclusion criteria

RCTs were considered eligible for inclusion if they met the following inclusion criteria:

- population: adults aged 18 years and above with RA
- intervention: anakinra (kineret) alone or in combination with other drugs
- comparator: placebo, or other drug treatments for RA
- study design: randomised or quasi-randomised controlled trials
- publication: all data were included irrespective of publication status
- outcomes: mortality, morbidity (e.g. disability/mobility, disease progression, joint damage, pain, adverse events), composite response rates and quality of life.

Exclusion criteria

RCTs that recruited children with juvenile idiopathic arthritis, those with no comparator arm, and articles reporting only on laboratory measures aimed at investigating disease or treatment mechanisms were excluded from the review.

Quality assessment

The reviewers independently assessed the methodological quality of included trials using the Jadad checklist and calculated 5-point methodological quality scores, where a score of five represents trials of the highest quality. This checklist examines the methods of randomisation, concealment of treatment, blinding, losses to follow-up and methods of analysis.

Data synthesis

Data were pooled to obtain a summary measure of treatment effect. Three outcomes, Health Assessment Questionnaire (HAQ), patient global assessment and swollen joint counts, were reported as continuous data. Three other outcomes, described by the American College of Rheumatology (ACR) as ACR20, ACR50 or ACR70 (where figures refer to percentage improvement in the clinical measures), were presented as binary data.

Trials included and sources of evidence in the review

Included studies

The review included five RCTs. Two short-term, dose-ranging, placebo-controlled trials (0560 and 0182) evaluated the efficacy of anakinra monotherapy and three studies (0180, 0145 and 0757) evaluated anakinra in combination with other disease-modifying antirheumatic drugs (DMARDs), one of which was a safety trial (0757). A summary of RCTs included and data sources identified in the review is provided in *Table 8*, and *Table 31* in Appendix 3.

Sources of evidence

Of the five included trials, only two efficacy studies, by Bresnihan (0560) and by Cohen (0180), were fully published in peer-reviewed journals. The one efficacy trial (0145) and the safety trial (0757) were not published in full and were only available as conference abstracts. Of these, interim data were available for trial 0145 and for the safety trial (0757). There were no conference abstracts or presentations identified for trial 0182. At the time of preparation of the review, the assessment group also had access to the clinical trial reports on four trials (including trial 0182), provided in confidence by the pharmaceutical manufacturers. These reports were used in conjunction with the data from conference abstracts and published trial reports.

A total of ten conference abstracts relating to four studies (0560, 0180, 0145 and 0757) was included in the review. Nine of these were presented in conferences in 2001 and one in 2002. One abstract (by Shergy) listed as an included source for the trial 0145 was cited in error and relates to another trial. The TAR team identified a number of duplicate publications, which included abstracts for trials subsequently published in full, abstracts on the same data presented at more than one meeting, and full reports of the same trial published in more than one journal. Fully published papers reporting on the same trial were included (if available) where outcome data were presented in different publications. In the case of duplicate abstracts, data from the most recent abstract were included. Where there were duplicates of fully reported trials the original report was considered in the TAR.

Subsequent publications identified

Two further full publications were identified, published in 2003 (0757, Fleischmann) and 2004 (0145, Cohen) (*Table 31* in Appendix 3). Trial 0182 remains unpublished.

TABLE 8 *Anakinra review: trials included and data sources identified*

Study name	Abstracts included in review (*n*)		Year(s) published/ presented	Full publications included in review (month/year published)		Subsequent publications identified (month/year published)	
0560 Bresnihan *et al.*	Abstract	3	2001	Full paper	December 1998		
0182	Unpublished			Unpublished			Unpublished
0180 Cohen *et al.*	Abstract	2	2001	Full paper	March 2002		
0145 Cohen *et al.*	Abstract	1	2001–2002			Full paper	September 2004
0757 Fleischmann *et al.*	Abstract	3	2001			Full paper	April 2003
Total	Abstract	9		Full paper	2	Full paper	2

TABLE 9 *Anakinra review: summary of quality assessment of included trials by data sources*

Checklist items[a]		Abstracts *n*/*N* (%)	Full papers
Randomisation	Truly random	0/9	0/4
	Allocation concealment	0/9	0/4
	Number stated	7/9 (78%)	4/4 (100%)
Baseline comparability	Presented	3/9 (33%) (All partly addressed)	4/4 (100%)
	Achieved	1/9 (11%) (As stated)	4/4 (100%)
Eligibility criteria		5/9 (56%) (Partly addressed in 3)	4/4 (100%)
Co-interventions identified		3/9 (33%) (Partly addressed in 1)	4/4 (100%)
Blinding	Assessors	1/9 (11%)	3/4 (75%)
	Administration	1/9 (11%)	2/4 (50%)
	Participants	2/9 (22%)	4/4 (100%)
	Process assessed	0/9	0/4
	Not stated	6/9 (67%)	0/4
Withdrawals	>80% in final analysis	2/9 (22%)	4/4 (100%)
	Reasons stated	1/9 (11%)	4/4 (100%)
ITT		0/9	3/4 (75%)

[a] Based on CRD Report 4[34] (Appendix 4).

Quality assessment

Quality assessment of included trials

A summary of quality assessment according to data sources is available in *Table 9*. The methodological quality of trials using available sources to date is presented in *Table 10*.

It should be noted that the assessment team had access to the data for all included trials supplied by the pharmaceutical manufacturers at the time of the original review. Quality assessment of trials was primarily based on these sources that were used in conjunction with the data available from

TABLE 10 *Anakinra review: quality assessment of included trials available as abstracts and full publications*

			Randomisation			Baseline comparability		Eligibility criteria		Blinding				With-drawals		
Trial name	**Data sources**	**Checklist items**	**Truly random**	**Allocation concealment**	**Number stated**	**Presented**	**Achieved**	**Eligibility criteria specified**	**Co-interventions identified**	**Assessors**	**Administration**	**Participants**	**Procedure assessed**	**>80% in final analysis**	**Reasons stated**	**ITT**
0560	Abstract	Bresnihan, 2001	NS	NS	✓×	✓	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS
Bresnihan	Abstract	Bresnihan, 2001a	NS	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
et al.	Abstract	Emery, 2001	NS	NS	✓×	NS	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS
	Full paper	Bresnihan, 1998	NS	NS	✓	✓	✓	✓	✓	✓	NS	✓	NS	✓	✓	NS
0180	Abstract	Cohen, 2001	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Cohen	Abstract	Cohen, 2001a	NS	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
et al.	Full paper	Cohen, 2002	NS	NS	✓	✓	✓	✓	✓	✓	×	✓	NS	✓	✓	✓
0145	Abstract	Cohen, 2001	NS	NS	✓	NS	✓	✓	✓	✓	×	✓	NS	✓	NS	NS
Cohen	Full paper	Cohen, 2004	NS	NS	✓	✓	✓	✓	✓	✓	×	✓	NS	✓	✓	✓
et al.																
0757	Abstract	Fleischmann, 2001	NS	NS	✓	✓×	✓	✓	✓×	NS	NS	NS	NS	✓	✓×	NS
Fleischman	Abstract	Fleischmann, 2002	NS	NS	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
et al.	Abstract	Tesser, 2002	NS	NS	✓	NS	NS	✓×	✓	NS	✓	✓	NS	NS	NS	NS
	Full paper	Fleischmann, 2003	NS	NS	✓	✓	✓	✓	✓	×	✓	✓	NS	✓	✓	✓
0182		Unpublished														

✓, yes (item adequately addressed); ×, no (item not adequately addressed); ✓/× partially (item partially addressed), NS, not stated (Appendix 4).

the conference abstracts and two papers published in full.[35] The assessment of trial 0182 was solely based on the data supplied from the pharmaceutical company as this trial had never been published.

Results

A total of nine abstracts belonging to four trials was included in the review. Overall quality of reporting in abstracts was poor compared with the subsequent publications included in the review. The exception is that items relating to the method of randomisation were poorly reported in both abstracts and full publications. In each trial, although it was stated that the treatment allocation was randomised, none of the abstracts or full reports described the method used for randomisation or concealment of allocation of treatment. In two abstracts only the number of participants randomised in the trial was stated. No details of quality of the trial were reported in one other abstract.

Although seven (78%) abstracts stated the total number of participants randomised, in six of these patient numbers allocated to each treatment group were not stated. Baseline comparability was not presented in six and was only partially addressed in the remaining three abstracts. Eligibility criteria were reported in five (56%) abstracts; in three of these this was partly addressed. In six abstracts the trial was described as double-blinded, whereas there was no mention of blinding in the remainder. However, it was unclear from the abstracts whether it was the participants, administrators or outcome assessors who were blinded to the treatment allocation.

The use of intention-to-treat (ITT) analysis was explicitly stated in three full publications. None of

the conference abstracts reported the use of ITT analysis.

Data discrepancies

Outcome data were extracted from each conference abstract and subsequent full publication included in the review (*Table 34*, *Appendix 5*). No discrepancies were identified in the outcome data reported in any of these sources.

Data analysis

Pooled analyses for ACR improvements were presented in the review as both relative risk and risk difference. Meta-analyses figures presented in the review indicate that two conference abstracts of two studies (trial 0145 by Cohen, 2001, and trial 0757 by Fleischmann, 2001) were used as the source of data. A closer examination of data available in these abstracts revealed that the number of patients randomised to each treatment arm was not reported in either of these sources. It is most likely that the assessment team used the outcome data from these trials that were available in the manufacturers' submissions to NICE. As there were no discrepancies in data between abstracts and their subsequent full publications, sensitivity analyses were not carried out to determine the effect of inclusion of these abstracts in the analyses.

Case study 2: Systematic review of infliximab and etanercept

This review[41] was published in September 2002, and was carried out to assess the clinical and cost-effectiveness of infliximab and etanercept in the treatment of RA in adults.

Methods for reviewing clinical effectiveness reported in the review

Search strategy

The literature review was based on a search of a range of databases. Electronic searches included MEDLINE, EMBASE, SCI, Cochrane Library and NRR, and covered the period from 1966 to March 2001. Searches were based on medical subject headings and keywords that included rheumatoid arthritis, tumour necrosis factor (TNF), anti-TNF, quality of life, etanercept and infliximab.

Handsearching of three rheumatology meetings was conducted for the years 1999–2001. Pharmaceutical manufacturer and sponsor submissions to NICE and the FDA website were examined for information on clinical trials.

Inclusion criteria

RCTs were considered eligible for inclusion if they fulfilled the following inclusion criteria:

- population: adults with RA
- intervention: infliximab or etanercept
- comparator: placebo, or other drug treatments for RA
- study design: randomised or quasi-randomised controlled trials
- publication: all data were included irrespective of publication status
- outcomes: mortality, morbidity (e.g. disability/mobility, disease progression, joint damage, pain, adverse events), composite response rates and quality of life.

Exclusion criteria

RCTs comparing etanercept or infliximab in childhood arthritis, Crohn's disease, psoriatic arthritis or other forms of spondyloarthiritis, RCTs reporting only laboratory measures and observational studies of anti-TNF therapies that did not include a control group were excluded from the review.

Quality assessment

The reviewers independently assessed the methodological quality of included trials using the Jadad checklist.

Data synthesis

Meta-analyses included six measures of treatment effect and combined treatment arms where different drug doses were used. Three outcomes, HAQ, patient global assessment and swollen joint counts, were reported as continuous data. Three other outcomes, the ACR20, ACR50 and ACR70, represent an overall measure of treatment effect and were presented as binary data.

Trials included and sources of evidence in the review

Included studies and sources of evidence

Ten RCTs of anti-TNF therapy met the inclusion criteria. Of these, four [Elliott, 1994; Maini, 1998, Kavanaugh, 2000; Anti-TNF Trial in Rheumatoid Arthritis with Concomitant Therapy (ATTRACT)] focused on infliximab and six [Moreland, 1996; Moreland, 1997; Moreland, 1999, Weinblatt, 1999; European Investigators Group Study (EIGS); Etanercept Early RA (ERA) trial] on etanercept.

Sources of evidence

The assessment team identified 80 abstracts of conference proceedings by handsearching. However, the majority of these were excluded from

TABLE 11 *Infliximab and etanercept review: trials included and data sources identified*

Trial name	Abstracts included in review (n = 4)		Year(s) published/ presented	Full publications identified (month/year published)	Subsequent publications (month/year published)
ATTRACT	Abstract	2	2000	Full paper December 1999 Full paper November 2000	
EIGS	Abstract	2	1999–2000		Remains unpublished
ERA				Full paper 2000	
Elliott, 1994				Full paper 1994	
Maini, 1998				Full paper 1998	
Kavanaugh, 2000				Full paper 2000	
Moreland, 1996				Full paper 1996	
Moreland, 1997				Full paper 1997	
Moreland, 1999				Full paper 1999	
Weinblatt, 1999				Full paper 1999	
Total	Abstract	4		Full paper 10	

the review as they were duplicate publications or included non-RCT data or data superseded by subsequent publications. One abstract (Ericson, 1999) was cited in the review as an included source, but was also listed as excluded in the appendices. The review team included only the most recent abstract where identical data was presented at more than one meeting. Abstracts were only included if pertinent outcome data, not found in other sources (e.g. published trial reports or industry submissions), were presented.

A total of 18 reports with potentially relevant data was included in the review. These included ten fully published reports of nine studies and four conference abstracts of two studies (*Table 11*). The remainder were the internal clinical trial reports supplied by the pharmaceutical manufacturers that provided more detailed information on the ten included RCTs.

The ATTRACT trial was available as both abstracts and full reports (full reports were used for data extraction). The EIGS trial was not published in full and was only available as published abstracts of conference proceedings. The unpublished data from key trials, provided by the pharmaceutical manufacturers, were used in conjunction with the data from published trial reports.

Subsequent publications identified

The primary author of the EIGS has confirmed that this trial remains unpublished. No other subsequent publications were identified for the remaining trial.

Quality assessment

Quality assessment of included trials

A summary of quality assessment according to data sources is available in *Table 12*. The methodological quality of trials using available sources to date is presented in *Table 13*.

All trials included in the original review scored 5/5 on the Jadad scale. However, it should be noted that the assessment team had access to the unpublished data for all included trials which were provided by the pharmaceutical manufacturers at the time of the review. Quality assessment of trials for the most part was based on these sources, which were used in conjunction with the data available from the conference abstracts and two papers published in full.[41] The present review reports only data from sources that were both available as abstracts and/or subsequent full reports published in peer-reviewed journals included in the review.

In total, four abstracts belonging to two studies were included in the review. Of these, one abstract, although cited in the data extraction tables and meta-analyses in the review, was later listed as an excluded source in the appendix.

The reviewers' ability to judge the methodological quality of trials was considerably limited by the available information in the abstracts. None of the abstracts reported the participants' baseline characteristics or information regarding follow-up. One out of four abstracts stated the number of patients randomised but did not provide

TABLE 12 *Infliximab and etanercept review: summary of quality assessment of included trials available as abstracts and full publications*

Checklist items[a]		Abstracts, *n*/*N* (%)	Full papers, *n*/*N* (%)
Randomisation	Truly random	0/4	0
	Allocation concealment	0/4	0
	Number stated	1/4 (25%) (Partly addressed)	2/2 (100%)
Baseline comparability	Presented	0/4	2/2 (100%)
	Achieved	0/4	2/2 (100%)
Eligibility criteria		0/4	2/2 (100%)
Co-interventions identified		0/4	2/2 (100%)
Blinding	Assessors	0/4	2/2 (100%)
	Administration	2/4 (50%)	2/2 (100%)
	Participants	2/4 (50%)	2/2 (100%)
	Process assessed	0/4	0/2
	Not stated	2/4 (50%)	0/2
Withdrawals	>80% in final analysis	0/4	2/2 (100%)
	Reasons stated	2/4 (50%) (All partly addressed)	2/2 (100%)
ITT		0/4	2/2 (100%)

[a] Based on CRD Report 4[34] (Appendix 4).

TABLE 13 *Infliximab and Etanercept review: quality assessment of included trials available as abstracts and full publications*

			Randomisation			Baseline comparability		Eligibility criteria		Blinding				With-drawals		
Trial name	**Data sources**	**Checklist items**	**Truly random**	**Allocation concealment**	**Number stated**	**Presented**	**Achieved**	**Eligibility criteria specified**	**Co-interventions identified**	**Assessors**	**Administration**	**Participants**	**Procedure assessed**	**>80% in final analysis**	**Reasons stated**	**ITT**
ATTRACT	Abstract	Antoni, 2000	NS	NS	NS	NS	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS
	Abstract	Kavanaugh, 2000	NS	NS	✓×	NS	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS
	Full paper	Maini, 1999	NS	NS	✓	✓	✓	✓	✓	✓	✓	✓	NS	✓	✓	✓
	Full paper	Lipsky, 2000	NS	NS	✓	✓✓	✓	✓	✓	✓	✓	NS	✓	✓	✓	
EAIS	Abstract	Ericson, 1999	NS	NS	NS	NS	NS	✓×	NS	×	✓	✓	NS	NS	✓×	NS
	Abstract	Wajdula, 2000	NS	NS	NS	NS	NS	✓×	NS	×	✓	✓	NS	NS	✓×	NS

✓, yes (item adequately addressed); ×, no (item not adequately addressed); ✓/× partially (item partially addressed), NS, not stated (Appendix 4).

information on patient numbers for each treatment arm. The method of randomisation and concealment of allocation of treatment was not reported in any of the abstracts or full publications. In two abstracts, there was no mention of the blinding procedure. None of the abstracts stated the use of ITT analysis.

Data discrepancies

Outcome data were extracted from each conference abstract and subsequent full publication included in the review (*Table 35*, Appendix 4). No discrepancies were identified in the outcome data reported in any of the sources.

Data analysis

Pooled analyses for ACR improvements were presented in the review as both relative risk and risk difference. Meta-analyses figures presented in the review indicate that one conference abstract of a trial by the European Etanercept Investigators Group (Ericson, 1999) was used as the source of data. This abstract was later listed as an excluded source in the review. A closer examination of data available in this abstract showed that the number of patients randomised to each treatment arm was not reported in this source. The assessment team probably used the relevant outcome data for this trial from the manufacturers' submissions to NICE. Therefore, sensitivity analyses were not carried out to determine the effect of inclusion of this abstract in the analyses.

Case study 3: Systematic review of drug-eluting stents

This review[39] was part of the systematic review of coronary artery stents, published in September 2004, and was conducted to assess the clinical and cost-effectiveness of the use of drug-eluting stents (DES) compared with non-DES in patients with coronary artery disease.

Some of the authors of the DES review are also authors of this report.

Methods for reviewing clinical effectiveness reported in the review

Search strategy

General search strategies in the DES review included electronic databases [MEDLINE, EMBASE, Web of Science, CCTR, Cochrane Database of Systematic Reviews (CDSR), HTA and DARE] and covered the period from 1990 to December 2002. Explicit searches were carried out to identify other relevant studies published as abstracts or available as conference presentations. These included electronic searches (SCI/ISI Proceedings), and handsearching of recent issues of cardiology journals (including supplement issues) and six Internet-based cardiology conference proceedings.

Inclusion criteria

RCTs were included in the review if they met the following criteria:

- population: adults with coronary artery disease, patients with stable angina or acute coronary syndrome [includes acute myocardial infarction (MI) and unstable angina]
- comparators: non-DES versus DES
- study design: RCTs
- publication: all data were included irrespective of publication status
- outcomes: death, AMI, event rate (composite of adverse events), and restenosis (renarrowing or blockage of a coronary artery).

Exclusion criteria

RCTs that were continuing to recruit patients or those reporting only unplanned, interim findings or data on only a subgroup of patients were excluded from the review.

Quality assessment

The review team independently assessed the included trials for methodological quality using the quality assessment checklists for clinical studies based on CRD Report 4.

Data synthesis

Meta-analysis was presented in the assessment report for event rate, mortality, acute MI and binary restenosis. Data were pooled in the form of odds ratios (OR) and 95% confidence intervals (CIs) were estimated using a fixed-effect model.

Trials included and sources of evidence in the review

Included studies

Of 12 RCTs included in the DES review, seven (ASPECT, DELIVER, ELUTES, PATENCY, TAXUS I, TAXUS II, SCORE) focused on stents eluting taxane compounds (paclitaxel, 7-hexanolytaxol), four (E-SIRIUS, FUTURE, RAVEL, SIRIUS) investigated sirolimus or everolimus-eluting stents, and one trial involved actinomycin-dosed stents (ACTION).

Three trials (ASPECT, ELUTES and SCORE) evaluated the effects of differing doses of the same agent, and TAXUS II evaluated the effects of slow

TABLE 14 *DES review: trials included and data sources identified*

Trial name	Abstracts/ presentations identified in review (*n*)		Year(s) published/ presented	Full publications identified in review (month/year published)		Subsequent publications identified (month/year published)	
ACTION	Abstract Presentation	0 2	 2002	Not available		Full paper	October 2004
ASPECT	Abstract Presentation	5 2	2001–2002 2001–2002	Not available		Full paper	April 2003
DELIVER	Abstract Presentation	1 3	2002 2003	Not available		Full paper Presentation	April 2004 2003
ELUTES	Abstract Presentation	5 3	2001–2002 2002	Not available		Full paper	February 2004
PATENTCY	Abstract Presentation	0 1	2002	Not available		Trial suspended	
TAXUS I	Abstract Presentation	1 4	2001 2002	Full paper	January 2003		
TAXUS II	Abstract Presentation	0 2	2002–2003	Not available		Full paper Presentation	August 2003 2003
SCORE	Abstract Presentation	7 2	2001–2002 2002	Not available		Full paper	October 2004
RAVEL	Abstract Presentation	7 0	2001–2002	Full paper	June 2002		
SIRIUS	Abstract Presentation	2 3	2002 2002	Not available		Full paper Full paper	October 2003 February 2004
E-SIRIUS	Abstract Presentation	1 0	2002	Not available		Full paper	October 2003
FUTURE	Abstract Presentation	1 1	2002 2002	Not available		Full paper Presentations (2)	May 2004 2003
Total	Abstract Presentation	30 23		Full paper	2	Full paper Presentation	10 4

and moderate drug release. The results from these trials were combined in the review for the purposes of the analysis.

Sources of evidence

Of the 12 included RCTs, only two (RAVEL and TAXUS I) were fully published in peer-reviewed journals at the time of the submission of the DES review (February 2003). Sources of information primarily included conference abstracts, Internet-based conference sites (i.e. conference presentations, reports) and confidential data provided by pharmaceutical manufacturers to NICE (RAVEL, SIRIUS, E-SIRIUS).

A total of 30 conference abstracts and 23 presentations was identified in the review. A summary of included RCTs and data sources identified at the time of the DES review is provided in *Table 14*, and *Table 33* in Appendix 3.

Subsequent publications identified

Two further trials were identified that had been published in full in peer-reviewed journals by the time the NICE guidance was issued on the use of coronary artery stents in October 2003. By the end of 2004, all but one trial had been fully published (*Table 14*). In addition, four further conference presentations of three studies included in the review were identified.

PATENCY has not yet been published as the trial was suspended owing to low efficacy. Recruitment

TABLE 15 *DES review: summary of quality assessment of included trials by data sources*

Checklist items[a]		**Abstracts, *n/N* (%)**	**Presentations, *n/N* (%)**	**Full papers, *n/N* (%)**
Randomisation	Truly random	0/30	0/27	6/12 (50%)
	Allocation concealment	0/30	0/27	7/12 (58%)
	Number stated	18/30 (60%)	18/27 (67%)	12/12 (100%)
Baseline comparability	Presented	5/30 (17%) (All partly addressed)	18/27 (67%) (Partly addressed in 1)	12/12 (100%)
	Achieved	8/30 (27%) (Partly addressed in 6)	18/27 (67%) (Partly addressed in 6)	12/12 (100%) (Partly addressed in 2)
Eligibility criteria		17/30 (57%) (Partly addressed in 12)	15/27 (56%) (Partly addressed in 5)	12/12 (100%) (Partly addressed in 1)
Co-interventions identified		9/30 (30%)	5/27 (19%)	11/12 (92%)
Blinding	Assessors	5/30 (17%)	8/27 (30%)	3/12 (25%)
	Administration	10/30 (33%)	12/27 (44%)	9/12 (75%)
	Participants	13/30 (43%) (Partly addressed in 1)	18/27 (67%)	11/12 (92%)
	Process assessed	0/30	0/27	0/12
	Not stated	17/30 (57%)	7/27 (26%)	0/12
Withdrawals	>80% in final analysis	5/30 (17%)	21/27 (78%) (Partly addressed in 1)	12/12 (100%)
	Reasons stated	1/30 (3%)	4/27 (15%)	7/12 (58%) (Partly addressed in 1)
ITT		0	1/27 (4%)	8/12 (67%)

[a] Based on CRD Report 4[34] (Appendix 4).

in the ACTION trial was stopped after interim analysis of the first 90 enrolled patients showed a higher than average restenosis rate in patients randomised to both arms of the trial. This trial has now been published in full.

Quality assessment

Quality assessment of included trials

A summary of quality assessment according to data sources is available in *Table 15*. The methodological quality of studies according to their sources identified to date is presented in detail in *Table 16*.

The ability to judge the methodological quality of studies was limited by the available information at the time of preparation of this review. Many of the reports were only available as conference abstracts and presentations rather than as full peer-reviewed publications. In the original review, quality assessment was carried out for 11 studies using conference abstracts and presentations and data provided by pharmaceutical manufacturers. Only the RAVEL trial was available as a published journal article. TAXUS I was published in full after the quality assessment had been completed.

Results

The included trials scored well in general on key aspects of quality assessment (randomisation, blinding and follow-up). In each trial, the treatment allocation was randomised, although none of the abstracts and presentations described the method of randomisation or allocation concealment. Method of allocation concealment was reported in only seven studies published in full. Baseline comparability was only partially described in five (17%) and partly or adequately achieved in eight (27%) abstracts. This was partially reported in one (4%) and adequately presented in 17 (63%) presentations and partially (six) or adequately (12) achieved in 67% of the presentations. Eligibility criteria were presented in all full reports (partially presented in one report), and were at least partially or adequately presented in 57% (17/30) of the abstracts and 56% (15/27) of the presentations. There was no mention of

TABLE 16 *DES review: quality assessment of trials available as abstracts/presentations and full publications*

			Randomisation			Baseline comparability		Eligibility criteria		Blinding				Withdrawals		
Trial name	**Data sources**	**Checklist items**	**Truly random**	**Allocation concealment**	**Number stated**	**Presented**	**Achieved**	**Eligibility criteria specified**	**Co-interventions identified**	**Assessors**	**Administration**	**Participants**	**Procedure assessed**	**>80% in final analysis**	**Reasons stated**	**ITT**
ACTION	Presentation	Linnemeier, 2002	NS	NS	NS	×	NS	×	×	×	×	✓	NS	NS	NS	NS
	Presentation	Serruys, 2002	NS	NS	NS	✓	✓	✓	×	×	×	✓	NS	✓	×	NS
	Full paper	Serruys, 2004	✓	NS	✓	✓	✓	✓	NS	×	×	✓	NS	✓	✓	✓
ASPECT	Abstract	Shim, 2001	NS	NS	NS	×	NS	✓×	×	NS	NS	NS	NS	NS	NS	NS
	Abstract	Park, 2001	NS	NS	NS	×	NS	✓	✓	✓	✓	✓	NS	NS	NS	NS
	Abstract	Park, 2002	NS	NS	✓	×	NS	✓	✓	NS	NS	NS	NS	NS	NS	NS
	Abstract	Hong, 2002	NS	NS	✓	×	NS	✓×	✓	NS	NS	NS	NS	×	×	NS
	Abstract	Kaluza, 2002	NS	NS	✓	×	NS	×	×	NS	NS	NS	NS	NS	NS	NS
	Presentation	Park, 2001	NS	NS	✓	✓	✓	✓	✓	✓	✓	✓	NS	✓	×	NS
	Presentation	Lee, 2002	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	✓	×	NS
	Full paper	Park, 2003	NS	NS	✓	✓	✓	✓	✓	✓	✓	✓	NS	✓	×	✓
DELIVER	Abstract	Knopf, 2002	NS	NS	✓	×	NS	✓×	NS	NS	✓×	✓×	NS	NS	NS	NS
	Presentation	O'Neill, 2002	NS	NS	✓	NS	NS	✓×	NS	×	×	✓	NS	NS	NS	NS
	Presentation	O'Neill, 2003	NS	NS	✓	✓	✓	✓	✓	NS	NS	NS	NS	✓	NS	✓
	Presentation	Knopf, 2003a	NS	NS	NS	✓	✓	✓×	NS	NS	NS	NS	NS	✓	NS	NS
	Presentation	Knopf, 2003b	NS	NS	✓	✓	✓	✓	NS	×	×	✓	NS	✓×	NS	NS
	Full paper	Lansky, 2004	NS	NS	✓	✓	✓	✓	✓	NS	NS	✓	NS	✓	✓	✓
ELUTES	Abstract	Gershlick, 2001a	NS	NS	✓	×	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS
	Abstract	Gershlick, 2001b	NS	NS	✓	×	NS	✓×	NS	✓	✓	✓	NS	NA	NA	NS
	Abstract	De Scheerder, 2002	NS	NS	NA	NA	NA	✓	✓	✓	✓	✓	NS	NA	NA	NS
	Abstract	Chevalier, 2002	NS	NS	NS	×	NS	✓×	NS	✓	✓	✓	NS	NA	NA	NS
	Abstract	Gershlick, 2002	NS	NS	✓	×	NS	×	NS	✓	✓	✓	NS	NS	NS	NS
	Presentation	Gershlick, 2002	NS	NS	NS	✓	✓×	✓×	✓	✓	✓	✓	NS	✓	NS	NS
	Presentation	Chevalier, 2002	NS	NS	✓	✓	✓×	×	NS	✓	✓	✓	NS	✓	NS	NS
	Presentation	De Scheerder, 2002	NS	NS	NS	X	NS	X	NS	✓	✓	✓	NS	✓	✓	NS
	Full paper	Gershlick, 2004	✓	✓	✓	✓	✓×	✓	✓	✓	✓	✓	NS	✓	✓	✓
E-SIRIUS	Abstract	Schofer, 2002	NS	NS	✓	NA	NA	✓×	NS	×	✓	✓	NS	NA	NA	NS
	Full paper	Schofer, 2003	✓	✓	✓	✓	✓	✓	✓	NS	✓	✓	NS	✓	✓	✓
FUTURE	Abstract	Grube, 2002	NS	NS	✓	×	NS	✓×	NS	×	×	✓	NS	NA	NA	NS
	Presentation	Grube, 2002	NS	NS	×	✓	✓×	✓	NS	×	×	✓	NS	✓	NA	NS
	Presentation	Grube, 2003a	NS	NS	✓	×	NS	✓×	NS	NS	NS	NS	NS	✓	NS	NS
	Presentation	Grube, 2003b	NS	NS	✓	✓	✓×	✓	NS	×	×	✓	NS	✓	✓	NS
	Full paper	Grube, 2004	NS	NS	✓	✓	✓×	✓×	✓	×	×	✓	NS	✓	✓×	NS
PATENCY	Presentation	Heldman, 2002	NS	NS	✓	✓	✓×	✓×	NS	✓	NS	NS	NS	✓	✓	NS
RAVEL	Abstract	Sousa, 2001	NS	NS	✓	×	NS	✓×	✓	×	✓	✓	NS	NA	NA	NS
	Abstract	Reagar, 2002a	NS	NS	✓	×	NS	×	NS	NS	NS	NS	NS	✓	NA	NS
	Abstract	Reagar, 2002b	NS	NS	NS	×	NS	×	NS	NS	NS	NS	NS	NS	NS	NS
	Abstract	Degertekin, 2002a	NS	NS	NS	×	NS	×	NS	×	✓	✓	NS	NS	NS	NS
	Abstract	Degertekin, 2002b	NS	NS	NS	×	NS	NS	NS	NS	NS	NS	NS	✓	NA	NS
	Abstract	Abizaid, 2002	NS	NS	NS	×	NS	✓×	✓	NS	NS	✓	NS	✓	NA	NS
	Abstract	Colombo, 2002	NS	NS	✓	×	NS	✓	✓	×	✓	✓	NS	NS	NS	NS
	Full paper	Morice, 2002	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	NS	✓	NS	✓

continued

TABLE 16 *DES review: quality assessment of trials available as abstracts/presentations and full publications (cont'd)*

			Randomisation			Baseline comparability		Eligibility criteria		Blinding				With-drawals		
Trial name	**Data sources**	**Checklist items**	**Truly random**	**Allocation concealment**	**Number stated**	**Presented**	**Achieved**	**Eligibility criteria specified**	**Co-interventions identified**	**Assessors**	**Administration**	**Participants**	**Procedure assessed**	**>80% in final analysis**	**Reasons stated**	**ITT**
SCORE	Abstract	Kataoka, 2001a	NS	NS	NS	✓×	✓×	×	NS	NS	NS	NS	NS	×	NS	NS
	Abstract	Kataoka, 2001b	NS	NS	NS	✓×	✓×	×	NS	NS	NS	NS	NS	NA	NA	NS
	Abstract	Honda, 2002	NS	NS	✓	×	✓	×	NS	NS	NS	NS	NS	NA	NA	NS
	Abstract	Kataoka, 2002	NS	NS	NS	×	✓×	×	NS	NS	NS	NS	NS	NA	NA	NS
	Abstract	Lansky, 2002	NS	NS	✓	✓×	✓×	×	NS	NS	NS	NS	NS	×	NS	NS
	Abstract	Grube, 2002a	NS	NS	✓	✓×	✓×	×	NS	NS	NS	NS	NS	×	NS	NS
	Abstract	Grube, 2002b	NS	NS	✓	×	NS	×	NS	NS	NS	NS	NS	✓	✓	NS
	Presentation	Stone, 2002	NS	NS	✓	✓	✓	✓	NS	NS	NS	NS	NS	×	✓	NS
	Presentation	Grube, 2002	NS	NS	✓	✓	✓	×	NS	×	×	×	NS	✓	NS	NS
	Full paper	Grube, 2004	NS	NS	✓	✓	✓	✓	✓	×	×	×	NS	✓	✓	NS
SIRIUS	Abstract	Ako, 2002	NS	NS	×	✓×	✓×	×	NS	NS	NS	NS	NS	NS	NS	NS
	Abstract	Moses, 2002	NS	NS	✓	×	✓	✓×	✓	×	✓	✓	NS	✓	NS	NS
	Presentation	Leon, 2002a	NS	NS	✓	✓	✓	✓	✓	×	✓	✓	NS	×	NS	NS
	Presentation	Leon, 2002b	NS	NS	✓	✓×	✓×	×	NS	×	✓	✓	NS	✓	NS	NS
	Presentation	Moses, 2002	NS	NS	✓	✓	✓	✓	✓	×	✓	✓	NS	✓	NS	NS
	Full paper	Moses, 2003	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	NS	✓	NS	NS
	Full paper	Holmes, 2004	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	NS	✓	NS	NS
TAXUS I	Abstract	Grube, 2001	NS	NS	✓	×	NS	✓×	✓	NS	NS	NS	NS	NS	NS	NS
	Presentation	Grube, 2001	NS	NS	✓	×	NS	✓	NS	NS	✓	✓	NS	NS	NS	NS
	Presentation	Grube, 2002	NS	NS	NS	×	NS	✓×	NS	NS	NS	NS	NS	NS	NS	NS
	Presentation	Stone, 2002	NS	NS	✓	×	NS	×	NS	NS	NS	NS	NS	NS	NS	NS
	Presentation	Grube, 2003	NS	NS	✓	✓	✓	×	NS	×	✓	✓	NS	✓	NS	NS
	Full paper	Grube, 2003	NS	✓	✓	✓	✓	✓	✓	×	✓	✓	NS	✓	NS	NS
TAXUS II	Presentation	Colombo, 2002	NS	NS	NS	✓	✓	✓×	NS	✓	✓	✓	NS	✓	NS	NS
	Presentation	Colombo, 2003a	NS	NS	✓	×	NS	×	NS	✓	✓	✓	NS	✓	NS	NS
	Presentation	Colombo, 2003b	NS	NS	✓	✓	✓	×	NS	✓	✓	✓	NS	✓	NS	NS
	Full paper	Colombo, 2003	NS	✓	✓	✓	✓	✓	✓	✓	✓	✓	NS	✓	NS	✓

✓, yes (item adequately addressed); ×, no (item not adequately addressed); ✓/× partially (item partially addressed), NS, not stated (Appendix 4). NA, Not applicable.

blinding in nearly 57% (17/30) of the abstracts and in 22% (6/27) of the presentations. Only one presentation (4%) and eight (67%) full papers explicitly stated use of ITT analysis. Reasons for withdrawals from the trial were stated in only one abstract (3%) and four presentations (15%), and were reported in seven (58%) full reports. It is interesting to note that although the conference presentation of FUTURE trial put forward the eligibility criteria and reasons for withdrawals adequately, these were only partially reported in its full subsequent report.

Data discrepancies

As previously stated, at the time of the writing of the DES review, ten out of 12 included trials were only available as conference abstracts or presentations rather than full-text journal articles. Therefore, the review team carried out data extraction relying primarily on conference presentations or PowerPoint slides from such presentations with only partial presentation of the data. It was found that nine of the 10 trials have now been published in full as peer-reviewed publications. Only the PATENCY trial remains unpublished, owing to suspension of the trial.

Outcome data were extracted from each conference abstract and presentation identified in the review and their subsequent full publications (*Tables 36–39* in Appendix 5).

Incomplete or inconsistent reporting of data was apparent between the electronic and printed abstract/presentation sources used. The overall quality of reporting in abstracts and presentations was generally poor, especially in abstracts, possibly because of limited space.

Data discrepancies identified between conference abstracts and presentations and their subsequent full publications are presented (highlighted in bold) in *Tables 40–43* in Appendix 5.

The majority of the inconsistencies found were between the conference slide presentations and data reported in published full-text reports. In nine trials reporting event rates (*Table 40*, Appendix 5), seven trials reporting mortality (*Table 41*, Appendix 5), seven trials reporting any MI (*Table 42*, Appendix 5) and three trials reporting binary stenosis (*Table 43*, Appendix 5), a trial result was inconsistent with that in the subsequently published full reports. There were often discrepancies in the numbers of patients reported in different conference presentations with no explanation for these differences. Examples include the ACTION trial, where one reference lists numbers in the stent allocation arm as 121, DES 2.5 µg as 120 and DES 10 µg as 119 participants, whereas another reference lists stent as 119 (and 118), DES 2.5 µg as 120 and DES 10 µg as 121 for patient allocations. In an abstract regarding SCORE for ACC 2002, numbers of participants reported for each intervention arm appear to be reversed (DES 134, stent 126), as in a presentation for Cardiovascular Research Foundation (CRF) Drug-Eluting Stent Symposium 2002 and other sources numbers reported are Stent 138, DES 128. Reasons for these differences remain unclear.

Possible reasons for discrepancies include:

- changes in nominators and denominators
- typographic errors
- change in definitions across abstracts/presentations and full publications (e.g. DELIVER reporting event rates) Some combined event rates differ in their inclusion of, for example, all-cause or cardiac deaths only or target vessel revascularisation or target lesion revascularisation
- selective reporting (e.g. DELIVER reporting mortality)
- unknown reasons (e.g. ACTION reporting any MI).

Data analysis

Meta-analyses are presented for event-rate, mortality, any MI and binary stenosis. Data are pooled using a fixed-effect model with odds ratios and 95% confidence intervals.

Using the data presented in the meta-analyses in the DES review, sensitivity analyses were carried out to determine the effect of inclusion and exclusion of data from conference abstracts and presentations on the meta-analysis pooled effect estimates.

Meta-analyses were also presented using the data from 11 trials that are currently published in full in peer-reviewed journals to determine whether it would make any difference if the review had been delayed until all trials were published.

Stents loaded with related compounds are labelled and grouped for ease of reference. Three trials (ASPECT, ELUTES and SCORE) evaluated the effects of differing doses of the same agent, and TAXUS II evaluated the effects of slow and moderate drug release. For the purposes of analysis, the drug groups within these trials have been combined.

Results of the meta-analysis are presented here in *Tables 17–26* and in forest plots in *Figures 2–11* in Appendix 6.

Event rates

All trials used a combination of major adverse events and thus the definition of event rates varied considerably across the studies. Given that death is an infrequent event, event rates are primarily comprised of the combination of repeat revascularisations and of any MI.

If data available at the time of review are limited to those from published papers only, there is a lack of evidence of a difference between treatments in the event rate in the short term (no events occurred in either group in the single published trial that reported this outcome during this period). There is no substantial difference in the overall pooled event rate and confidence interval in the short term between the groups when data from abstracts/presentations are also included in this analysis compared with only including data from full papers published to date.

At both 6 and 12 months, there were only two studies reporting data on this outcome at the time of the review, and the pooled effect size was

significantly in favour of DES. When data from abstracts/presentations are included, the effect size is still significant but moves closer to unity and the confidence interval is narrower owing to the increased information available. At 6 months, using data from published trials to date resulted in a very similar effect size and confidence interval to that published in the review that included both abstracts/presentations and papers. However, at 12 months, when data from fully published trials to date are included, the direction of effect is the same, but the result is no longer significant and there is a substantial increase in heterogeneity (I^2 = 91.4%). This is because data are now available from a trial (ACTION) that reported results in favour of non-DES.

Results of meta-analyses are available in *Tables 17–19* and are provided in forest plots in *Figures 2–11* in Appendix 6.

Summary
Excluding abstracts/presentations at the time of the review would lead to a lack of evidence of any difference between treatment groups in the short term instead of the marginally beneficial effect of non-DES over DES that was indicated in the review, but there would not be a substantial difference to the review at the other two time-points. If the review was carried out now including papers published to date only, the short-term and 6-month results would not differ largely from those that were published in the review, but the 12-month results would no longer be significant.

Mortality
If data available at the time of the review are limited to those from published papers only, there is a lack of evidence of a difference in the mortality rate between treatments groups in the short term, as no deaths occurred in either group in the two published trials that reported this outcome during this period. The point estimates are also very close to unity in the short term when data from all sources available at the time of the review were included (OR 1.03, 95% CI 0.28 to 3.81). When data from full papers published to date only are included the point estimate moves away from unity in favour of non-DES but remains non-significant (OR 1.59, 95% CI 0.44 to 5.74).

Only one trial that was published at the time of the review reported on this outcome, but no deaths occurred in either treatment, so as for the short term, the mortality rate at 6 months is not estimable when limiting data to those from published papers at the time of the review only. There is very little difference in the pooled odd ratios and 95% confidence intervals when data from all sources at the time of review and from full papers published to date are included.

At 12 months, when using data from published studies available at the time of the review, the short-term mortality rate, estimated from data from only one trial, is very close to unity. Inclusion of data from abstracts/presentations causes the pooled estimate to deviate substantially (but not significantly) away from unity in favour of non-DES, and data from the full published papers to date support this, although the pooled odd ratio is reduced slightly.

Results of meta-analyses are presented in *Tables 20–22*, and are available in forest plots in *Figures 5–7* in Appendix 6.

Summary
Excluding abstracts/presentations at the time of the review would lead to no evidence of a difference between treatment groups in the short term as was found in the review, and at 6 months, instead of the marginally beneficial effect of non-DES over DES that was indicated in the review, there would again be a lack of evidence of a difference between treatment groups. Similarly, at 12 months the large (but not significant) benefit in favour of non-DES that is suggested when abstracts/presentations were included in the review would not be supported. If the review was carried out now excluding abstracts/presentations, the direction of effect at the three time-points would be the same and the significance of results similar to that published in the review.

Myocardial infarction
The pooled estimate based on data from two full reports available at the time of the review indicates no difference between treatment arms in the short term. When data from abstracts/presentations are included, the difference between treatments increases in favour of non-DES, although it remains non-significant. However, this difference becomes significant when only using data from full published reports to date. This is because data reported in an abstract/presentation from one trial are not subsequently included in its full report.

No fully published papers available at the time of the review reported on this outcome at 6 months. The pooled estimate when abstracts/presentations

TABLE 17 *Event rate effect estimates (up to 36 days)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	1.11 (0.57 to 2.16)	6, 2059	46.4	Not estimable[a]	1, 61	NA	1.25 (0.70 to 2.24)	5, 1228	71.7
Rapamycin	1.62 (0.66 to 3.93)	2, 1094	NA	Not available			1.62 (0.66 to 3.93)	2, 1100	NA
Actinomycin	2.50 (0.29 to 21.64)	1, 360	NA	Not available			Not available		
Total	1.34 (0.80 to 2.24)	9, 3513	24.4	1.34 (0.80 to 2.24)			1.35 (0.83 to 2.20)	7, 2328	63.2

[a] No events reported in this trial in either arm.

TABLE 18 *Event rate effect estimates (6 months)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	0.48 (0.31 to 0.72)	5, 1014	38.1	0.18 (0.01 to 3.93)	1, 61	NA	0.68 (0.48 to 0.96)	5, 1215	75.1
Rapamycin	0.32 (0.23 to 0.45)	2, 1410	0	0.30 (0.16 to 0.57)	1[a], 352	NA	0.33 (0.23 to 0.46)	3, 1450	0
Actinomycin	2.66 (1.25 to 5.63)	1, 329	NA	Not available			Not available		
Total	0.49 (0.38 to 0.61)	8, 2753	78.1	0.29 (0.15 to 0.55)	2, 413	0	0.46 (0.36 to 0.58)	8, 2665	72.0

[a] E-SIRIUS was not published in full, but company data were available for event rates at 9 months.

TABLE 19 *Event rate effect estimates (12 months)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	0.80 (0.42 to 1.52)	3, 426	34.6	0.31 (0.03 to 3.17)	1, 60	NA	0.59 (0.42 to 0.83)	4, 1039	81.7
Rapamycin	0.32 (0.23 to 0.44)	2, 1296	0	0.26 (0.11 to 0.62)	1, 238	NA	0.15 (0.06 to 0.36)	1, 238	NA
Actinomycin	Not available			Not available			3.88 (2.09 to 7.22)	1, 343	NA
Total	0.38 (0.28 to 0.50)	5, 1722	54.6	0.26 (0.11 to 0.60)	2, 298	0	0.79 (0.61 to 1.02)	6, 1620	91.4

TABLE 20 *Mortality rate effect estimates (up to 36 days)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	0.79 (0.18 to 3.43)	6, 2043	0	Not estimable	1, 61	NA	1.39 (0.34 to 5.69)	5, 1228	0
Rapamycin	2.96 (0.12 to 72.84)	3, 1332	NA	Not estimable	1, 238	NA	2.96 (0.12 to 72.84)	3, 1338	NA
Actinomycin	Not estimable	1, 360	NA	Not available			Not estimable	1, 360	NA
Total	1.03 (0.28 to 3.81)	10, 3735	0	Not estimable	2, 299	NA	1.59 (0.44 to 5.74)	9, 2926	0

TABLE 21 *Mortality rate effect estimates (6 months)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	1.22 (0.55, 2.74)	7, 2309	0	Not estimable	1, 61	NA	1.70 (0.43 to 6.64)	5, 1214	0
Rapamycin	1.65 (0.39, 6.93)	1, 1058	NA	Not available			1.74 (0.51 to 5.98)	3, 1452	0
Actinomycin	1.10 (0.04, 27.35)	1, 329	NA	Not available			0.14 (0.01 to 3.43)	1, 342	NA
Total	1.31 (0.66, 2.59)	9, 3696	0	Not estimable	1, 61	NA	1.37 (0.59 to 3.19)	9, 3008	0

TABLE 22 *Mortality rate effect estimates (12 months)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	3.81 (0.71 to 20.38)	4, 692	0	Not estimable	1, 61	NA	5.13 (0.68 to 38.67)	3, 516	41.9
Rapamycin	1.48 (0.52 to 4.19)	2, 1296	0	0.98 (0.14 to 7.10)	1, 238	NA	1.48 (0.52 to 4.19)	2, 1296	0
Actinomycin	Not available			Not available			0.14 (0.01 to 3.57)	1, 343	NA
Total	2.05 (0.87 to 4.84)	6, 1988	0	0.98 (0.14 to 7.10)	2, 299	NA	1.67 (0.74 to 3.79)	6, 2155	13.5

are included is very similar to that obtained from data from papers published to date, indicating a non-significant difference between treatments, marginally in favour of non-DES.

At 12 months, the pooled estimate obtained from two published studies at the time of review indicates a marginal (but non-significant) benefit of DES over non-DES. When data from abstracts/presentations are included, the difference between treatments becomes significant in favour of non-DES. When data from papers published to date alone are used, the direction of effect remains in favour of non-DES, but is no longer significant.

Results of the meta-analysis are presented here in *Tables 23–25* and in forest plots in *Figures 8–10* in Appendix 6.

Summary
Excluding abstracts/presentations at the time of the review would mean that the 6-month estimates could not have been estimated. The short-term estimate would indicate no evidence of a difference between treatments, and at 12 months there would be a marginal (but not significant) effect of treatment in the opposite direction to that indicated in the review. If the review was carried out today including only published papers, the direction of effect for all results would be the same as observed in the review, but the significance of short-term and 12-month results would change compared with the review.

Binary stenosis

This outcome is reported only at 6–9 months in all data sources. Data from published studies available at the time of the review suggest a significant benefit of DES over stents with no heterogeneity across studies. Analyses of data from all sources available at the time of the review, and data from full papers published to date, also indicate a statistically significant difference in favour of DES, but the pooled estimates are slightly closer to unity and there is increased heterogeneity.

Results of meta-analyses are presented in *Table 26*, and forest plots are provided in *Figure 11* in Appendix 6.

Summary
Analyses of data when abstracts/presentations are included or excluded from sources available at the time of the review, and from papers published to date, all indicate a significant benefit favouring DES.

Summary

Through these case studies we assessed the ability to judge the quality of trials available as conference abstracts or presentations, the effect of inclusion of these sources on review conclusions in three case studies, and the timeliness of conducting the TAR.

Of the 13 TARs of RETs, there were only three that included abstract/presentation data in a quantitative analysis, and these were used as case studies. Two of these case studies did not use data from abstracts/presentations in their meta-analysis despite citing these sources in the forest plots. Therefore, the reviewers were unable to carry out further sensitivity analyses to assess the effect of including data from these sources on the review results. However, there were almost no data discrepancies found between the abstracts/presentations cited in these TARs and their subsequent full reports. This may be because the abstracts/presentations appear to be reporting final, rather than interim, results. Although these case studies could not be included in the discussion regarding the effect of data discrepancies, they are referred to when discussing the quality assessment issues.

The case study of DES is a very good example of an HTA appraisal that assesses an RET. The speed of development of the stent technology was such that, at the time of the preparation of this review, not only was there a rapid evolution of publications, but also new data were being released at regular intervals as part of specialist meetings.

The DES review was severely hampered by the non-availability of complete trial data. At the time of completion of the DES review in 2002, only two of the 12 included trials were published in full. The remaining trials were only available as conference abstracts or presentations, rather than as full peer-reviewed papers. Two further fully published trials were identified by the time the NICE guidance was issued on the use of coronary stents in October 2003, and by the end of 2004 all but one trial had been published in full.

It could be argued that conference presentations (available as electronic slides) are even less appropriate sources of evidence than abstracts as they are not easily obtainable because of lack of indexing, and are not often viewed as traditional sources of evidence. Although they tend to contain more trial results than abstracts, they do not

TABLE 23 *Myocardial infarction effect estimates (up to 36 days)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	2.12 (0.52 to 8.63)	5, 1507	0	Not estimable	1, 61	NA	3.92 (1.40 to 10.98)	4, 692	7.7
Rapanmycin	1.35 (0.62 to 2.96)	3, 1332	0	0.98 (0.19 to 4.97)	1, 238	NA	1.35 (0.62 to 2.96)	3, 1338	0
Actinomycin	1.49 (0.15 to 14.45)	1, 360	NA	Not available			Not available		
Total	1.52 (0.79 to 2.91)	9, 3199	0	0.98 (0.19 to 4.97)	2, 299	NA	2.12 (1.15 to 3.88)	7, 2030	14.3

TABLE 24 *Myocardial infarction effect estimates (6 months)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	1.38 (0.81 to 2.36)	6, 2248	72.4	Not available			1.56 (0.87 to 2.82)	4, 1153	80.4
Rapamycin	0.87 (0.43 to 1.75)	1, 1058	NA	Not available			1.09 (0.60 to 1.99)	3, 1450	32.4
Actinomycin	1.47 (0.16 to 13.32)	1, 329	NA	Not available			Not available		
Total	1.18 (0.78 to 1.78)	8, 3635	60.2				1.31 (0.86 to 2.00)	7, 2603	70.6

TABLE 25 *Myocardial infarction effect estimates (12 months)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	5.88 (2.35 to 14.73)	4, 692	31.7	Not estimable	1, 61	NA	2.02 (1.13, 3.61)	4, 1039	86.8
Rapamycin	0.89 (0.48 to 1.65)	2, 1296	0	0.78 (0.20 to 2.98)	1, 238	NA	0.85 (0.46, 1.57)	2, 1296	0
Actinomycin	Not available			Not available			1.75 (0.19, 15.88)	1, 343	NA
Total	1.85 (1.16 to 2.96)	6, 1988	70.8	0.78 (0.20 to 2.98)	2, 299	NA	1.36 (0.91, 2.04)	7, 2678	70.5

TABLE 26 *Binary stenosis effect estimates (12 months)*

Subcategory by drug	Including *both* abstracts/presentations *and* full papers			Including *only* full papers available at the time of DES review			Including *only* full papers published *to date*		
	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic	OR (95% CI)	No. of studies, patients	I^2 statistic
Taxane	0.22 (0.15 to 0.32)	6, 1164	57.7	0.12 (0.01 to 2.51)	1, 59	NA	0.41 (0.29 to 0.59)	5, 1028	62.5
Rapamycin	0.12 (0.08 to 0.17)	3, 1218	75.4	0.04 (0.02 to 0.10)	2, 517	5.1	0.06 (0.04 to 0.10)	3, 1047	0
Actinomycin	2.17 (0.93 to 5.07)	1, 292	NA	Not available			2.21 (0.95 to 5.15)	1, 293	NA
Total	0.21 (0.16 to 0.26)	8, 2674	83.5	0.05 (0.02 to 0.10)	3, 576	0	0.24 (0.19 to 0.31)	9, 2368	89.5

always include the same methodological detail. Therefore, the use of these data could be criticised. It would not, however, make sense to exclude the data from these sources because in an RET a conference abstract submitted in advance of a conference often does not contain sufficient data. At the time of preparation of the DES review, the assessment team had little option but to depend mostly on conference presentations or the slides from such presentations with only partial presentation of the data, which were sometimes of uncertain quality.

In all three case studies, incomplete reporting of the methodological details of the trial in conference abstracts (and presentations in the DES review) severely hampered the ability to judge key aspects of the quality assessment of the trials (randomisation, blinding and follow-up). The overall quality of reporting in these sources, particularly in printed conference abstracts, was generally poor.

None of the abstracts and presentations described the method of randomisation or allocation concealment and only a small number of abstracts presented baseline characteristics and comparability in the trial. There was no mention of blinding in nearly half of the abstracts and one-fifth of the presentations. The view that it is difficult to judge trial quality from abstracts is supported by other studies.[24–26] This may be because of limited space or because the data were not yet available or were not released at the time for commercial reasons.

Discrepancies were found in the DES review both between conference abstracts and presentations and later full publications. These discrepancies were usually small, but as the trials themselves were often small, a difference in reporting of, for instance, one death may be both clinically and significantly important. However, it is unlikely that these differences would alter the direction of effect or statistical significance in a meta-analysis.

Selective reporting (i.e. selection of a subset of the original variables recorded for inclusion in publication of trials) may lead to more substantial differences between sources, and different sources may typically report outcomes at different time-points. For example, shorter term results may appear in an abstract/presentation but not in the full paper. In addition, the definition of an outcome (e.g. composition of event rates) may vary across sources, leading to possible apparent discrepancies between them.

Sensitivity analyses were carried out to compare the effect on meta-analysis of including only full reports available at the time of the review, both full reports and abstracts/presentations as included in the review, or only full reports published by April 2005. In summary, the conclusions would have changed substantially in terms of direction of effect in one outcome at 12 months (MI) if abstracts/presentations had been excluded at the time of the review. Statistical significance varied in three outcomes (event rate at 12 months, and MI in the short term and at 12 months) across the three scenarios. These differences, as well differences observed in precision and I^2 between the three scenarios, resulted because including abstracts/presentations or more recently published trials increases the pooled sample size and available data.

Clinical and policy decisions on healthcare interventions need to be made according to best available evidence. There are concerns that evidence from studies available only as abstracts/presentations may potentially be inaccurate. It is well recognised that the methodological quality of abstracts is usually poorly reported and difficult to assess. However, there are also strong arguments for including such data in the case of RETs, particularly if there is a limited amount of fully published data. The case studies in this report confirm that quality assessment of abstracts/presentations is highly problematic, and that abstract/presentation data are often inconsistent with other abstracts/presentations from the same trial, or full publications. If abstracts/presentations include interim data from potentially large trials of high methodological quality, it may be worthwhile waiting for the trial to be completed and published in full before the TAR is undertaken.

However, another issue to consider is the effect of time-lag bias in publishing the results of trials. This may be important particularly in areas of RETs, as trials with significant results are more likely to be published as full journal articles, whereas trials with non-significant or null results may take longer to reach full publication, or may not be published at all.[6–8,10]

Chapter 6
Discussion

Study results available as conference abstracts/presentations are commonly identified in TARs. Results from the survey indicate that most TAR groups (five out of seven) reported a general policy regarding searching for abstracts. Six groups would routinely assess and use data from these sources, and the seventh group would do so if there was no other evidence available. In the audit, 38 (60%) TARs identified at least one RCT available as a conference abstract or presentation. Of these, 26 (68%) included trials available as abstracts/presentations.

Responses to the survey questionnaire indicate that approaches adopted by TAR teams regarding inclusion or exclusion of abstracts and presentations in the reviews vary considerably both across and within teams. These include (1) listing abstracts/presentations in an appendix, but excluding them from meta-analyses; (2) including abstracts/presentations in meta-analyses; and (3) including abstracts/presentations in the review depending on the availability of data from fully reported RCTs. In general, however, it appears that TAR teams adopt a pragmatic approach when conducting TARs. If there is published evidence in the relevant area, they indicated that they are not likely to include data from abstracts/presentations in their reviews, but if evidence is limited, they would.

As shown in the survey and audit, the reviewers apply the same quality assessment tools to conference abstracts and presentations as to full reports. It is rare to exclude any source of evidence purely because of poor quality assessment, and thus if the reviewers were able to quality assess these abstracts/presentations, the data would still be included even if these sources were found to be lacking in methodological quality. However, the reader would be made aware of the potential bias caused by inclusion of potentially unreliable studies and would take this into account when generalising the results.

Limited and insufficient information in abstracts/presentations inevitably constrains the ability of reviewers to judge confidently the methodological quality of a trial. This issue needs to be considered when assessing and including data from these sources. In all three case studies included in this study, the overall quality of reporting in abstracts and presentations was generally poor. In the DES review, this was more apparent in the conference abstracts than in the online conference presentations, possibly because of limited space available in abstracts. In all case studies abstracts and presentations failed to describe the method of randomisation or allocation concealment. Overall, there was no mention of blinding in 66% (25/38) of the abstracts and in 26% (7/27) of the presentations included in case studies, and one presentation (4%) explicitly stated the use of ITT analysis.

Results from the DES case study demonstrate discrepancies in data available in abstracts or online conference presentations. Not only are discrepancies evident between these sources, but also comparison of conference abstracts and presentations with subsequently published full-length articles indicates discrepancies in reporting of results. Even though these differences tend to be small and are therefore unlikely to make statistically significant changes to the overall pooled estimates, they may be clinically important.

The sensitivity analyses indicated a change in significance of two outcome measures (event rate and MI). The former showed a difference at one time-point (12 months) and the latter at two time-points (short term and 12 months).

Only using data from full papers published to date would not have altered the direction of effect of any of the results compared with those published in the original review. If abstracts/presentations were excluded from data available at the time of the review, the direction of effect, and hence the conclusions of the review, would not have changed substantially, except in one of the ten results (MI at 12 months).

It is important to note that sensitivity analyses could be carried out using only one case study. Findings from these analyses therefore may be of limited generalisability.

Another issue discussed in this study relates to the timeliness of conducting a TAR. That is, the implication of delaying the TAR until all sources

of evidence are published in full, and what difference this would make to the conclusions of the review. This issue could be investigated in only one case study (DES review). The other two case studies did not use data from abstracts/presentations in meta-analyses, despite giving references for these sources in the forest plots.

At the time of the original submission of the DES review to NICE in February 2003, full data were available from only two studies published in peer-reviewed journals. By the end of 2004, data from nine further trial reports, previously available as abstracts/presentations, were available. Sensitivity analyses were carried out to compare meta-analysis results from the review which included the original reports with and without data from abstracts/presentations. These analyses were then compared with meta-analysis of data from all 11 trials that are now published in full.

Limitations of the study

This study has a number of limitations. It has only looked at searching for and inclusion of RCTs available as abstracts/presentations for the clinical effectiveness part of the review, and has not considered other study designs identified as conference abstracts/presentations and included in TARs, for example non-randomised trials, cohort studies and case series.

The findings of this report related to searching, quality assessment and availability of data may not be generalisable to other clinical areas, or TARs including data from conference abstracts/presentations of studies other than RCTs. For instance, interim analysis may not be such an important issue for observational studies. However, searching and quality assessment may be more challenging for non-RCTs.

For case studies, only TARs that included meta-analysis were considered as it would be difficult to assess the influence of abstracts/presentations in narrative reviews. TARs that identified abstracts/presentations but excluded them from meta-analysis, were not considered either. One could argue that it might have been worthwhile extracting data from these sources and carrying out the meta-analysis including them, as well as searching for subsequently published papers of the trials identified as abstracts/presentations at the time of the review and carrying out meta-analysis including just full publications.

In addition, owing to the limitations of data in two of the case studies included in this study, it was not possible to address quantitatively the effect of the inclusion or exclusion of abstracts/presentations in these reviews.

Practice and policy implications

These findings have important implications in terms of identification and selection of studies for inclusion in TARs. Despite their methodological limitations, studies available as conference abstracts and presentations are commonly identified, and data from these sources are used in TARs. Both the exclusion and inclusion of studies available as abstracts/presentations create particular difficulties for reviewers, especially those assessing rapidly evolving health technologies.[48]

Development of effective and extensive search strategies (e.g. handsearching of journal supplements, conference books and sites) to identify studies available as abstracts or presentations, and subsequent retrieval of these sources, is a difficult and expensive undertaking which is often constrained by limitations of staff time. At present, there are no specific search strategies available for the identification of studies available as abstracts/presentations.

It is acknowledged that, ideally, high-quality systematic reviews should always identify and include all relevant studies, regardless of publication status. Where reviews are carried out within a limited timescale (as within the NICE appraisal process), exhaustive searching for conference abstracts and presentations that are not indexed in major electronic databases inevitably increases the use of limited resources. One of the key findings of a methodology review for NCCHTA carried out by Royle and Waugh[18] indicates that exhaustive searching beyond a small number of electronic databases (e.g. MEDLINE, EMBASE, CCTR and SCI) provides limited additional benefit. When searching for studies to be included in the review, TAR teams need to weigh up the potential benefits against the additional workload of exhaustive searching for abstracts/presentations in their reviews within the period available to complete the review.

The general finding of limited reporting of outcomes and information on details of trial methodology in conference abstracts and presentations is a source for concern in systematic reviews. The audit of completed TARs found that none of the TARs excluded a trial available as an abstract/presentation solely because of poor quality assessment. There is a possibility that bias could

be introduced into the review by including these studies, which may be of poor methodological quality.[20] There is evidence that poorer quality trials (especially those that did not have allocation concealment or double blinding) overestimate treatment effects; empirical studies indicate that reports of trials in which concealment is inadequate or unclear are associated with as much as 30% exaggeration of the treatment effect.[49] However, it should also be noted that poor reporting of methods does not necessarily reflect the conduct of the trial.[50]

As demonstrated in this study, conference abstracts and presentations almost never mention methods of allocation concealment, and only rarely mention blinding; hence it is not possible to assess these important aspects of quality. Inability to assess the quality of a trial included in the review may potentially lead to uncertainty regarding the reliability and validity of results and conclusions obtained from the review. One may argue that reviewers could acquire further information from the investigators, but this may be a difficult task and such attempts may not always be successful.[48,51–53]

In addition, because of a scarcity of relevant information about study characteristics in abstracts/presentations, different abstracts/presentations of one study may not be easily recognised as referring to the same study. Inclusion of duplicate publications unidentified as such would lead to biased estimates of the efficacy of an intervention through double-counting of patients.[54] As indicated by Egger and colleagues in their review on extensive searching,[20] careful assessment of methodological quality of included studies in the review should take priority over extensive literature searches in the TAR process where resources are limited.

The purpose of the TAR is to inform health policy decisions using best available evidence within the NICE appraisal process. However, NICE appraisals need to be timely, that is before the integration of RETs into clinical practice. This may lead to limited availability of published data and a requirement of TAR teams to include data from conference abstracts and presentations. There is a potential risk that exclusion of these sources may decrease the statistical power and precision of treatment effects in meta-analyses of results in the review.

There is also the issue of publication bias, as unpublished abstracts have been shown to be more likely to have negative or inconclusive effects compared with published trials in some reviews.[6,10] Similar arguments apply even in narrative reviews without quantitative synthesis. If very few published trials are identified, exclusion of data from trials available only as abstracts/presentations could potentially present a misleading picture of an intervention's efficacy.

In addition, of particular concern is the possibility that adverse events may be different in published compared with unpublished trials, and this may influence estimates of the risk–benefit ratio of new treatments.[55]

Another benefit of the use of abstracts/presentations is in their role related to identification of planned and ongoing trials. Conference abstracts and presentations are important sources of information regarding such trials, as they may present information regarding the design of a study and provide initial findings, as well as giving an indication as to when data from such studies will be available. However, recent developments in national and international trial registries and databases of ongoing trials have made it an easier task to identify such trials,[56] and major medical journals are changing policies to publish only trials that are registered. This may have implications in the future for identifying ongoing and unpublished trials without extensive searching for conference abstracts and presentations.

As part of the appraisal process,[32,33] before a decision is made on whether the technology appraisal is required, NICE undertakes an initial scoping exercise by carrying out a preliminary literature search and working with the TAR group. Manufacturers of the technology and groups that represent patients, carers and health professionals are then invited to attend a scoping workshop. This workshop is an opportunity to comment on the draft scope and other issues concerning the potential appraisal, including availability of existing evidence (e.g. published or unpublished ongoing trials). If the scoping workshop and initial searches of the existing literature fail to identify sufficient evidence or there are ongoing trials identified, for example in abstract/presentation form, it may be appropriate for NICE to adjust appraisal schedules to allow for inclusion of data.

There are also implications for the economic analyses of the review. Any evaluation of cost-effectiveness depends on the measure of clinical efficacy arising from the clinical data. In the case where conference abstracts and presentations

provide a significantly different picture of clinical efficacy in comparison with the subsequently published full-text articles, the danger arises of a misleading economic evaluation. If data from abstracts/presentations are included, it is important to carry out sensitivity analyses for both clinical and cost-effectiveness by including and excluding abstracts/presentations to determine whether the results are consistent under different inclusion criteria.

Finally, although data for this research were obtained exclusively from TARs that were associated with the NICE appraisal process, it is reasonable to believe that these results are also generalisable to the preparation of health technology assessments in general, and thus may have broader implications for the general conduct of systematic reviews.

Chapter 7
Conclusions

Several issues involved in the use of conference abstracts and presentations in TARs have been identified in this report as being particularly challenging (*Table 27*).

It was evident from the survey and audit that there are variations in policy and practice across TAR groups regarding searching for and inclusion of studies available as conference abstracts and presentations. Evidence from the audit reflects this variation in the TAR reports. It would be appropriate to establish a standard practice regarding searching for and inclusion of abstracts/presentations. However, there is a need for clarity and transparency related to the research process. Therefore, TAR groups should be encouraged to state explicitly their search strategies for identifying conference abstracts and presentations, their methods for assessing these for inclusion, and where appropriate how the data were used and their effect on the results.

Comprehensive searching for trials available as conference abstracts and presentations is time-consuming and may be of questionable value, particularly where there are published studies with sufficient data available. Given the time constraints and difficulties involved in locating

TABLE 27 *Outline of the pros and cons of searching for and inclusion of abstracts/presentations*

Searching for abstracts/presentations		**Inclusion of data from abstracts/presentations**	
Pros	**Cons**	**Pros**	**Cons**
Minimises publication bias (only half of abstracts are published in full)	Time-consuming (e.g. handsearching journal articles, conference books)	Increases the statistical power in meta-analysis	Difficult to assess methodological quality of studies (limited detail to allow critical appraisal)
Identifies ongoing trials and gives an indication as to when data will be available	Search strategies are difficult to design (e.g. search filters)	Increases the precision (i.e. narrower confidence intervals) of treatment effects in meta-analysis	Risk of including studies with poor methodological quality
	Abstracts/presentations are difficult to locate (not indexed in major bibliographic databases)	May decrease heterogeneity across trials	Difficult to extract data confidently
	Expensive to retrieve references (e.g. cost of inter-library loans)	May lead to less biased conclusions in the review	There may be limited and selective reporting of outcomes
	Search results may not be representative of all studies available as abstracts/presentations		There may be discrepancies in data reported in abstracts/presentations
			Risk of duplicate publication (i.e. double-counting of patients)
			Difficult and time-consuming (and not always successful) to obtain further details from authors

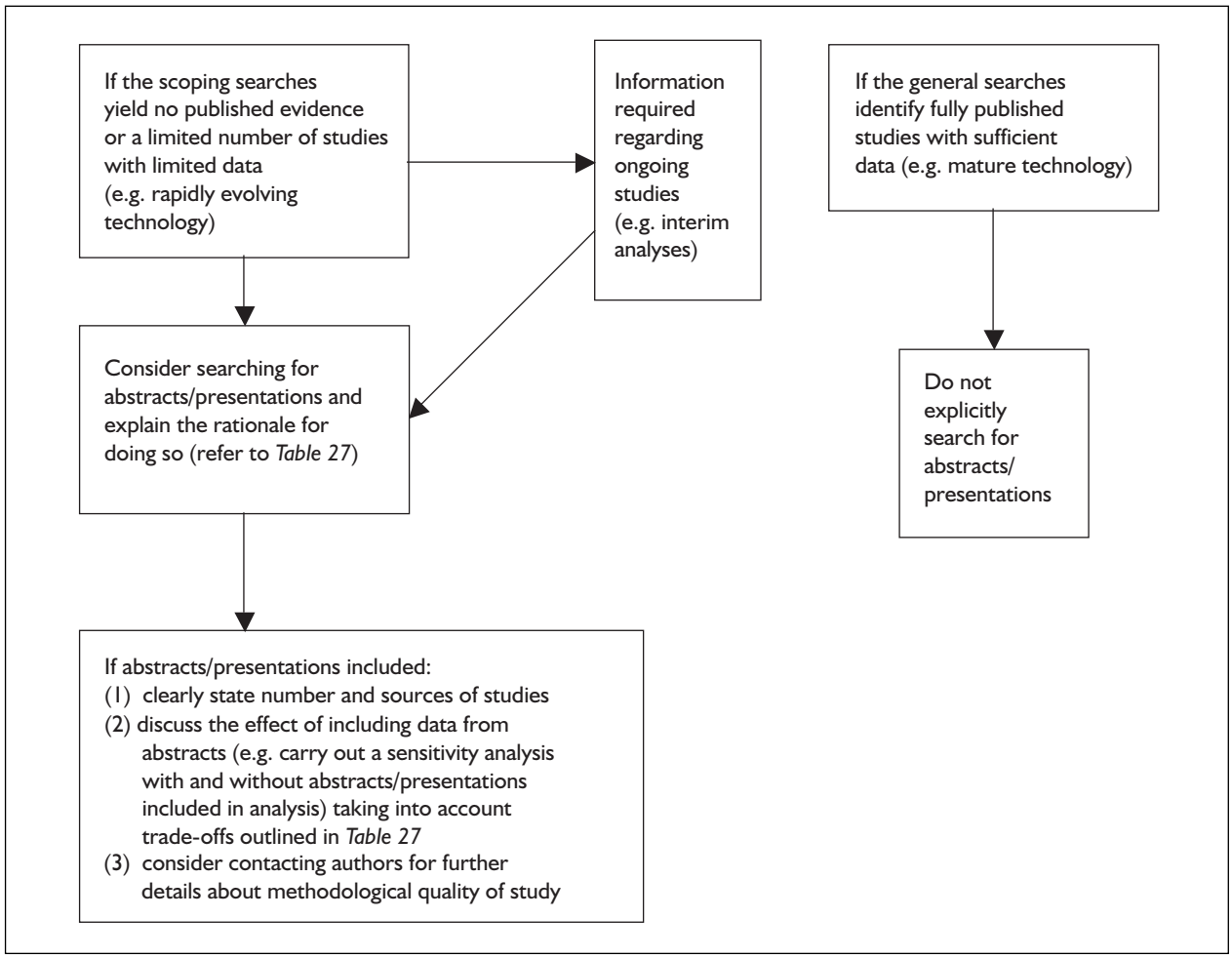

FIGURE 1 *Decision process regarding searching for conference abstracts and presentations*

and retrieving these sources, TAR groups should carefully consider for each TAR whether exhaustive searching (e.g. handsearching conference sites), which may often be necessary to identify conference abstracts and presentations, is likely to provide data that can be integrated into the report. If the scoping searches yield no published evidence or a limited number of studies with a limited data, this would indicate a need to search explicitly for conference abstracts and presentations, in which case the TAR team needs to allocate additional time for searching and managing data from abstracts/presentations. If TAR teams decide to include abstracts and presentations, they should state explicitly their rationale for doing so in the methods section of the review (see *Figure 1*).

The results of this study add to the body of evidence that a lack of study details reported in conference abstracts and presentations limits the ability of reviewers to assess confidently the methodological quality of trials available only as abstracts/presentations. Conference abstracts particularly tend to provide limited details of study methodology and reporting outcomes. Where conference abstracts and presentations are considered for inclusion in the review, the review teams should increase their efforts to obtain further study details by contacting trialists.

Results from one case study demonstrate discrepancies in reporting outcome data between conference abstracts and presentations and their subsequent full publications. Any data discrepancies identified across sources in TARs should be highlighted and their impact discussed in the review.

Sensitivity analyses based on one case study indicate that exclusion of conference abstracts and presentations would not have changed the direction of treatment effect substantially (except in one outcome at one time-point). However, this may not be the case in all reviews. Therefore, where abstract/presentation data are included,

reviewers should discuss the effect of including data from these sources by, for example, carrying out a sensitivity analysis with and without data from conference abstracts and presentations included in the analysis.

Research recommendations

There is a need for research into the development of search strategies specific to identification of studies available as conference abstracts and presentations in TARs. This would include guidance with regard to identification of relevant electronic databases and finding appropriate conference sites relevant to certain clinical areas.

As there are limited case studies included in this report, analyses should be repeated as more TARs accrue, or include the work of other international HTA groups [e.g. Canadian Coordinating Office for Health Technology Assessment (CCOHTA), the Blue Cross Blue Shield Association (BCBSA), Swedish Council for Technology Assessment in Health Care (SBU), Australian HTA] to support the findings.

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Contribution of authors

Yenal Dundar (Research Fellow) developed the research protocol and submission for funding, developed the study design, carried out literature searching, data extraction and analysis, and wrote the report. Susanna Dodd (Research Associate in Medical Statistics) assisted in the data extraction, provided statistical advice, and commented on draft and final versions of the report. Rumona Dickson (Director of Liverpool Reviews and Implementation Group) assisted in the development of the concepts to be investigated, the development of research protocol and the submission for funding, and commented on draft and final versions of the report. Tom Walley (Professor of Pharmacology and Therapeutics) developed the concepts to be investigated, advised on case selection, and commented on draft and final versions of the report. Alan Haycox (Senior Lecturer in Health Economics) assisted in the development of the research protocol and commented on the draft versions of the report. Paula Williamson (Professor of Medical Statistics) developed the concepts to be investigated, developed the research protocol and submission for funding, advised on study design, case selection, data extraction and analysis, and commented on draft and final versions of the report.

About home unit

The Liverpool Reviews and Implementation Group (LRiG) was established within the Department of Pharmacology and Therapeutics in April 2001. It is a multidisciplinary research group whose purpose, in the first instance, is to conduct systematic reviews commissioned by the HTA Programme.

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103. Main C, Palmer S, Griffin S, Jones L, Orton V, Sculpher M, *et al.* Clopidogrel used in combination with aspirin compared with aspirin alone in the treatment of non-ST-segment-elevation acute coronary syndromes: a systematic review and economic evaluation. *Health Technol Assess* 2004;**8**(40):iii–iv, xv–xvi, 1–141.

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Appendix 1

Survey questionnaire

Dear colleague,

We are currently conducting a methodological review funded by the National Coordinating Centre of Health Technology Assessment. The objectives of this research are to:

- assess the extent of use of data from conference abstracts[1] and presentations[2] in health technology assessments of *rapidly evolving technologies*[3]
- compare and contrast the outcome data from submitted conference abstracts and presentations with those subsequently published in full in peer-reviewed journals
- assess the ability to judge the quality of trials from the conference abstracts and presentations.

As part of this research project, we wish to carry out a survey of the technology assessment review (TAR) groups to collect information on the identification and extent of use of data from conference abstracts and presentations, particularly in the case of systematic reviews of rapidly evolving technologies provided as part of the NICE appraisal process. The results of this survey will be summarised in the assessment report in structured tables and as a narrative description.

I would be most grateful if you could please respond to the questions attached. Your further comments on each of these questions are most welcome.

Please feel free to contact me if you have any questions or require further information regarding this project either by email: yenal@liv.ac.uk. or by telephone on 0151 794 5541.

Thank you in advance for taking the time to complete this survey.

Yenal Dundar

Questions related to searching

Identification of conference abstracts and presentations in TARs

1. Do you have a policy of trying to identify studies that are available only as conference abstracts/presentations (e.g. PowerPoint slide presentations) to inform your TARs?
   - Yes
   - No
2. If yes, is this achieved by
   - a general search strategy?
   - an explicit search strategy?
   - both general and explicit search strategies?
3. If you carry out an explicit search to identify studies available as abstracts/presentations, please list the databases and sources that you search routinely to identify such studies.
4. Are there any other aspects that you would like to comment on (e.g. examples of difficulties/experiences) identifying/obtaining abstracts/presentations?

Questions related to inclusion of abstracts/presentations in TARs for NICE

Assessment of conference abstracts/presentations in TARs

1. Have you undertaken a TAR where at least one study is available only as a conference abstract/presentation?
   - Yes → How many TARs?
   - No
2. Does your group have a specific policy regarding *inclusion* or *exclusion* of data from studies available *only* as abstracts or presentations?
   - Yes → Please provide details
   - No
3. Inclusion of studies *only* available as abstracts/presentations:

[1] Includes conferences, meetings, workshops or symposia.

[2] Oral or poster presentations.

[2] *Rapidly evolving health technologies* (e.g. pharmaceutical interventions, procedures or devices) are those that have not previously widely been used within the National Health Service (e.g. those recently gained a licence) where there is rapid evolution of publication of evidence.

   a) Do you routinely assess for inclusion studies that have *only* been published as conference abstracts or presentations?
      - Yes
      - No → Do you report the findings of such studies, and how?
   b) If you include conference abstracts/presentations, do you apply the same inclusion criteria to both full publications and abstracts/presentations?
      - Yes
      - No → Please describe differences
4. If you include studies *only* available as abstracts/presentations:
   a) Do you carry out a methodological quality assessment of such studies?
      - Yes → What tools do you use?
      - No
   b) Do you extract data from such studies for presentation in tables and/or use in analyses?
      - Yes → Please provide details
      - No → How are these data described/managed?
5. Have you been involved in a TAR where *both* conference abstracts/presentations *and* subsequent full publications are also available?
   - Yes → How many? Please list
   - No
6. Where *both* abstracts/presentations *and* subsequent full publications are available, what would you do if relevant outcome data were reported in
   a) the abstract/presentation alone? Please give details
   b) the full publication alone? Please give details
   c) both the abstract/presentation and full publications? Please give details
7. Have you been involved in a TAR where there are *discrepancies of data* between abstracts/presentations and full publications?
   - Yes → How many? Please list
   - No
8. If you have been involved in a TAR where there are discrepancies of data between abstracts/presentations and full publications, would you be willing to provide us with the information regarding any discrepancies identified?
   - Yes → Please give details on separate sheets
   - No
9. Do you assess the possible impact of inclusion of data from abstracts/presentations on the (a) data analysis and (b) review conclusions and recommendations, and if so, how?
   - Yes → Please give details.
   - No
10. If your policy is to *exclude* studies available *only* as abstracts/presentations, are there any circumstances in which you would make an *exception* by including such studies?
    - Yes → Please give details.
    - No
11. Does your group experience difficulties related to inclusion/exclusion of data available *only* from abstracts/presentations (e.g. data management, quality assessment or analysis of results)?
    - Yes → Please give details.
    - No
12. Please list any TARs that you have conducted for NICE that involved rapidly evolving technologies recently.

Appendix 2

Audit data tables

TABLE 28 *Data extracted from the completed TARs*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no. of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts (e.g. hand-searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
4 (15)[57]	July 2000	Surgical procedure	Third molar removal	Impact of third molars	40	2	Narrative	No	No	1	0/1 (ongoing RCT)	1	Yes	Yes
4 (17)[45]	September 2000	Pharmaceutical agent	Paclitaxel or docetaxel	Breast and ovarian cancer	14	14	Narrative	No	No	8	0/8	8	Yes	Yes
4 (18)[58]	July 2000	Therapeutic procedure	Liquid-based cytology	Cervical screening	48	0	Narrative	No	No	0	NA	0	NA	NA
4 (23)[52]	November 2000	Device	Stent	Coronary artery disease	35	35	MA	Yes	No	16	0/16[a]	16	Yes	Yes
4 (26)[59]	November 2000	Device	Implantable defibrillators	Cardiac arrhythmias	8	7	Narrative	Yes	No	2	2/2	1	Yes	Yes
4 (30)[42]	December 2000	Pharmaceutical agent	Glycoprotein antagonists	Unstable angina	11	11	Narrative	No	Yes (CPI on DIALOG, IDEA)	4	0/4	4	Yes	Yes
4 (33)[38]	December 2000	Pharmaceutical agent	Combination therapy (interferon-α, ribavirin)	Hepatitis C	21	19	MA	No	No	13 (listed in appendix)	Unclear (abstracts excluded)	0	No	No
5 (1)[60]	March 2001	Pharmaceutical agent	Donepezil, rivastigmine, galantamine	Alzheimer's disease	29	22	Narrative	No	Yes (ISTP, BIOSIS)	43 abstracts listed in Appendix	Unclear (abstracts excluded)	0	No	No
5 (2)[61]	December 2001	Pharmaceutical agent	Riluzole	Motor neurone disease	4	4	MA	Yes	No	0	NA	NA	NA	NA
5 (11)[62]	May 2001	Surgical procedure	Autologous chondrocyte transplantation	Hyaline cartilage defects in knees	17	0	Narrative	Yes	No	0	NA	NA	NA	NA
5 (13)[63]	May 2001	Pharmaceutical agent	Temozomolide	Malignant glioma	7	1	Narrative	No	Yes (BIOSIS)	0	NA	NA	NA	NA
5 (14)[64]	May 2001	Pharmaceutical agent	Debriding agents	Surgical wounds	17	15	Narrative	Yes	Yes (Inside Conferences Index to Conference Proceedings on DIALOG)	3	2/3	3	Yes	Yes

continued

TABLE 28 *Data extracted from the completed TARs (cont'd)*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no. of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts (e.g. hand-searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
5 (18)[65]	May 2001	Pharmaceutical agent	Orlistat	Obesity	14	14	MA	No	Yes (BIOSIS, ISTP)	0	NA	NA	NA	NA
5 (19)[36]	September 2001	Pharmaceutical agent	Pioglitazone	Type 2 diabetes mellitus	15	15	Narrative	No	No	7	1/7	11	No (only trials for which full reports were available were assessed for quality)	Yes
5 (24)[66]	September 2001	Pharmaceutical agent	Gemcitabine	Pancreatic cancer	64	7	Narrative	No	No	3	0/3	3	Yes	Yes
5 (25)[66]	September 2001	Pharmaceutical agent	Irinotecan, oxaliplatin and raltitrexed	Colorectal cancer	27	27	Narrative	Yes	No	16	0/16	16	No	Yes
5 (28)[44]	September 2001	Pharmaceutical agent	Topotecan	Ovarian cancer	2	2	Narrative	No	Yes (BIOSIS, ISTP)	2	1/2	2	No (quality assessment was based on company data)	Yes
5 (32)[43]	May 2002	Pharmaceutical agent	Paclitaxel, docetaxel, gemcitabine, vinorelbine	Non-small-cell lung cancer	33	33	Narrative	No	No	30 abstracts identified and listed in appendix	Unclear (abstracts excluded)	0	No	No
6 (2)[67]	February 2002	Pharmaceutical agent	Fludarabine as second-line therapy	B-cell lymphocytic leukaemia	9	2	Narrative	No	No	5 (ongoing or completed, RCTs, not included in the review, listed in appendix)	0/5 (abstracts excluded)	0	No	No
6 (3)[68]	April 2002	Pharmaceutical agent	Rituximab as third-line treatment	Follicular non-Hodgkin's lymphoma	4	0	Narrative	No	No	0	NA	0	No	NA
6 (5)[69]	July 2002	Device	Inhaler devices	Asthma	56	38	Narrative	No	Yes (Biological Abstracts)	7 abstracts listed in excluded list	0/7 (abstracts excluded)	0	No	No

continued

TABLE 28 *Data extracted from the completed TARs (cont'd)*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no. of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts (e.g. hand-searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
6 (6)[70]	April 2002	Pharmaceutical agent	Sibutramine	Obesity	16	16	MA	No	Yes (BISOSIS, ISTP)	0	NA	0	No	NA
6 (9)[47]	May 2002	Pharmaceutical agent	Zanamivir	Influenza	11	11	MA	Yes (9 studies provided by company)	No	7	7/7	0 (9 studies provided by company)	No	No
6 (12)[71]	July 2002	Surgical procedure	Surgery	Morbid obesity	19	17	Narrative	No	Yes (BIOSIS)	5 abstracts, excluded from the review, listed in appendix	0/5 (abstracts excluded)	0	No	No
6 (13)[72]	June 2002	Pharmaceutical agent	Trastuzumab	Breast cancer	4	2	Narrative	Yes	Yes (BIOSIS, ISTP)	2	2/2	2	No (full papers used)	Yes
6 (14)[73]	July 2002	Pharmaceutical agent	Vinorelbine	Breast cancer	72	7	Narrative	No	Yes (BISOSIS, ISTP)	6	5/6	6	Yes	Yes
6 (15)[74]	June 2002	Device	Metal-on-metal hip resurfacing arthroplasty	Osteoarthritis (hip disease)	25	1	Narrative	No	No	0	NA	NA	NA	NA
6 (16)[75]	September 2002	Pharmaceutical agent	Bupropion and nicotine replacement therapy	Smoking cessation	? 148	? 44	MA	No	Yes (BIOSIS, ISTP)	0	NA	NA	NA	NA
6 (17)[76]	Augusut 2002	Pharmaceutical agent	Etanercept	Juvenile idiopathic arthritis	1	1	Narrative	Yes	No	0	NA	NA	NA	NA
6 (18)[77]	November 2002	Pharmaceutical agent	Growth hormone	Indications for use of GH in children	32 (1 ext. of RCT)	21 (1 ext. of RCT)	Narrative	No	Yes (BIOSIS, WOS Proceedings)	1	0/1	1	Yes (could not be adequately assessed)	Yes
6 (19)[78]	September 2002	Pharmaceutical agent	Growth hormone	Indications for use of GH in adults	17	17	MA	Yes	Yes (BIOSIS, ISTP)	2	0/2	2	Yes (Jadad score not measured)	No (insufficient data)

continued

TABLE 28 *Data extracted from the completed TARs (cont'd)*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no. of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts (e.g. hand-searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
6 (21)[41]	October 2002	Pharmaceutical agent	Infliximab and etanercept	Rheumatoid arthritis	10	10	MA	Yes	No	5 (80 abstracts listed in appendix)	4/5	2 (full reports or company data available)	Yes (full reports or company data available)	Yes (one abstract included with company data)
6 (22)[79]	October 2002	Therapeutic procedure	Computerised cognitive behaviour therapy	Depression and anxiety	16	11	Narrative	No	Yes (Biological Abstracts)	1	(poster)	0/1	1	Yes Yes
6 (23)[80]	October 2002	Pharmaceutical agent	Pegylated liposome doxorubicin hydrochloride	Ovarian cancer	8	6	Narrative	Yes	Yes (BIOSIS, ISTP)	2	1/2	2	No (company data and full paper used for 1 abstract)	No (company data and full paper used for 1 abstract)
6 (25)[81]	December 2002	Pharmaceutical agent	Glycoprotein IIb/IIIa antagonists	Acute coronary syndrome	22	5	Narrative	No	Yes (CPI on DIALOG)	0	NA	NA	NA	NA
6 (33)[82]	March 2003	Pharmaceutical agent	Imatinib	Myeloid leukaemia	51	11	Narrative	Yes	Yes (WOS Proceedings)	0	NA	NA	NA	NA
7 (2)[83]	April 2003	Therapeutic procedure	Home versus hospital or satellite unit haemodialysis	End-stage renal failure	27	1	Narrative	No	Yes (BIOSIS)	0	NA	NA	NA	NA
7 (3)[84]	April 2003	Pharmaceutical agent	Infliximab	Crohn's disease	4	4	Narrative	No	No	0	NA	NA	NA	NA
7 (4)[85]	Februaray 2003	Pharmaceutical agent	Anti-D prophylaxis	Haemolytic disease	11	2	MA	No	Yes (Biological Abstracts)	0	NA	NA	NA	NA
7 (9)[37]	March 2003	Therapeutic procedure	Photodynamic therapy	Macular degeneration	6	6 (4 ongoing)	MA	Yes	No	4 (ongoing RCTs)	(abstracts excluded)	0	No	NA
7 (12)[86]	March 2003	Device	Ultrasound locating devices for central venous access	Emergency and elective situations	20	20	MA	No	Yes (Biological Abstracts)	2	0/2	2	Yes	No

continued

TABLE 28 *Data extracted from the completed TARs (cont'd)*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no. of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts (e.g. hand-searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
7 (13)[53]	June 2003	Pharmaceutical agent	Atypical antipsychotic drugs	Schizophrenia	223	171 (21 included CIC data)	MA	No	Yes (CPI, IPA, BLIC, MHA, Biological Abstracts)	23	1/23 (company data available)	23[b]	Yes	Yes
7 (15)[87]	April 2003	Pharmaceutical agent	Thrombolytic drugs treatment	Acute myocardial infarction	20	20	MA	No	No	1	1/1	1	No	No
7 (21)[88]	August 2003	Surgical procedure	Tension-free vaginal tape	Urinary stress incontinence	104	13	Narrative	Yes	Yes (ISI STP, BIOSIS)	5	1/5	5	Yes	Unclear
7 (22)[89]	August 2003	Patient education (educational model)	Patient education models	Diabetes	24	18	Narrative	No	Yes (WOS Proceedings, BIOSIS)	0	NA	NA	NA	NA
7 (32)[90]	November 2003	Pharmaceutical agent	Capecitabine and tegafur with uracil	Metastatic colorectal cancer	5	4	Narrative	No	Yes (Biological Abstracts)	0	NA	NA	NA	NA
7 (35)[91]	November 2003	Prevention and treatment outcome	Decision modelling (for prevention and treatment)	Influenza A and B	29	29	MA	No	No	1	0/1	1	Yes	No
8 (3)[92]	February 2004	Surgical procedure	Microwave and thermal balloon endometrial ablation	Heavy menstrual bleeding	12	?8	Narrative	No	Yes (WOS Proceedings)	0	NA	NA	NA	NA
8(5)[93]	February 2004	Pharmaceutical agent	Capecitabine (Xeloda)	Metastatic breast cancer	17	1	Narrative	No	Yes (CPI, ISTP)	1	1/1	0	No	No
8 (13)[94]	April 2004	Pharmaceutical agent	Pioglitazone and rosiglitazone	Type 2 diabetes	9	9 (8 from company)	Narrative	No	No	0	NA	0	No	NA
8 (18)[35]	May 2004	Pharmaceutical agent	Anakinra	Rheumatoid arthritis	5	5	MA	Yes	Yes (ISTP)	4	2/4	4	Yes	Yes

continued

TABLE 28 *Data extracted from the completed TARs (cont'd)*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no. of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts (e.g. hand-searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
8 (19)[95]	May 2004	Pharmaceutical agent	Quetiapine, olanzapine, valproate semisodium	Mania associated with bipolar affective disorder	18	18	MA	No	Yes (BIOSIS)	7	1/7	7	Yes	Yes
8 (20)[96]	May 2004	Therapeutic procedure	Liquid-based cytology	Cervical screening	5	0	MA	No	No	0	NA	NA	NA	NA
8 (23)[97]	June 2004	Therapeutic procedure	Prehospital intravenous fluids	Trauma	4	4	Narrative	No	No	0	NA	NA	NA	NA
8 (24)[98]	June 2004	Pharmaceutical agent	Zaleplon, zolpidem, zopiclone	Insomnia	24	4	MA	No	Yes (WOS Proceedings)	4	0/4	4	Yes	No
8 (28)[40]	July 2004	Pharmaceutical agent	Imatinib	Chronic myeloid leukaemia	10	5	Narrative	No	Yes (BIOSIS)	5	0/5	0	No	No
8 (30)[99]	July 2004	Device	Myocardial perfusion scintigraphy	Angina and myocardial infarction	70	0	MA	No	Yes (BIOSIS, WOS Proceedings)	0	NA	NA	NA	NA
8 (35)[39]	September 2004	Device	Stent	Coronary artery disease	68	68	MA	Yes	Yes (WOS Proceedings)	19	4/19 (2 from company reports)	19	Yes	Yes
8 (37)[100]	September 2004	Pharmaceutical agent	Rituximab (MabThera)	Non-Hodgkin's lymphoma	1	1	Narrative	No	Yes (BIOSIS, WOS proceedings)	0	NA	NA	NA	NA
8(38)[101]	October 2004	Pharmaceutical agent	Clopidogrel and modified-release dipyridamole	Occlusive vascular events	2	2	Narrative	No	Yes (Inside Conferences, DIALOG)	0	NA	NA	NA	NA

continued

TABLE 28 *Data extracted from the completed TARs (cont'd)*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no. of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts (e.g. hand-searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
8 (39)[102]	October 2004	Pharmaceutical agent	Pegylated interferon α-2a/2b in combination with ribavarin	Chronic hepatitis C	6	6	MA	No	Yes (BISOSIS, WOS Proceedings)	20 abstracts listed in appendix	Unclear	0 (listed in appendix and briefly discussed in the report)	No	No
8 (40)[103]	October 2004	Pharmaceutical agent	Clopidogrel used in combination with aspirin	Acute coronary syndromes	7 (6 SR)	1	Narrative	No	Yes (Inside Conferences, DIALOG)	NA	NA	NA	NA	NA
8(43)[104]	October 2004	Pharmaceutical agent	Continuous subcutaneous insulin infusion	Diabetes	20	17	MA	No	Yes (SCI limited to meeting abstracts, WOS Proceedings, BIOSIS)	21 recent abstracts listed in appendix	(abstracts excluded)	0	No	No

BLIC: British Library Inside Conferences (Datastar service); CIC, commercial in confidence; CPI: Conference Papers Index; IDEA: Internet Database of Evidence-Based Abstracts; IPA: International Pharmaceutical Abstracts (DIALOG service); ISTP: Index to Scientific and Technical Proceedings; MA, meta-analysis; MHA: Mental Health Abstracts (DIALOG); SR, systematic reviews; WOS, Web of Science.

[a] Where only abstracts were available, letters requesting further information were sent to the first authors. For some of the fully reported trials the longer term follow-up results were only available in abstract form, but no letters were sent to the investigators for those trials.

[b] Where only conference abstracts were available; the review authors made an attempt to contact the trial authors but were often not able to obtain further information.

TABLE 29 *Statements reported in TARs regarding assessment of conference abstracts and presentations*

HTA vol. (issue)	Section in the report	Statements regarding abstracts/presentations as reported in TARs
4 (33)[38]	Methods	Only full papers (published or unpublished) used for analysis. Other materials such as conference abstracts could be used with caution for purposes such as sensitivity analysis
5 (1)[60]	Methods	Abstracts and conference poster presentations were excluded from the review; it was believed that these provided insufficient information on methods and results to judge accurately the rigour of the study and the reliability of the evidence presented
5 (19)[36]	Quality assessment	Because of the paucity of information relating to the included studies, formal quality assessment was possible in only four studies. No studies were excluded on the basis of methodological quality
5 (25)[46]	Quality assessment	In some cases formal quality assessment was not possible because the trials were published only in abstract form. No studies were excluded on the basis of methodological quality
5 (28)[44]	Data extraction	Only the most recent publication was reported except in cases where only abstracts were available. In such cases, the abstract was included as well as any full reports of interim analyses
6 (2)[67]	Search strategy	Although it was indicated in the protocol that attempts would be made to search for abstracts, this was not possible in the time available
6 (3)[68]	Search strategy	Although it was indicated in the protocol that attempts would be made to search for abstracts, this was not possible in the time available
6 (5)[69]	Methods	Studies available only as abstracts were excluded
6 (12)[71]	Study selection	Abstracts and poster presentations were excluded
6 (13)[72]	Results	In one study the results in the two publications (full paper and abstract) differed and, therefore, only information from the published paper is used in the review
6 (18)[77]	Data extraction	Study quality could not be fully assessed
6 (21)[41]	Results	Data from some studies were presented at more than one meeting. In cases where several abstracts reported subsets of data or details of specific outcome where identical data were presented, only the most recent abstract was included. In other cases, abstracts were included if data not found in other sources were presented
6 (23)[80]	Data extraction	Only data from the most recent publication were reported and used in analyses. These included data from abstracts if the most recent data were only available in these forms
7 (12)[86]	Results	Abstracts have been included in the data extraction but excluded from the meta-analysis. The authors felt it unnecessary to look for further evidence
7 (22)[89]	Study selection	Studies available as abstracts were excluded
8 (3)[92]	Study selection	Studies were excluded if they were reports published as conference abstracts only
8 (18)[35]	Results	Data from some studies were presented at more than one meeting or subsequently published in full. Where identical data were presented in different publications, the fully published report was included. Where there were duplicate abstracts, the most recent report was included. In cases of duplicates of full reports, the original report was included. In other cases, several abstracts and full papers presented subsets of data of a specific outcome. These were included if data not found in other sources was presented
8 (28)[40]	Inclusion criteria	If studies were reported only in abstract form, the reviewers tried to obtain the full report. If this was not available, the abstract was excluded
8 (30)[99]	Inclusion criteria	Abstracts were not considered in the effectiveness review
8 (39)[102]	Inclusion criteria	Fully published reports were used for analysis. Unpublished material (including conference abstracts) was used primarily for background information and context. Where relevant, studies reported in abstract form were summarised in the report but their results were not used

TABLE 30 *TARs of rapidly evolving technologies*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no.of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts/ presentations (e.g. hand searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
4 (17)[45]	September 2000	Pharmaceutical agent	Paclitaxel or docetaxel	Breast and ovarian cancer	14	14	Narrative	No	No	8	0/8	8	Yes	Yes
4 (30)[42]	December 2000	Pharmaceutical agent	Glycoprotein antagonists	Unstable angina	11	11	Narrative	No	Yes (CPI on DIALOG, IDEA)	4	0/4	4	Yes	Yes
4 (33)[38]	December 2000	Pharmaceutical agent	Combination therapy (interferon α, ribavirin)	Hepatitis C	21	19	MA	No	No	13 (listed in appendix)	Unclear (abstracts excluded)	0	No	No
5 (19)[36]	September 2001	Pharmaceutical agent	Pioglitazone	Type 2 diabetes mellitus	15	15	Narrative	No	No	7	1/7	11	No (only trials for which full reports were available were assessed for quality)	Yes
5 (25)[46]	End of 2001	Pharmaceutical agent	Irinotecan, oxaliplatin and raltitrexed	Colorectal cancer	27	27	Narrative	Yes	No	16	0/16	16	No	Yes
5 (28)[44]	September 2001	Pharmaceutical agent	Topotecan	Ovarian cancer	2	2	Narrative	No	Yes (BIOSIS, ISTP)	2	1/2	2	No (quality assessment was based on company data)	Yes
5 (32)[43]	May 2002	Pharmaceutical agent	Paclitaxel, docetaxel, gemcitabine, vinorelbine	Non-small-cell lung cancer	33	33	Narrative	No	No	30 abstracts identified and listed in appendix	Unclear (abstracts excluded)	0	No	No
6 (9)[47]	May 2002	Pharmaceutical agent	Zanamivir	Influenza	11	11	MA	Yes	0	7	7/7	0 (9 studies provided by company)	No	No

continued

TABLE 30 *TARs of rapidly evolving technologies (cont'd)*

HTA vol. (issue)	Date published	Type of technology	Technology	Disease/ condition	Total no.of studies	No. of RCTs	Evidence synthesis	Explicit search for abstracts/ presentations (e.g. hand searching journals, conference sites)	Not explicit search (electronic databases searched)	No. of RCTs identified in abstract/ presentation form	No. of full reports for RCTs where data from abstracts/ presentations included in TAR	No. of RCTs included in the review in abstract/ presentation form	Quality assessment of abstracts/ presentations	Data from abstracts/ presentations included in analyses
6 (21)[41]	October 2002	Pharmaceutical agent	Infliximab and etanercept	Rheumatoid arthritis	10	10	MA	Yes	No	5 (80 abstracts listed in appendix)	4/5	2 (full reports or company data available)	Yes (full reports or company data available)	Yes (one abstract included with company data)
7 (9)[37]	March 2003	Therapeutic procedure	Photodynamic therapy	Macular degeneration	6	6 (4 ongoing)	MA	Yes	No	4 (ongoing RCTs)	(abstracts excluded)	0	No	NA
8 (18)[35]	May 2004	Pharmaceutical agent	Anakinra	Rheumatoid arthritis	5	5	MA	Yes	Yes (ISTP)	4	2/4	4	Yes	Yes
8 (28)[40]	July 2004	Pharmaceutical agent	Imatinib	Chronic myeloid leukaemia	10	5	Narrative	No	Yes (BIOSIS)	5	0/5	0	No	No
8 (35)[39]	September 2004	Device	Stent	Coronary artery disease	68	68	MA	Yes	Yes (WOS Proceedings)	19	4/19 (2 from company reports)	19	Yes	Yes

Appendix 3

Data sources

TABLE 31 *References included in case study 1: anakinra review*[35]

Study:	Reference(s)
Trial 0560 Bresnihan *et al*.	Bresnihan B, Alvaro-Gracia JM, Cobby M, Doherty M, Domljan Z, Emery P, *et al*. Treatment of rheumatoid arthritis with recombinant human interleukin-1 receptor antagonist. *Arthritis Rheum* 1998;**41**:2196–204.
	Bresnihan B, McCabe D, Watt I, Genant HK, Robbins S, Newmark RD. FR10061. Anakinra arrests joint destruction in patients with RA and established erosions [abstract]. EULAR 2001 Conference Proceedings, Prague.
	Bresnihan B, Chan WW, Woolley JM. SAT0242. Anakinra increases days of work and domestic activity in patients with rheumatoid arthritis [abstract]. EULAR 2001 Conference Proceedings, Prague.
	Emery P, Woolley JM, Chan WW. SAT0245. Improvement in health-related quality of life from anakinra therapy in patients with rheumatoid arthritis not using DMARDs [abstract]. EULAR 2001 Conference Proceedings, Prague.
Trial 0180 Cohen *et al*.	Cohen S, Hurd E, Cush J, Schiff M, Weinblatt ME, Moreland LW, *et al*. Treatment of rheumatoid arthritis with anakinra, a recombinant human interleukin-1 receptor antagonist, in combination with methotrexate: results of a twenty-four-week, multicenter, randomized, double-blind, placebo-controlled trial. *Arthritis Rheum* 2002;**46**:614–24.
	Cohen SB, Woolley JM, Chan WW. SAT0246. Characterizing the effects of anakinra therapy functional status of patients with rheumatoid arthritis using methotrexate [abstract]. EULAR 2001 Conference Proceedings, Prague.
	Cohen SB, Woolley JM, Chan WW. FR10042. Anakinra improves functional status in patients with rheumatoid arthritis using methotrexate [abstract]. EULAR 2001 Conference Proceedings, Prague.
Trial 0145 Cohen *et al*.	Cohen SB, Moreland LW, Cush JJ, Greenwald MW, Block S, Shergy WJ, *et. al.* 990145 Study Group. A multicentre, double blind, randomised, placebo controlled trial of anakinra (Kineret), a recombinant interleukin 1 receptor antagonist, in patients with rheumatoid arthritis treated with background methotrexate. *Ann Rheum Dis* 2004;**63**:1062–8. Epub 13 April 2004.
	Cohen SB, Moreland LW, Cush JJ, Greenwald MW, Block JA, Shergy WJ, *et al*. Anakinra (recombinant interleukin-1 receptor antagonist): a large, placebo controlled efficacy trial of anakinra in patients with erosive rheumatoid arthritis disease [abstract]. *Arthritis Rheum* 2001;**44**:LB1.
Trial 0757 Fleischmann *et al*.	Fleischmann RM, Schechtman J, Bennett R, Handel ML, Burmester GR, Tesser J, *et al*. Anakinra, a recombinant human interleukin-1 receptor antagonist (r-metHuIL-1ra), in patients with rheumatoid arthritis: a large, international, multicenter, placebo-controlled trial. *Arthritis Rheum* 2003;**48**:927–34.
	Fleischmann R, Tesser J, Schechtman J, Modafferi D, Poulakos J, Bennett R, *et al*. A safety trial of anakinra: recombinant interleukin-1 receptor antagonist (IL-1RA), in a large placebo controlled heterogeneous population of patients with rheumatoid arthritis [abstract]. *Arthritis Rheum* 2001;**44**:190.
	Tesser J, Schectman J, Dore R, Joh T, Dale C, Solinger A. The safety of Kineret (anakinra) in combination with other RA therapies [abstract]. EULAR 2002 Conference Proceedings, Stockholm.
	Fleischmann R, Tesser J, Schechtman J, Sun G. Safety of anakinra (interleukin-1 receptor antagonist) in rheumatoid arthritis (RA) subjects with potential high risk for infection [abstract]. ACR 66th Annual Scientific Meeting, New Orleans, 2002.

TABLE 32 *References included in case study 2: infliximab and etanercept review*[41]

Study	Reference(s)
ATTRACT	Lipsky PE, van der Heijde DM, St Clair EW, Furst DE, Breedveld FC, Kalden JR, *et al*. Infliximab and methotrexate in the treatment of rheumatoid arthritis. Anti-Tumor Necrosis Factor Trial in Rheumatoid Arthritis with Concomitant Therapy Study Group. *N Engl J Med* 2000;**343**:1594–602.
	Maini R, St Clair EW, Breedveld F, Furst D, Kalden J, Weisman M, *et al.* Infliximab (chimeric anti-tumour necrosis factor alpha monoclonal antibody) versus placebo in rheumatoid arthritis patients receiving concomitant methotrexate: a randomised phase III trial. ATTRACT Study Group. *Lancet* 1999;**354**:1932–9.
	Antoni C, Kavanagh A, Manger B, Kalden J, Keenan G, Schaible T. Responses to infliximab therapy in the ATTRACT trial assessed with the disease acticity score (DAS); clinical response measured by DAS correlated with arrest of radiologic progression and shows higher response rates than ACR20 criteria. *Arthritis Rheum* 2000;**43**(Suppl):S227 [abstract 961].
	Kavanaugh A, Lipsky P, Furst D, Weisman M, St Clair W, Smolen J, *et al*. Infliximab improves long-term quality of life and functional status in patients with rheumatoid arthritis. *Arthritis Rheum* 2000;**43**(Suppl):S147 [abstract.483].
Trial 0180 Cohen *et al*.	Ericson M, Wajdula J, on behalf of the European Etanercept Investigators Group. A double-blind, placebo controlled study of the efficacy and safety of four different doses of etanercept in patients with rheumatoid arthritis. *Arthritis Rheum* 1999;**42**(Suppl):S82 [abstract 69].
	Wajdula J. A double-blind, placebo controlled study of the efficacy and safety of four different doses of etanercept in patients with rheumatoid arthritis. *Ann Rheum Dis* 2000; **59**(Suppl 1):S82:163. [abstract POS-414].

TABLE 33 *References included in case study 3: DES review*[39]

Study	Reference(s)
ACTION	Serruys PW, Ormiston JA, Sianos G, Sousa JE, Grube E, den Heijer P, *et al*. Actinomycin-eluting stent for coronary revascularization: a randomized feasibility and safety study: the ACTION trial. *J Am Coll Cardiol* 2004;**44**:1363–7.
	Linnemeier T. The ACTION Study. Slide presentation, CRF Drug-Eluting Stent Symposium. TCTMD online database. URL: http://www.tctmd.com/display/expert/pdf/23073/ACTION.pdf. 2002.
	Serruys P. Final ACTION results (ActinomycinD) ACTinomycin eluting stent Improves Outcomes by reducing Neointimal hyperplasia. ACTION TCT 2002, Washington DC, September 25–28, 2002. URL: http://www.tctmd.com/expert-presentations/table-2.html?product_id=3801. 2002.
ASPECT	Park SJ, Shim WH, Ho DS, Raizner AE, Park SW, Hong MK, *et al*. A paclitaxel-eluting stent for the prevention of coronary restenosis. *N Engl J Med* 2003;**348**:1537–45.
	Shim WH, Park SJ, Ho DS, Raizner AE, Cho SY, Jang YS, *et al*. Angiographic appearance of coronary arteries after four to six month implantation of paclitaxel-voated Stents. URL: http://aha.agora.com/abstractviewer/search.asp 2001.
	Park SJ. Paclitaxel eluting stent for prevention of in-stent restenosis. ASPECT. EuroPCRonline (database online). 2001.
	Park S, Shim WH, Ho D, Raizner AE. Long-term follow-up in the ASPECT clinical study. *Am J Cardiol* 2002;**90**(Suppl 6A):1H.
	Hong M, Mintz GS, Park S, Kim J, Lee CW, Fearnot NE, *et al*. Paclitaxel coating reduces in-stent restenosis: a serial volumetric intravascular ultrasound analysis. *J Am Coll Cardiol* 2002;**39** (Suppl 1–2):823–6.
	Kaluza GL, Raizner AE, Park SJ, Shim WH, Ho DS, Voorhes WD, *et al*. Dramatic inhibition of neointimal proliferation by the paclitaxel-eluting stents showing radiation-like results without radiation: insights from the QCA core laboratory. *J Am Coll Cardiol* 2002;**39**:26A.

continued

TABLE 33 *References included in case study 3: DES review*[39]

Study	Reference(s)
	Park SJ. ASPECT Clinical Study. Transcatheter Cardiovascular Therapeutics (TCT) 2001 Conference. Slide presentation. URL: http://www.tctmd.com/display/expert/pdf/24722/Park-ASPECT.pdf. 2001
	Lee C. ASPECT: 12-Month clinical results. American Heart Association (AHA) Scientific Sessions 2002. URL: http://www.tctmd.com/display/expert/pdf/52714/ASPECT-AHA.pdf. 2002.
DELIVER	Lansky AJ, Costa RA, Mintz GS, Tsuchiya Y, Midei M, Cox DA, *et al*. Non-polymer-based paclitaxel-coated coronary stents for the treatment of patients with *de novo* coronary lesions: angiographic follow-up of the DELIVER clinical trial. *Circulation* 2004;**109**:1948–54. Epub 12 April 2004.
	Knopf W, O'Neill W, Midei M, Cox D, O'Shaughnessy B, Applegate R, *et al*. The DELIVER clinical trial: 30-day safety data from a multicenter, randomized clinical evaluation of the ACHIEVE drug-eluting coronary stent system. *Am J Cardiol* 2002;**90**(Suppl 6A)(6):70H.
	O'Neill WW. An overview of the DELIVER clinical trial. An evaluation of the ACHIEVE drug eluting coronary stent system. Transcatheter Cardiovascular Therapeutics (TCT) 2002.
	O'Neill WW. The DELIVER trial: a randomized comparison of paclitaxel-coated versus metallic stents for treatment of coronary lesions. American College of Cardiology (ACC) 2003. Available from: http://www.tctmd.com/
	Knopf WD. DELIVER I. Final results and after thoughts. Transcatheter Cardiovascular Therapeutics (TCT), 2003 (2003a).
	Knopf W, O'Neill W, Fitzgerald P. A premier presentation of DELIVER trial results at CRT 2003. CRT 2003, Washington, USA. URL: http://www.crtonline.org/body2.cfm?id=205&ArticleID=79 (2003b).
ELUTES	Gershlick A, De Scheerder I, Chevalier B, Stephens-Lloyd A, Camenzind E, Vrints C, *et al*. Inhibition of restenosis with a paclitaxel-eluting, polymer-free coronary stent: the European evaLUation of pacliTaxel Eluting Stent (ELUTES) trial. *Circulation* 2004;**109**:487–93. Epub 26 January 2004.
	Gershlick A, De Scheerder I, Lloyd AS, Swanson N, Chevalier B. Stent-based drug delivery: a new modality for preventing in-stent restenosis. Demographics of the paclitaxel-eluting stent (ELUTES) trial. *Heart* 2001;**85**:P37–P64 (2001a).
	Gershlick AH, Descheerder I, Chevalier B, Camenzind E, Gommeaux A, Vrints C, *et al*. Local drug delivery to inhibit coronary artery stenosis. Data from the ELUTES (EvaLUation of paclitaxel Eluting Stent) clinical trial. URL: http://aha.agora.com/abstractviewer/search.asp 2001 (2001b).
	De Scheerder I. The in-stent ELUTES study: a prospective, randomized, controlled, multicenter study to evaluate the V-Flex plus PTX drug-eluting coronary stent to treat in-stent restenosis. *Am J Cardiol* 2002;**90**:71H.
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	Gershlick A, De Scheerder I, Chevalier B. Long-term follow-up in the ELUTES clinical study. *Am J Cardiol* 2002;**90**(Suppl 6A):1H.
	Gershlick A. The ELUTES trial. Cardiovascular Radiation Therapy (CRT), February 2002, Slide presentation. URL: http://www.tctmd.com/display/expert/pdf/20737/ELUTES.pdf. 2002.
	Chevalier BR. New insights from the ELUTES study. CRF Drug-Eluting Stent Symposium, March 2002. Slide presentation. URL: http://www.tctmd.com/display/expert/pdf/22409/ELUTES-Chevalier.pdf. 2002.
	De Scheerder I. ELUTES trial: 12-month clinical follow-up. American Heart Association (AHA) Scientific Sessions 2002. URL: http://www.tctmd.com/display/expert/pdf/52801/ELUTES.pdf. 2002.
E-SERIUS	Schofer J, Schluter M, Gershlick AH, Wijns W, Garcia E, Schampaert E, Breithardt G. Sirolimus-eluting stents for treatment of patients with long atherosclerotic lesions in small coronary arteries: double-blind, randomised controlled trial (E-SIRIUS). *Lancet* 2003;**362**:1093–9.
	Schofer J, Breithardt G, Kuntz RE, Popma JJ. A European multi-centre, randomized, double-blind study of the sirolimus-eluting stent in patients with *de novo* coronary artery lesions. *Eur Heart J* 2002;**4** (Abstract Suppl):265.

continued

TABLE 33 *References included in case study 3: DES review*[39] *(cont'd)*

Study	Reference(s)
FUTURE	Grube E, Sonoda S, Ikeno F, Honda Y, Kar S, Chan C, *et al*. Six- and twelve-month results from first human experience using everolimus-eluting stents with bioabsorbable polymer. *Circulation* 2004;**109**:2168–71. Grube E, Gerckens U, Buellsfeld L, Bootsveld A, Techen G, Stabercok M, *et al*. First human experience using a new everolimus stent coating: early findings of the FUTURE trial. TCT Abstracts/Poster. *Am J Cardiol* 2002;**90**(Suppl 6A):71H. Grube E. Animal and first human results with the biosensors everolimus-eluting stent (FUTURE-I). TCT 2002, 25–28 September 2002, Washington DC. URL: http://www.tctmd.com/display/expert/pdf/53477/Grube-Everolimus.pdf. 2002. Grube E. Everolimus. Late-breaking clinical trials FUTURE I & FUTURE II. Transcatheter Cardiovascular Therapeutics (TCT) 2002 (2003a). Grube E. Clinical results from FUTURE I and future plans. Paris Course for Revascularization (PCR) 2003 (2003b).
PATENCY	Heldman A. The PATENCY pilot trial: first report/PATENCY PAclitaxel-coated LogicsTENt for the Cytostatic prevention of restenosis. A roll-in feasibility study. Transcatheter Cardiovascular Therapeutics (TCT) 2002. URL: http://www.tctmd.com/display/expert/pdf/47017/Heldman-PATENCY.pdf. 2002.
RAVEL	Morice MC, Serruys PW, Sousa JE, Fajadet J, Ban Hayashi E, Perin M, *et al*. A randomized comparison of a sirolimus-eluting stent with a standard stent for coronary revascularization. *N Engl J Med* 2002;**346**:1773–80. Sousa JE, Morice M, Serruys PW, Fajadet J, Perin EM, Hayashi EB, *et al*. The RAVEL study: a randomized study with the sirolimus coated BX velocity balloon-expandable stent in the treatment of patients with *de novo* native coronary artery lesion. URL: http://aha.agora.com/abstractviewer/search.asp. 2001. Regar E, Morice MC, Sousa J, Fajadet J, Perin M, Hayashi EB, *et al*. Can sirolimus-eluting stents prevent restenosis in diabetic patients? A subanalysis of the randomized, multicenter RAVEL trial. *Eur Heart J* 2002;**4**:142 (2002a). Regar E, Laarman G, Blanchard D, Eltchaninoff H, Sousa JE, Fajadet J, *et al*. Sirolimus inhibits restenosis irrespective of the vessel size: a subanalysis of the multicenter RAVEL trial. *J Am Coll Cardiol* 2002;**39**:58A (2002b). Degertekin M, Tanabe K, Sousa E, Colombo A, Guagliumi G, Wijns W, *et al*. Evaluation of incomplete stent apposition at six month follow-up in the multicenter RAVEL trial. *Eur Heart J* 2002;**4**:690 (2002a). Degertekin M, Regar E, Tanabe K, Sousa JE, Colombo A, Guagliumi G, *et al*. Incidence of incomplete stent apposition at six month follow-up in the multicenter RAVEL trial. *J Am Coll Cardiol* 2002;**39**:38A (2002b). Abizaid AS, Sousa JE, De Feyter P, Abizaid A, Wuelfert E, Wijns W, *et al*. Edge effect does not occur after implantation of sirolimus-eluting stents: a three-dimensional intravascular ultrasound analysis From the RAVEL trial. *J Am Coll Cardiol* 2002;**39**:70A. Colombo A, Fajadet J, Schuler G, Barragan P, Bode C, Sousa JE, *et al*. 365-day follow-up of the RAVEL study: a randomized study with the sirolimus-eluting BX velocity TM balloon-expandable stent. *Eur Heart J* 2002;**4**:264.
SCORE	Grube E, Lansky A, Hauptmann KE, Di Mario C, Di Sciascio G, Colombo A, *et al*. High-dose 7-hexanoyltaxol-eluting stent with polymer sleeves for coronary revascularization: one-year results from the SCORE randomized trial. *J Am Coll Cardiol* 2004;**44**:1368–72. Kataoka T, Grube E, Hauptmann KE, Hur S, Morino Y, Hassan AHM, *et al*. Prevention of restenosis by a new drug eluting stent: an intravascular ultrasound substudy of the SCORE trial. URL: http://aha.agora.com/abstractviewer/search.asp 2001. (2001a) Kataoka T, Grube E, Hauptmann KE, Honda Y, Hur S, Morino Y, *et al*. The impact of drug eluting stent to prevent coronary restenosis: a volumetric intravascular ultrasound analysis from the SCORE trial. *Am J Cardiol* 2001;**88** (2001b).

continued

TABLE 33 *References included in case study 3: DES review*[39] *(cont'd)*

Study	Reference(s)
	Honda Y, Grube E, Kataoka T, Hauptmann KE, Morino Y, Hur S, *et al*. Optimal endpoint for drug-eluting stent: predictive value of minimum stent area for long-term stent patency. *J Am Coll Cardiol* 2002;**39**:71A.
	Kataoka T, Grube E, Honda H, Hauptmann KE, Morino Y, Hur S, *et al*. Three-dimensional IVUS assessment of edge effects following drug-eluting stent implantation. *J Am Coll Cardiol* 2002;**39**:70A.
	Lansky AJ, Reifart N, Fajadet J, Disciascio G, DiMario C, Hauptmann K, *et al*. *Effects of the QUADDS-QP2 drug-eluting stent extend beyond the targeted area into adjacent nonstented zones: results of the SCORE trial*. *J Am Coll Cardiol* 2002;**39**:26A.
	Grube E, Lansky AJ, Reifart N, Fajadet J, Disciascio G, DiMario C, *et al*. SCORE six-month angiographic results: improved restenosis in patients receiving the QUADDS-QP2 drug-eluting stent compared with the control, bare stents. *J Am Coll Cardiol* 2002;**39**:59A (2002a).
	Grube E, Hauptmann K, Colombo A, Disciascio G, Silber S, Bach R, *et al*. SCORE trial interim safety results: despite efficacy, late stent thrombosis with the QuaDDS-QP2 stent. *J Am Coll Cardiol* 2002;**39**:38A (2002b).
	Stone G. Adverse outcomes from a taxane-loaded polymeric sleeved stent: final results from the SCORE trial. CRF Drug-Eluting Stent Symposium 2002. Slide presentation. URL: http://www.tctmd.com/display/expert/pdf/22539/SCORE-Stone.pdf. 2002.
	Grube E. The SCORE randomized trial QuaDDS-QP2 stent with a polymer sleeve delivery system lessons learned from a pioneering study. TCT 2002, 25–28 September 2002, URL: http://www.tctmd.com/display/expert/pdf/58043/Grube-SCOREDESS2.pdf. 2002.
SIRIUS	Moses JW, Leon MB, Popma JJ, Fitzgerald PJ, Holmes DR, O'Shaughnessy C, *et al*. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. *N Engl J Med* 2003;**349**:1315–23.
	Holmes DR Jr, Leon MB, Moses JW, Popma JJ, Cutlip D, Fitzgerald PJ, *et al*. Analysis of 1-year clinical outcomes in the SIRIUS trial: a randomized trial of a sirolimus-eluting stent versus a standard stent in patients at high risk for coronary restenosis. *Circulation* 2004;**109**:634–40.
	Ako J, Morino Y, Sonoda S, Terashima M, Hassan AHM, Honda Y, *et al*. Effect of sirolimus eluting stents on neointimal hyperplasia: a serial in-stent intravascular ultrasound interim analysis from the SIRIUS trial. *Am J Cardiol* 2002;**90**:1H.
	Moses JW, O'Shaughnessy C, Caputo R, Kereiakes D, Brown C, Williams D, *et al*. The US multicenter, randomized, double-blind study of the sirolimus-eluting stent in coronary lesions: safety outcomes at 9 months. *Eur Heart J* 2002;**4**(suppl.):264.
	Leon M, Moses JW, Popma JJ, Fitzgerald P. A US Multicenter, randomized, double-blind study of the sirolimus-eluting stent in *de novo* native coronary lesions. TCT 2002. Slide presentation. URL: http://www.tctmd.com/display/expert/pdf/44484/Leon-SIRIUS.pdf (2002a).
	Leon MB, Moses JW, Popma JJ, Fitzgerald P. SIRIUS 400: a US multicenter, randomized, double-blind study of the SIRollmUS-eluting stent in *de novo* coronary lesions: preliminary analysis of the first 400 patients. Paris Course on Revascularization (EURO-PCR) 2002. Slide presentation. URL: http://www.tctmd.com/display/expert/pdf/31948/SIRIUS400%20TCTMD1.pdf I(2002b).
	Moses JW, Leon MB, Popma JJ, Kuntz RE, Fitzgerald P. A US multicenter, randomized, double-blind study of the sirolimus-eluting stent in de novo native coronary lesions. TCT2002. Slide presentation. URL: http://www.tctmd.com/display/expert/pdf/44544/Moses-SIRIUSrevised.pdf (2002).
TAXUS I	Grube E, Silber S, Hauptmann KE, Mueller R, Buellesfeld L, Gerckens U, *et al*. TAXUS I: six- and twelve-month results from a randomized, double-blind trial on a slow-release paclitaxel-eluting stent for *de novo* coronary lesions. *Circulation* 2003;**107**:38–42.
	Grube E, Silber SM, Hauptmann KE. TAXUS I: Prospective, randomized, double-blind comparison of NIRx stents coated with paclitaxel in a polymer carrier in de-novo coronary lesions compared with uncoated controls. URL: http://aha.agora.com/abstractviewer/search.asp. 2001.
	Grube E. Paclitaxel eluting stent for prevention of in-stent restenosis. TAXUS I trial. AHA Scientific Sessions 2001. URL: http://www.europcronline.com. 2001.

continued

TABLE 33 *References included in case study 3: DES review*[39] *(cont'd)*

Study	Reference(s)
	Grube E. TAXUS I. Paclitaxel-eluting stent for prevention of in-stent restenosis. TCT 2002. Manual of Interventional Trials. URL: http://www.tctmd.com/clinical-trials/tct2002/one.html?mic_id=1450. 2002.
	Stone G. Results and trials with a polymer-based paclitaxel delivery system. TAXUS I–VI. CRF Drug-Eluting Stent Symposium. Slide presentation. URL: http://www.tctmd.com/display/expert/pdf/24833/Stone-TAXUS-I-VI.pdf. 2002.
	Grube E. TAXUS I two year results – sustained benefit over time. Slide presentation. EuroPCR, 21 May, Paris.
TAXUS II	Colombo A, Drzewiecki J, Banning A, Grube E, Hauptmann K, Silber S, *et al*. Randomized study to assess the effectiveness of slow- and moderate-release polymer-based paclitaxel-eluting stents for coronary artery lesions. *Circulation* 2003;**108**:788–94.
	Colombo A. TAXUS II: slow- and moderate-release formulations. Transcatheter Cardiovascular Therapeutics (TCT) 2002 Conference coverage. URL: http://www.medscape.com/viewarticle/442693. 2002.
	Colombo A. TAXUS II. Cardiovascular Radiation Therapy (CRT) 2003. URL: http://www.tctmd.com/display/expert/pdf/61158/TAXUS2-CRT03.pdf (2003a).
	Colombo A. TAXUS II. Twelve month clinical follow up of TAXUS II Paclitaxel-eluting study. American College of Cardiology Meeting ACC 2003 (2003b).

Appendix 4

Quality assessment checklists

Quality assessment checklist for clinical studies

Based on CRD Report No. 4, University of York.[34]

- Was the method used to assign participants to the treatment groups really random? (Computer-generated random numbers and random number tables will be accepted as adequate, while inadequate approaches will include the use of alternation, case record numbers, birth dates or days of the week.)
- Was the allocation of treatment concealed? (Concealment will be deemed adequate where randomisation is centralised or pharmacy controlled, or where the following are used: serially numbered containers, on-site computer-based systems where assignment is unreadable until after allocation, other methods with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients. Inadequate approaches will include: the use of alternation, case record numbers, days of the week, open random number lists and serially numbered envelopes, even if opaque.)
- Was the number of participants who were randomised stated?
- Were details of baseline comparability presented in terms of treatment-free interval, disease bulk, number of previous regimens, age, histology and performance status?
- Was baseline comparability achieved for treatment free interval, disease bulk, number of previous regimens, age, histology and performance status?
- Were the eligibility criteria for study entry specified?
- Were any co-interventions identified that may influence the outcomes for each group?
- Were the outcome assessors blinded to the treatment allocation?
- Were the individuals who were administered the intervention blinded to the treatment allocation?
- Were the participants who received the intervention blinded to the treatment allocation?
- Was the success of the blinding procedure assessed?
- Were at least 80% of the participants originally included in the randomisation process followed up in the final analysis?
- Were the reasons for any withdrawals stated?
- Was an intention-to-treat analysis included?

Items graded as:

✓ yes (item adequately addressed), × no (item not adequately addressed), ✓/× partially (item partially addressed), NA not applicable or NS not stated.

Appendix 5

Data tables

Case study 1: Anakinra review[35]

TABLE 34 *Anakinra review data extraction tables*

Study name	Abstracts		Presentations			Full paper(s)	
0560 Bresnihan *et al*.	Bresnihan, 2001 Subgroup analysis of results reported (the effect of anakinra on progressive joint damage)		Bresnihan, 2001a Subgroup analysis of results reported (the effect of anakinra treatment on days of work and domestic activity)		Emery, 2001 Subgroup analysis of results reported (the effect of anakinra treatment on health related quality of life in subjects not using DMARDs)	Bresnihan, 1998 *ACR responses at 24 weeks* Placebo IL-1Ra 30 IL-1Ra 75 IL-1Ra 150 Components of ACR criteria reported match those reported in abstract	32/119 (27%) 47/119 39/115 49/115 (43%)
	N enrolled	472	*N* randomised	473	*N* randomised 473	*N* randomised Placebo 30 mg per day 75 mg per day 150 mg perday	472 121 119 116 116
0182 Unpublished							

continued

TABLE 34 *Anakinra review data extraction tables (cont'd)*

Study name	Abstracts			Full paper(s)	
0180 Cohen *et al.*	Cohen, 2001	Cohen 2001a		*Cohen, 2002*	
	Subgroup analysis of results reported (the effect of anakinra on the functional status)	Subgroup analysis of results reported (the effect of anakinra, with respect to dose response and speed of effect, on the functional status)		*ACR responses at 24 weeks* – results from the 1 mg kg^{-1} dose: ACR 20 Placebo/MTX IL-1Ra/MTX ACR 50 Placebo/MTX IL-1Ra/MTX ACR 70 Placebo/MTX IL-IRa/MTX	 11/48 (23%) 25/59 (42%) 2/48 (4%) 14/59 (24%) 0/48 6/59 (10%)
	N randomised not reported	*N* randomised	419	*N* randomised Placebo 0.04 mg kg^{-1} 0.1 mg kg^{-1} 0.4 mg kg^{-1} 1.0 mg kg^{-1} 2.0 mg kg^{-1}	419 48 63 46 55 59 46

continued

TABLE 34 *Anakinra review data extraction tables (cont'd)*

Study name	Abstracts	Full paper(s)
0145 Cohen *et al*.	Cohen, 2001 *ACR responses at 24 weeks* ACR 20 Placebo/MTX 22% IL-1Ra/MTX 38% ACR 50 Placebo/MTX 8% IL-1Ra/MTX 17% ACR 70 Placebo/MTX 2% IL-1Ra/MTX 6% *N* randomised 506 Not stated for each group	Cohen, 2004 (full publication identified) *ACR responses at 24 weeks* ACR 20 Placebo/MTX 55/251 (22%) IL-1Ra /MTX 95/250 (38%) ACR 50 Placebo/MTX 20/251 (8%) IL-1Ra/MTX 43/250 (17%) ACR 70 Placebo/MTX 5/251 (2%) IL-1Ra/MTX 15/250 (6%) *N* randomised 506 Placebo/MTX 203 IL-1Ra/MTX 203 (2 patients in placebo, 3 patients in intervention group not given any drug and excluded in analyses)

continued

TABLE 34 *Anakinra review data extraction tables (cont'd)*

Study name	Abstracts	Presentations	Full paper(s)
0757 Fleischmann *et al.*	Fleischmann, 2001 *Overall AEs* Anakinra 1027/1116 Placebo 261/283 *Deaths* Anakinra 4/1116 Placebo 1/283 *Serious AEs* Anakinra 86/1116 Placebo 22/283 *Severe AEs* Anakinra 173/1116 Placebo 37/283 *Withdrawal due to AEs* Anakinra 150/1116 Placebo 26/283 Infection episodes Anakinra 460/1116 Placebo 123/283 *Serious infections* Anakinra 23/1116 Placebo 1/283 *N* randomised 1414 Anakinra 1116 Placebo 283	Tesser, 2002 *Upper respiratory infections* Anakinra 160/1116 Placebo 54/283 *Serious AEs* Anakinra 86/1116 Placebo 22/283 *Serious infections* Anakinra 23/1116 Placebo 1/283 *Injection site reactions* Anakinra 810/1116 Placebo 93/283 *N* randomised 1414 Anakinra 1116 Placebo 283	Fleischmann, 2002 Subgroup analysis of results reported (safety of anakinra) *N* randomised not stated	Fleischmann, 2003 (full publication identified) *Overall AEs* Anakinra 1027/1116 Placebo 261/283 *Deaths* Anakinra 4/1116 Placebo 1/283 *Serious AEs* Anakinra 86/1116 Placebo 22/283 *Severe AEs* Anakinra 173/1116 Placebo 37/283 *Withdrawal due to AEs* Anakinra 150/1116 Placebo 26/283 *Infection episodes* Anakinra 460/1116 Placebo 123/283 *Serious infections* Anakinra 23/1116 Placebo 1/283 *Injection site reactions* Anakinra 810/1116 Placebo 93/283 *Malignancies* Anakinra 4/1116 Placebo 5/283 *Worsening of RA* Anakinra 223/1116 Placebo 78/283 *N* randomised 1414 Anakinra 1116 Placebo 283

AE, adverse event; MTX, methotrexate.

Case study 2: Infliximab and etanercept review[41]

TABLE 35 *Infliximab and etanercept review data extraction tables*

Study name	Abstracts	Presentations	Full paper(s)	
ATTRACT	Antoni, 2000	Kavanaugh, 2000	Maini, 1999	Lipksy, 2000
	ACR responses at 54 weeks	Subgroup analysis assessing functional status and quality of life	*ACR responses at 30 days presented*	*ACR responses at 54 weeks*
	ACR 20 response	*N* randomised 428	*N* randomised	*ACR 20 response*
	MTX alone 15/88		MTX alone 88	MTX alone 15/88
	Infliximab+ MTX		Infliximab + MTX	Infliximab + MTX
	3 mg kg^{-1} q. 8 weeks 36/86		Infliximab + MTX	3 mg kg^{-1} q. 8 weeks 36/86
	3 mg kg^{-1} q. 8 weeks 41/86		3 mg kg^{-1} q. 8 weeks 86	3 mg kg^{-1} q. 8 weeks 41/86
	10 mg kg^{-1} q. 4 weeks 51/87		3 mg kg^{-1} q. 8 weeks 86	10 mg kg^{-1} q. 8 weeks 51/87
	10 mg kg^{-1} q. 4 weeks 48/81		10 mg kg^{-1} q. 8 weeks 87	10 mg kg^{-1} q. 8 weeks 48/81
	ACR 20 (overall)		10 mg kg^{-1} q. 8 weeks 81	*ACR 50 response*
	Infliximab + MTX 177/340			MTX alone 7/88 (8%)
	N randomised			Infliximab + MTX
	Not stated			3 mg kg^{-1} q. 8 weeks 18/86
	Analysis of the disease activity score from ATTRACT trial			3 mg kg^{-1} q. 8 weeks 29/86 (34%)
				10 mg kg^{-1} q. 8 weeks 34/87 (39%)
				10 mg kg^{-1} q. 8 weeks 31/81
				ACR 70 response
				MTX alone 2/88 (2%)
				Infliximab + MTX
				3 mg kg^{-1} q. 8 weeks 9/86 (10%)
				3 mg kg^{-1} q. 8 weeks 14/86 (16%)
				10 mg kg^{-1} q. 8 weeks 22/87 (25%)
				10 mg kg^{-1} q. 8 weeks 15/81
				N randomised
				MTX alone 88
				Infliximab + MTX
				3 mg kg^{-1} q. 8 weeks 86
				3 mg kg^{-1} q. 8 weeks 86
				10 mg kg^{-1} q. 8 weeks 87
				10 mg kg^{-1} q. 8 weeks 81

continued

TABLE 35 *Infliximab and etanercept review data extraction tables (cont'd)*

Study name	Abstracts		Full paper(s)
European Etanercept Investigators Study	Ericson, 1999 *ACR responses- etanercept* 25 mg twice per week 70% 10 mg once per week 47% Placebo 12% *N* randomised for each group Not stated *N* enrolled 559 *N* completed study 506	Wajdula, 2000 *ACR responses – etanercept* 25 mg twice per week 70% 10 mg once per week 47% Placebo 12% *N* randomised for each group Not stated *N* enrolled 559 *N* completed study 506	Author contacted: this study has not been published in full
ERA	Finck, 1999 *ACR AUC rates at 12 months* Etanercept (10) 28.5% Etanercept (25) 34.9% *N* randomised 632		Bathon, 2000 ACR AUC rates reported at 12 months in Figure 1 match data in abstract by Finck ACR responses reported at 12 months *N* randomised 632 MX 217 Etanercept (10) 208 Etanercept (25) 207
Elliott, 1994 Maini, 1998 Kavanaugh, 2000 Moreland, 1996 Moreland, 1997 Moreland, 1999 Weinblatt, 1999	No abstracts were identified for these studies, and only full papers were included in the review		

AUC, area under the curve.

Case study 3: Drug-eluting stents review:[39] data tables

TABLE 36 *DES review data extraction tables: event rate*

Study name	Abstracts	Presentations		Full paper(s)	
ACTION	Not available	**Linnemeier, 2002**		**Serruys, 2002**	
		BMS		*BMS*	
		30 days	1/121	30 days*	1/119
		DES		6 months	9/88
		30 days		*DES*	
		Low dose	3/120	30 days*	
		High dose	1/119	Low dose	1/120
		N randomised unclear		High dose	4/121
				6 months	
				Low dose	22/120
				High dose	34/121†
				† 35/211 if TVR included as well	
				* MACE reported separately	

Study name	Full paper(s)	
	Serruys, 2004	
	BMS	
	30 days	1/119
	1 year	14/104
	DES	
	30 days	unclear
	1 year	90/239
	6 months	
	Low dose	22/120
	High dose	34/121

continued

TABLE 36 *DES review data extraction tables: event rate (cont'd)*

Study name	Abstracts	Presentations		Full paper(s)
ASPECT	Abstracts identified not reporting this outcome: *N* Shim, 2001 175 Park, 2001 175 Park, 2002 177 *MACE-free rates at 6 months:* BMS 96% DES Low dose 95% High dose 96% Hong, 2002 177 Kaluza, 2002 177 (High dose 60)	**Park, 2001** *BMS* 30 days 1/59 6 months 3/59 *DES* 30 days Low dose 3/58 High dose 4/60 6 months Low dose 4/58 High dose 6/60 MACE not reported explicitly. Calculated from event-free rates *N* enrolled 177 BMS 59 DES 118 Low dose 58 High dose 60	**Lee, 2002** *BMS* 30 days 1/59 6 months 3/59 1 year 6/58 *DES* 30 days Low dose 2/58 High dose 4/60 6 months Low dose 4/58 High dose 6/60 1 year Low dose 8/58 High dose 11/60 MACE not reported explicitly. Calculated from event-free rates (multiple events may occur in some patients). *N* randomised not explicitly stated	**Park, 2003** *BMS* 30 days 1/58 6 months 3/58 *DES* 30 days Low dose 2/58 High dose 4/59 6 months Low dose 4/58 High dose 6/60 MACE not reported explicitly. Calculated from event-free rates (multiple events may occur in some patients) *N* randomised 176 BMS 59 DES 117 Low dose 58 High dose 60 1 patient did not receive stent

continued

TABLE 36 *DES review data extraction tables: event rate (cont'd)*

Study name	Abstracts				Presentations						Full paper(s)	
DELIVER	**Knopf, 2002**		**O'Neill, 2002 (Presentation)**		**O'Neill, 2003**		**Knopf, 2003a**		**Knopf, 2003b**		**Lansky, 2004**	
	MACE at 30 days		MACE not reported		MACE		*BMS*		MACE not reported separately		MACE not reported	
	Group A	6/524	*N* randomised	1043	*BMS*		30 days	2/512				
	Group B	2/519			30 days	2/512	6 months	23/512				
					9 months	68/512	9 months	44/512	*N* randomised	1043	*N* randomised	1043
	N randomised	1043					1 year	48/512	BMS	519	BMS	519
	Group A	524			*DES*				DES	524	DES	524
	Group B	519			30 days	5/517	*DES*					
					9 months	53/517	30 days	5/517				
							6 months	18/517				
					N randomised	1043	9 months	34/517				
					BMS	519	1 year	39/517				
					DES	524						
					2 DES patients deregistered, 5 DES and 7 BMS patients did not receive stent							

continued

TABLE 36 *DES review data extraction tables: event rate (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
ELUTES	*N* Gershlick, 2000 97 recruited (Not reported MACE) Gershlick, 2001 200 (Not reported MACE) De Scheerder, 2002 (600 patients will be enrolled) Chevalier, 2002 190 MACE at 30 days 1.1%	**Gershlick, 2002 (oral abstract)** *MACE-free at 6 months* BMS 89% DES high-dose 89% *MACE-free at 1 year* BMS 82% DES high-dose 86% *N* enrolled 192	**Gershlick, 2002** *BMS* 30 days 1/38 6 months 4/38 (Calculated from event-free rates) *DES* 30 days 0.2 μg mm^{-2} 0/37 0.7 μg mm^{-2} 0/39 1.4 μg mm^{-2} 0/39 2.7 μg mm^{-2} 3/37 6 months 0.2 μg mm^{-2} 2/37 0.7 μg mm^{-2} 2/39 1.4 μg mm^{-2} 1/39 2.7 μg mm^{-2} 4/37 *N* randomised not explicitly reported	**Chevalier, 2002** *BMS* 30 days 1/38 6 months 4/38 *DES* 30 days 0.2 μg mm^{-2} 0/37 0.7 μg mm^{-2} 0/39 1.4 μg mm^{-2} 0/39 2.7 μg mm^{-2} 3/37 6 months 0.2 μg mm^{-2} 2/37 0.7 μg mm^{-2} 2/39 1.4 μg mm^{-2} 1/39 2.7 μg mm^{-2} 4/37 *N* randomised not explicitly reported	**Grube, 2001** (see TAXUS I presentation) *MACE 6 months* BMS 11% DES 0.2 μg mm^{-2} 5% 0.7 μg mm^{-2} 5% 1.4 μg mm^{-2} 3% 2.7 μg mm^{-2} 11%	**Gershlick, 2004** *BMS* 30 days 1/38 6 months 5/38 1 year 7/38 *DES* 30 days 0.2 μg mm^{-2} 0/37 0.7 μg mm^{-2} 0/39 1.4 μg mm^{-2} 0/39 2.7 μg mm^{-2} 3/37 6 months 0.2 μg mm^{-2} 1/37 0.7 μg mm^{-2} 1/39 1.4 μg mm^{-2} 3/39 2.7 μg mm^{-2} 4/37 1 year 0.2 μg mm^{-2} 2/37 0.7 μg mm^{-2} 3/39 1.4 μg mm^{-2} 4/39 2.7 μg mm^{-2} 5/37 * MACE rates reported separately in paper *N* randomised 192 BMS 39 DES 153 1 patient from each group did not receive stent

continued

TABLE 36 *DES review data extraction tables: event rate (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
E-SIRIUS	**Schofer, 2002** Not reported *N* randomised 350 BMS 175 DES 175	**Schofer, 2002** Results from E- and C-SIRIUS (blinded) *N* enrolled 353 1 patient deregistered because not treated with assigned stent			**Schofer, 2003** *9 months* BMS 40/177 DES 14/175 *N* randomised 353 1 patient deregistered because not treated with assigned stent BMS 177 DES 175
FUTURE I	**Grube, 2002** 24 patients recruited MACE in-hospital 0/24	**Grube, 2002** *30 days** BMS 0/12 DES 0/24 *Early findings	**Grube, 2003a** *BMS* 6 months 1/13 1 year 1/12 *DES* 6 months 2/26 1 year 2/24 *N* randomised 42 BMS 15 DES 27	**Grube, 2003b** *BMS* 30 days 0/13 6 months 1/12 *DES* 30 days 0/27 6 months 2/26 *N* randomised 42 BMS 15 DES 27	**Grube, 2004** *BMS* 30 days 0/15 6 months 1/14 *DES* 30 days 0/27 6 months 2/26 *N* randomised 42 BMS 15 DES 27
PATENCY		**Heldman, 2002** *BMS* 30 days 0/26 9 months 6/26 *DES* 30 days 0/24 9 months 3/24 *N* randomised 50 BMS 26 DES 24			

continued

TABLE 36 *DES review data extraction tables: event rate (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
RAVEL	Abstracts identified not reporting this outcome: Sousa, 2001 **Regar, 2002a** 6 months: diabetics: MACE: BMS 3/25 DES 0/19 Regar, 2002b Degertekin, 2002a Abizaid, 2002 **Degertekin, 2002b** Event-free survival at 1 year: BMS 72% DES 98%	**Colombo, 2002** *BMS* 210 days 32/118 1 year 34/118 *DES* 210 days 4/120 1 year 7/120 *N* included 238	**Beck, 2004** *BMS* 1 year 22/118 3 years 27/118 *DES* 1 year 7/120 3 years 18/120 *N* randomised not stated explicitly		**Morice, 2002** *BMS* 1 year 34/118 *DES* 1 year 7/120 *N* randomised 238 BMS 118 DES 120 **Regar, 2002** Not reported *N* randomised 238 BMS 118 DES 120
SCORE	Abstracts identified not reporting this outcome: Kataoka, 2001a Kataoka, 2001b Honda, 2002 Kataoka, 2002 **Lansky, 2002** (Angiographic results reported) *N* randomised 260 BMS 134 DES 126	**Grube, 2002a** (Angiographic results of the first 260 patients reported) **Grube, 2002b** Enrolment was stopped owing to increased early MACE events *N* randomised 266 (of 400) BMS 138 DES 128	**Stone, 2002** Not reported *N* randomised 266 (of 400) BMS 138 DES 128	**Grube, 2002** *1 year* BMS 42/138 DES 63/128 Cardiac deaths included in MACE (reported non-hierarchically) *N* randomised 266 (of 400) BMS 138 DES 128	**Grube, 2004** *BMS* 30 days 4/140 6 months 20/140 1 year 35/140 *DES* 30 days 16/126 6 months 26/126 1 year 37/16 MACE reported cumulatively *N* randomised BMS DES

continued

TABLE 36 *DES review data extraction tables: event rate (cont'd)*

Study name	Abstracts		Presentations		Full paper(s)	
SIRIUS	**Ako, 2002**	**Moses, 2002**	**Leon, 2002a**	**Leon, 2002b**	**Moses, 2002**	**Moses, 2003**
	(Interim IVUS analysis of 63 patients)	*30 days – MACE:* Group A 11/522 Group B 15/535	MACE not reported. Interim analysis of first 400 patients (SIRIUS 400)	MACE reported for subgroups (overlapping stents and diabetics) *N* randomised (all) 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered	*BMS* In-hospital 8/525 9 months 99/525 *DES* In-hospital 13/533 9 months 38/533 *N* randomised (all) 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered Incorrectly stated on 'study design' slide: BMS 556 DES 545	*BMS* In-hospital 8/525 9 months 99/525 *DES* In-hospital 13/533 9 months 38/533 *N* randomised 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered **Holmes, 2004** *BMS* In-hospital 8/525 9 months 99/525 1 year 117/525 *DES* In-hospital 13/533 9 months 38/533 1 year 44/533 *N* randomised 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered

continued

TABLE 36 *DES review data extraction tables: event rate (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
TAXUS I	**Grube, 2001** *30 days* MACE* 0/61 *N* randomised 61	**Grube, 2001** *MACE – 30 days* BMS 0% DES 0% *N* enrolled 61 BMS 30 DES 31 Grube 2002 **Grube, 2002** MACE not reported *N* randomised 61 BMS 30 DES 31	**Stone, 2002** *1 year* BMS 4/30 DES 1/31 *N* randomised 61 BMS 30 DES 31	**Grube, 2003** *BMS* 6 months 2/30 2 years 3/31 *DES* 6 months 0/31 2 years 1/30 MACE includes cardiac deaths *N* randomised 61 BMS 30 DES 31	**Grube, 2003** *BMS* 30 days 0/30 6 months 2/30 1 year 3/30 * * 1 patient had 2 events *DES* 30 days 0/31 6 months 0/31 1 year 1/30 *N* randomised 61 BMS 30 DES 31

continued

TABLE 36 *DES review data extraction tables: event rate (cont'd)*

Study name	Abstracts	Presentations						Full paper(s)	
TAXUS II		**Gruberg (Colombo), 2002**		**Colombo, 2003a**		**Colombo, 2003b**		**Colombo, 2003**	
		30 days		*30 days*		*6 months*		*30 days*	
		BMS		BMS		BMS		BMS	
		SR	5/136	SR	6/136	Combined	52/263	SR	6/136
		MR	5/134	MR	6/136	DES		MR	6/134
		(Denominator for MR stated as 136 in Figure 7, p. 6)		DES		SR	11/130	DES	
				SR	3/131	MR	10/129	SR	3/131
		DES		MR	3/135	*1 year*		MR	3/135
		SR	2/131	*6 months*		BMS		*6 months*	
		MR	3/135	BMS		Combined	57/263	BMS	
				Combined	52/263 (19.8%) or 52/262	DES		SR	26/133
						SR	14/129	MR	26/130
				DES		MR	13/131	DES	
				SR	11/129 (8.5%) or 11/130			SR	11/130
				MR	10/128 (7.8%) or 10/129			MR	10/129
				N randomised not explicitly stated				*1 year*	
								BMS	
								SR	29/132
								MR	28/131
								DES	
								SR	14/129
								MR	13/131
								N randomised	536
								BMS combined	270
								SR	136
								MR	134
								DES combined	266
								SR	131
								MR	135

BMS, bare-metal stents; MACE, major adverse cardiac events; IVUS, intravascular ultrasound; SR, slow release; MR, moderate release.

TABLE 37 *DES review data extraction tables: mortality*

Study name	Abstracts	Presentations				Full paper(s)	
ACTION	Not available	**Linnemeier, 2002**		**Serruys, 2002**		**Serruys, 2002**	
		BMS		*BMS*		*BMS*	
		30 days	0/121	30 days	0/119	30 days	0/119
		DES		6 months	0/88	6 months	1/101
		30 days		*DES*		1 year	1/104
		Low dose	0/120	30 days		*DES*	
		High dose	0/119	Low dose	0/120	30 days	
				High dose	0/121	Low dose	0/120
				6 months		High dose	0/121
				Low dose	1/120	6 months	
				High dose	0/121	Low dose	0/120
						High dose	0/121
						1 year	0/239
						N randomised BMS DES	
						Clinical follow-up at 6 months in paper reported as 101/119 in text and 104/119 in table	

continued

TABLE 37 *DES review data extraction tables: mortality (cont'd)*

Study name	Abstracts	Presentations	Full paper(s)
ASPECT	Abstracts identified not reporting this outcome: *N* Shim, 2001 175 Park, 2001 175 Park, 2002 177 (No death reported between 6 and 12 months in DES groups) Hong, 2002 177 Kaluza, 2002 177 (High dose 60)	**Park, 2001** *BMS* 30 days 0/59 6 months 0/59 *DES* 30 days Low dose 1/58 High dose 0/60 6 months Low dose 1/58 High dose 0/60 *N* randomised 177 BMS 59 DES 118 Low dose 58 High dose 60 **Lee, 2002** *BMS* 30 days 0/59 6 months 0/59 12 months 0/59 *DES* 30 days Low dose 1/58 High dose 0/60 6 months Low dose 1/58 High dose 0/60 12 months Low dose 1/58 High dose 0/60 *N* randomised not explicitly stated	**Park, 2003** *BMS* 30 days 0/58 6 months 0/58 *DES* 30 days Low dose 1/58 High dose 0/59 6 months Low dose 1/58 High dose 0/59 *N* randomised 177 BMS 59 DES 118 Low dose 58 High dose 60 1 patient did not receive stent

continued

TABLE 37 *DES review data extraction tables: mortality (cont'd)*

Study name	Abstracts	Presentations				Full paper(s)
DELIVER	**Knopf, 2002** Not reported *N* randomised 1043 Group A 524 Group B 519	**O'Neill, 2002 (Presentation)** Death not reported *N* randomised 1043	**O'Neill, 2003** *BMS* 30 days 1/512 9 months 5/512 *DES* 30 days 1/517 9 months 5/517 *N* randomised 1043 BMS 519 DES 524 2 DES patients deregistered 5 DES and 7 BMS patients did not receive stent	**Knopf, 2003a** *Cardiac deaths reported* *BMS* 30 days 1/512 6 months 1/512 9 months 4/512 1 year 4/512 *DES* 30 days 1/517 6 months 1/517 9 months 1/517 1 year 1/517	**Knopf, 2003b** *BMS* In-hospital 0/512 30 days 1/512 9 months 6/512 *DES* In-hospital 1/517 30 days 1/517 9 months 5/517 *N* randomised 1043 BMS 519 DES 524	**Lansky, 2004** Not reported *N* randomised 1043 BMS 519 DES 524

continued

TABLE 37 *DES review data extraction tables: mortality (cont'd)*

Study name	Abstracts			Presentations			Full paper(s)	
ELUTES		*N*	Gershlick, 2002	192	**Gershlick, 2002**		**Chevalier, 2002**		**Gershlick, 2004**	
	Gershlick, 2000	97 recruited	6 months (12 months?)	0/192	*BMS*		*BMS*		*BMS*	
	(This outcome, not reported)				30 days	0/38	30 days	0/38	30 days	0/38
					6 months	0/38	6 months	0/38	6 months	0/38
	Gershlick, 2001	200							1 year	0/38
	De Scheerder (600 patients will be enrolled)	2002			*DES*		*DES*		*DES*	
					30 days		30 days		30 days	
	Chevalier, 2002	190			0.2 μg mm^{-2}	0/37	0.2 μg mm^{-2}	0/37	0.2 μg mm^{-2}	0/37
	1 death in total (6 months?)				0.7 μg mm^{-2}	0/39	0.7 μg mm^{-2}	0/39	0.7 μg mm^{-2}	0/39
					1.4 μg mm^{-2}	0/39	1.4 μg mm^{-2}	0/39	1.4 μg mm^{-2}	0/39
					2.7 μg mm^{-2}	1/37	2.7 μg mm^{-2}	1/37	2.7 μg mm^{-2}	1/37
					6 months		6 months		6 months	
					0.2 μg mm^{-2}	0/37	0.2 μg mm^{-2}	0/37	0.2 μg mm^{-2}	0/37
					0.7 μg mm^{-2}	0/39	0.7 μg mm^{-2}	0/39	0.7 μg mm^{-2}	0/39
					1.4 μg mm^{-2}	0/39	1.4 μg mm^{-2}	0/39	1.4 μg mm^{-2}	0/39
					2.7 μg mm^{-2}	1/37	2.7 μg mm^{-2}	1/37	2.7 μg mm^{-2}	1/37
					N randomised not explicitly stated		*N* randomised not explicitly stated		1 year	
									0.2 μg mm^{-2}	0/37
									0.7 μg mm^{-2}	0/39
									1.4 μg mm^{-2}	0/39
									2.7 μg mm^{-2}	1/37
									N randomised	192
									BMS	39
									DES	153
									1 patient from each group did not receive stent	

continued

TABLE 37 *DES review data extraction tables: mortality (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
E-SIRIUS	**Schofer, 2002** Not reported *N* randomised 350 BMS 175 DES 175	**Schofer, 2002** Results from E- and C-SIRIUS (blinded) *N* randomised is not explicitly stated: 1 patient deregistered			**Schofer, 2003** *9 months* BMS 1/177 DES 2/175 *N* randomised 353 1 patient deregistered because not treated with assigned stent (therefore not strictly ITT) BMS 177 DES 175
FUTURE I	**Grube, 2002** 24 patients recruited Death not reported No in-hospital MACE (i.e. deaths)	**Grube, 2002** *30 days** BMS 0/12 DES 0/24 *Early findings: 0/36 30-day event-free survival	**Grube , 2003a** *BMS* 6 months 0/13 12 months 0/12 *DES* 6 months 1/26 12 months 1/24 *N* randomised 42 BMS 15 DES 27	**Grube, 2003b** *BMS* 30 days 0/13 6 months 0/12 *DES* 30 days 0/27 6 months 1/26 *N* randomised 42 BMS 15 DES 27	**Grube, 2004** *BMS* 30 days (MACE) 0/15 6 months 0/15 *DES* 30 days (MACE) 0/27 6 months 1/27 *N* randomised 42 BMS 15 DES 27
PATENCY		**Heldman, 2002** *BMS* 30 days 0/26 9 months 1/26 *DES* 30 days 0/24 9 months 0/24 *N* randomised 50 BMS 26 DES 24			

continued

TABLE 37 *DES review data extraction tables: mortality (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
RAVEL	Abstracts identified not reporting this outcome: Sousa, 2001 Regar, 2002a Regar, 2002b Degertekin, 2002a Degertekin, 2002b Abizaid, 2002	**Colombo, 2002** *BMS* 210 days 2/118 1 year 2/118 *DES* 210 days 0/120 1 year 2/120 *N* randomised 238 BMS 118 DES 120	**Beck, 2004** *BMS* 3 years 5/118 DES 3 years 9/120 *N* randomised not explicitly stated		**Morice, 2002** *BMS* In-hospital 0/118 1 year 2/118 *DES* In-hospital 0/120 1 year 2/120 *N* randomised 238 BMS 118 DES 120
SCORE	Abstracts identified not reporting this outcome: Kataoka, 2001a Kataoka, 2001b Honda, 2002 Kataoka, 2002 **Lansky, 2002** (Angiographic results reported) *N* randomised 260 BMS 134 DES 126	**Grube, 2002a** (Angiographic results reported) *N* randomised 267 (of 400) Report on first 260 BMS 126 DES 134 **Grube, 2002b** Cardiac deaths: 6 months BMS 0/138 DES 5/128 *N* randomised 266 (of 400) BMS 138 DES 128	**Stone, 2002** *6 months* BMS 0/138 DES 5/128 *N* randomised 266 (of 400) BMS 138 DES 128	**Grube, 2002** *Cardiac deaths* *1 year* BMS 0/138 DES 5/128 *N* randomised 266 (of 400) BMS 138 DES 128	**Grube, 2004** *Cardiac deaths* *BMS* 30 days 0/140 6 months 0/140 1 year 0/140 *DES* 30 days 2/126 6 months 3/126 1 year 5/126 *N* randomised BMS DES

continued

TABLE 37 *DES review data extraction tables: mortality (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
SIRIUS	**Ako, 2002** (Interim IVUS analysis of 63 patients, death not reported)	**Moses, 2002** *30 days* Group A 0/522 Group B 1/535 *N* randomised (550 per group) 1101	**Leon, 2002a** Death not reported. Interim analysis of first 400 patients (SIRIUS 400)	**Leon, 2002b** Death not reported *N* randomised (all) 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered	**Moses, 2002** *BMS* In-hospital 0/525 9 months 3/525 *DES* In-hospital 1/533 9 months 5/533 *N* randomised 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered *Incorrectly stated* BMS 556 DES 545 On 'study design' slide	**Moses, 2003** *BMS* In-hospital 0/525 9 months 3/525 *DES* In-hospital 1/533 9 months 5/533 *N* randomised 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered **Holmes, 2004** *BMS* In-hospital 0/525 9 months 3/525 1 year 4/525 *DES* In-hospital 1/533 9 months 5/533 1 year 7/533 *N* randomised 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered

continued

TABLE 37 *DES review data extraction tables: mortality (cont'd)*

Study name	Abstracts		Presentations				Full paper(s)	
TAXUS I	**Grube, 2001**		**Grube, 2001**		**Stone, 2002**		**Grube, 2003**		**Grube, 2003**	
	30 days		Mortality not reported		*1 year*		*Cardiac death*		*1 year*	
	Mortality (total)	0%	*N* enrolled	61	BMS	0/30	*BMS*		BMS	0/30
	N randomised	61	BMS	30	DES	0/31	6 months	0/30	DES	0/31
			DES	31			2 years	0/30		
			Grube, 2002				*DES*			
							6 months	0/31		
			N randomised	61	*N* randomised	61	9 months	0/31		
			BMS	30	BMS	30				
			DES	31	DES	31	*N* randomised	61	*N* randomised	61
							BMS	30	BMS	30
							DES	31	DES	31

continued

TABLE 37 *DES review data extraction tables: mortality (cont'd)*

Study name	Abstracts	Presentations						Full paper(s)	
TAXUS II		**Colombo, 2002**		**Colombo, 2003a**		**Colombo, 2003b**		**Colombo, 2003**	
		30 days		*30 days*		*6 months*		*6 months*	
		Not reported		BMS		BMS		BMS	
				SR	1/136	Combined	1/270	SR	1/133
				MR	0/136			MR	0/130
				DES		DES		*DES*	
				SR	0/131	SR	0/131	SR	0/130
				MR	0/135	MR	0/135	MR	0/129
		6 months		*6 months*		*1 year*		*1 year*	
		BMS		BMS		BMS		BMS	
		Combined	1/270	Combined	1/270	Combined	2/270	SR	2/132
								MR	0/131
		DES		DES		DES		DES	
		SR	0/131	SR	0/131	SR	0/131	SR	0/129
		MR	0/135	MR	0/135	MR	0/135	MR	0/131
		N randomised not explicitly stated		*N* randomised not explicitly stated		*N* randomised	536	*N* randomised	536
		BMS combined	270	BMS combined	270	BMS combined	270	BMS combined	270
		SR	136	SR	136	SR	136	SR	136
		MR	134	MR	134	MR	134	MR	134
		DES	266	DES	266	DES	266	DES	236
		SR	131	SR	131	SR	131	SR	131
		MR	135	MR	135	MR	135	MR	135

continued

TABLE 38 *DES review data extraction tables: any MI*

Study name	Abstracts	Presentations		Full paper(s)	
ACTION	Not available	**Linnemeier, 2002**		**Serruys, 2002**	
		30 days		*BMS*	
		BMS	0/121	30 days	1/119
		DES		6 months	1/88
		Low dose	3/120	*DES*	
		High dose	1/119	30 days	
		N randomised not clearly stated		Low dose	0/120
				High dose	3/121
				6 months	
				Low dose	0/120
				High dose	4/121
				N randomised not explicitly stated	
				Serruys, 2004	
				BMS	
				30 days	Unclear
				6 months	Unclear
				12 months	1/104
				DES	
				30 days	Unclear
				6 months	Unclear
				12 months	4//104
				N randomised	
ASPECT	Abstracts identified not reporting this outcome:	**Park, 2001**		**Lee, 2002**	
	N	*BMS*		*BMS*	
	Shim, 2001 175	30 days	1/59	30 days	1/59
	Park, 2001 175	6 months	1/59	6 months	1/59
	Park, 2002 177	30 days		*DES*	
	Hong, 2002 177	Low dose	1/58	30 days	
	Kaluza, 2002 177	High dose	2/60	Low dose	1/58
		6 months		High dose	2/60
		Low dose	1/58	6 months	
		High dose	2/60	DES	
		N randomised not clearly stated		Low dose	1/58
				High dose	2/60
				N randomised	177
				BMS	59
				DES	118
				Low dose	58
				High dose	60
				Park, 2003	
				BMS	
				30 days	1/58
				6 months	1/58
				DES	
				30 days	
				Low dose	1/58
				High dose	2/59
				6 months	
				Low dose	1/58
				High dose	2/59
				N randomised	177
				BMS	59
				DES	118
				Low dose	58
				High dose	60

continued

TABLE 38 *DES review data extraction tables: any MI*

Study name	Abstracts	Presentations				Full paper(s)
DELIVER	**Knopf, 2002** Not reported *N* randomised 1043 Group A 524 Group B 519	**O'Neill, 2002** (Presentation) MI not reported *N* randomised 1043	**O'Neill, 2003** *BMS* 30 days 1/512 9 months 5/512 *DES* 30 days 4/517 9 months 6/517 *N* randomised 1043 BMS 519 DES 524* *2 deregistered	**Knopf, 2003a** *BMS* 30 days 1/512 6 months 3/512 9 months 5/512 *DES* 30 days 4/517 6 months 4/517 9 months 6/517	**Knopf, 2003b** *BMS* 30 days 1/512 9 months 5/512 *DES* 30 days 4/517 9 months 5/517 *N* randomised 1043 BMS 519 DES 524	**Lansky, 2004** MI not reported *N* randomised 1043 BMS 519 DES 524
ELUTES	*N* Gershlick 2000 97 recruited (This outcome not reported) Gershlick, 2001 200 4 MI in total at the time of writing De Scheerder, 2002 (600 patients will be enrolled) Chevalier, 2002 190 5 MI in total (no time-point given)	Gershlick, 2002 192 6 months 0/192 Only report 0 Q-wave MIs; do not mention non-Q-wave MIs		**Gershlick, 2002** *BMS* 30 days 0/38 6 months 1/38 *DES* 30 days 0.2 μg mm^2 0/37 0.7 μg mm^2 0/39 1.4 μg mm^2 0/39 2.7 μg mm^2 1/37 6 months 0.2 μg mm^2 0/37 0.7 μg mm^2 1/39 1.4 μg mm^2 0/39 2.7 μg mm^2 1/37	**Chevalier, 2002** *BMS* 30 days 0/38 6 months 0/38 *DES* 30 days 0.2 μg mm^2 0/37 0.7 μg mm^2 0/39 1.4 μg mm^2 0/39 2.7 μg mm^2 1/37 6 months 0.2 μg mm^2 0/37 0.7 μg mm^2 1/39 1.4 μg mm^2 0/39 2.7 μg mm^2 1/37	**Gershlick, 2004** *BMS* 30 days 0/38 6 months 0/38 1 year 0/38 *DES* 30 days 0.2 μg mm^2 0/37 0.7 μg mm^2 0/39 1.4 μg mm^2 0/39 2.7 μg mm^2 1/37 6 months 0.2 μg mm^2 0/37 0.7 μg mm^2 1/39 1.4 μg mm^2 0/39 2.7 μg mm^2 1/37 1 year 0.2 μg mm^2 0/37 0.7 μg mm^2 1/39 1.4 μg mm^2 0/39 2.7 μg mm^2 1/37 *N* randomised 192 BMS 39 DES 153

continued

TABLE 38 *DES review data extraction tables: any MI (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
E-SIRIUS	**Schofer, 2002** Not reported *N* randomised 350 BMS 175 DES 175				**Schofer, 2003** *9 months* BMS 4/177 DES 8/175 *N* randomised 353 (1 patient did not receive assigned study stent and was excluded; not strictly ITT) BMS 177 DES 175
FUTURE I	**Grube, 2002** 24 patients recruited MI not reported	**Grube, 2002** *30 days** BMS 0/12 DES 0/24 *Early findings	**Grube, 2003a** Not reported *BMS* 6 months 0/13 12 months 0/12 *DES* 6 months 0/26 12 months 0/24 *N* randomised 42 BMS 15 DES 27	**Grube, 2003b** *BMS* 30 days 0/13 6 months 0/12 *DES* 30 days 0/27 6 months 0/26 *N* randomised 42 BMS 15 DES 27	**Grube, 2004** *BMS* 30 days (MACE) 0/15 6 months 0/14 *DES* 30 days (MACE) 0/27 6 months 0/26 *N* randomised 42 BMS 15 DES 27
PATENCY		**Heldman, 2002** *BMS* 30 days 0/26 9 months 0/26 *DES* 30 days 0/24 9 months 0/24 *N* randomised 50 BMS 26 DES 24			

continued

TABLE 38 *DES review data extraction tables: any MI (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
RAVEL	Abstracts identified not reporting this outcome: Sousa, 2001 Regar, 2002a Regar, 2002b Degertekin, 2002a Degertekin, 2002b Abizaid, 2002	**Colombo, 2002** *BMS* 210 days 3/118 1 year 4/118 *DES* 210 days 3/120 1 year 4/120 *N* randomised 238 BMS 118 DES 120	Beck, 2004 *BMS* 3 years 6/118 *DES* 3 years 4/120 *N* randomised not explicitly stated		**Morice, 2002** *BMS* In-hospital 3/118 1 year 5/118 *DES* In-hospital 3/120 1 year 4/120 *N* randomised 238 BMS 118 DES 120
SCORE	Abstracts identified not reported this outcome: Kataoka, 2001a Kataoka, 2002b Honda, 2002 Kataoka, 2002 **Lansky, 2002** (Angiographic results reported) *N* randomised 260 BMS 134 DES 126	**Grube, 2002a** (Angiographic results reported) *N* randomised 267 (of 400) BMS 126 DES 134 **Grube, 2002b** (Interim safety results reported) *N* randomised 266 (of 400) BMS 138 DES 128	**Stone, 2002** *6 months* BMS 3/131 DES 17/117 *N* randomised 266 (of 400) BMS 138 DES 128	**Grube, 2002** *1 year* BMS 4/138 DES 27/128 *N* randomised 266 (of 400) BMS 138 DES 128	**Grube, 2004** *30 day* BMS 3/140 DES 15/126 *6 months* BMS 3/140 DES 20/126 *1 year* BMS 4/140 DES 24/126 *N* randomised BMS DES

continued

TABLE 38 *DES review data extraction tables: any MI (cont'd)*

Study name	Abstracts		Presentations			Full paper(s)	
SIRIUS	**Ako, 2002**	**Moses, 2002**	**Leon, 2002a**	**Leon, 2002b**	**Moses, 2002**	**Moses, 2003**	
	(Interim IVUS analysis of 63 patients, MI not reported)	*30 days*	MI not reported. Interim analysis of first 400 patients (SIRIUS 400)	MI not reported	*BMS*	*BMS*	
		Group A 11/522		*N* randomised (all) 1101	In-hospital 8/525	In-hospital 8/525	
		Group B 13/535		BMS 545 (–20*)	9 months 17/525	9 months 17/525	
				DES 556 (–23*)	*DES*	*DES*	
					In-hospital 12/533	In-hospital 12/533	
				* Deregistered	9 months 15/533	9 months 15/533	
					N randomised 1101	*N* randomised 1101	
					BMS 545 (–20*)	BMS 545 (–20*)	
					DES 556 (–23*)	DES 556 (–23*)	
					* Deregistered	* Deregistered	
						Holmes, 2004	
						BMS	
						In-hospital 8/525	
						9 months 17/525	
						1 year 18/525	
						DES	
						In-hospital 12/533	
						9 months 15/533	
						1 year 16/533	
						N randomised 1101	
						BMS 545 (–20*)	
						DES 556 (–23*)	
						* Deregistered	

continued

TABLE 38 *DES review data extraction tables: any MI (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
TAXUS I	**Grube, 2001** *30 days* Q-wave MI 0% (both groups) *N* randomised 61	**Grube, 2001** MACE reported: 0 in both groups at 30 days (therefore 0 MI in both groups at 30 days) *N* randomised 61 BMS 30 DES 31 **Grube, 2002** *N* randomised 61 BMS 30 DES 31	**Stone, 2002** *Q-wave MI* *1 year* BMS 0/30 DES 0/31 *N* randomised 61 BMS 30 DES 31	**Grube, 2003** *BMS* 6 months 0/30 2 years 0/30 *DES* 6 months 0/3 9 months 0/31 *N* randomised 61 BMS 30 DES 31	**Grube, 2003** *BMS* 1 year 0/30 *DES* 1 year 0/31 *N* randomised 61 BMS 30 DES 31
TAXUS II		**Gruberg, 2002** *(presented by Colombo)* *30 days* Not reported *6 months* BMS Combined 14/270 DES SR 2/131 MR 3/135 *N* randomised 536 BMS combined 270 SR 136 MR 134 DES 236 SR 131 MR 135	**Colombo, 2003a** *30 days* BMS SR 5/136 MR 6/136 DES SR 2/131 MR 3/135 *6 months* BMS Combined 14/270 DES SR 2/131 MR 3/135 *N* randomised 536 BMS combined 270 SR 136 MR 134 DES 266 SR 131 MR 135	**Colombo, 2003b** *6 months* BMS Combined 14/270 DES SR 2/131 MR 3/135 *1 year* BMS Combined 14/270 DES SR 3/131 MR 5/135 *N* randomised 536 Not explicitly stated	**Colombo, 2003** *6 months* BMS SR 7/133 MR 7/130 DES SR 2/130 MR 3/129 *1 year* BMS SR 7/132 MR 7/131 DES SR 3/129 MR 5/131 *N* randomised 536 BMS combined 270 SR 136 MR 134 DES 266 SR 131 MR 135

TABLE 39 *DES review data extraction tables: binary restenosis*

Study name	Abstracts	Presentations			Full paper(s)
ACTION	Not available	**Linnemeier, 2002** Not reported *Study design* BMS 120 DES 240 Low dose 120 High dose 120	**Serruys, 2002** *6 months* BMS 7/64 DES Low dose 28/113 High dose 20/115		**Serruys, 2004** *6 months: in-stent restenosis* BMS 7/65 DES Low dose 28/113 High dose 20/115
ASPECT	Abstracts identified not reporting this outcome: *N* Shim, 2001 175 Park, 2001(blinded) 175 Park, 2002 177 Hong, 2002 177 **Kaluza, 2002** 177 (High dose 60) *DES* High dose 2% Numerator and denominator not given explicitly, and not stated whether all 60 were followed up	**Park, 2001** *6 months* BMS 27% DES Low dose 12% High dose 4% Numerator and denominator not given explicitly, and only 88% followed up *N* randomised 177 BMS 59 DES 118 Low dose 58 High dose 60	**Lee, 2002** *6 months* BMS 27% DES Low dose 12% High dose 4% *N* randomised not explicitly stated		**Park, 2003** *6 months* BMS 15/55 (27%) DES Low dose 6/50 (12%) High dose 2/50 (4%) *N* randomised 177 BMS 59 DES 118 Low dose 58 High dose 60 1 patient did not receive stent
DELIVER	**Knopf, 2002** *Postprocedure in-stent restenosis:* Group A 14/524 Group B 12/519 *N* randomised 1043 Group A 524 Group B 519	**O'Neill, 2002** (Presentation) BRR not reported N randomised 1043	**O'Neill, 2003** In-stent restenosis not reported *N* randomised 1043 BMS 519 DES 524 2 DES patients deregistered, 5 DES and 7 BMS patients did not receive stent	**Knopf, 2003a** *In-stent restenosis 240 days* BMS 44/214 DES 34/228	**Knopf, 2003b** In-stent restenosis not reported *N* randomised 1043 BMS 519 DES 524	**Lansky, 2004** *240 days* BMS 44/214 DES 34/228 *N* randomised 1043 BMS 519 DES 524

continued

TABLE 39 *DES review data extraction tables: binary restenosis (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
ELUTES	*N* Gershlick, 2000 97 recruited Gershlick, 2001 200 De Scheerder, 2002 (600 patients will be enrolled) Chevalier, 2002 190 Gershlick, 2002 192 BMS 20.6% DES-high-density 3.1%	**Grube, 2001** (See TAXUS I presentation) *In-stent restenosis* *6 months* BMS 20.6% DES 0.2 μg mm^{-2} 20% 0.7 μg mm^{-2} 11.8% 1.4 μg mm^{-2} 13.5% 2.7 μg mm^{-2} 3.1%	**Gershlick, 2002** *In-stent restenosis* *6 months* BMS 7/34 DES 0.2 μg mm^{-2} 7/35 0.7 μg mm^{-2} 4/34 1.4 μg mm^{-2} 5/37 2.7 μg mm^{-2} 1/32 *N* randomised not explicitly reported	**Chevalier, 2002** *In-stent restenosis* *6 months* BMS 7/34 DES 0.2 μg mm^{-2} 7/35 0.7 μg mm^{-2} 4/34 1.4 μg mm^{-2} 5/37 2.7 μg mm^{-2} 1/32 *N* randomised not explicitly reported	**Gershlick, 2004** *In-stent restenosis* *6 months* BMS 7/34 DES 0.2 μg mm^{-2} 7/34 0.7 μg mm^{-2} 5/35 1.4 μg mm^{-2} 5/37 2.7 μg mm^{-2} 1/31 *N* randomised 192 BMS 39 DES 153 1 patient from each group did not receive stent
E-SIRIUS	**Schofer, 2002** Not reported *N* randomised 350 BMS 175 DES 175	**Schofer, 2002** Results from E- and C-SIRIUS (blinded) *N* enrolled 353 1 patient deregistered because not treated with assigned stent			**Schofer, 2003** *9 months* BMS 65/156 DES 6/152 *N* randomised 353 1 patient deregistered because not treated with assigned stent BMS 177 DES 175
FUTURE I	**Grube, 2002** 24 patients recruited BRR not reported	**Grube, 2002** Not reported	**Grube, 2003a** *In-stent restenosis* *6 months* BMS 1/11 DES 0/25 *N* randomised 42 BMS 15 DES 27	**Grube, 2003b** *In-stent restenosis* *6 months* BMS 1/11 DES 0/25 *N* randomised 42 BMS 15 DES 27	**Grube, 2004** *In-stent restenosis* *6 months* BMS 1/11 DES 0/25 *N* randomised 42 BMS 15 DES 27

continued

TABLE 39 *DES review data extraction tables: binary restenosis (cont'd)*

Study name	Abstracts	Presentations	Full paper(s)
PATENCY		**Heldman, 2002** *9 months* BMS 6/17 DES 8/21 *N* randomised 50 BMS 26 DES 24	
RAVEL	Abstracts identified not reporting this outcome: Sousa, 2001 Regar, 2002a *6 months: diabetics* BMS 42% DES 0% Denominators not stated Regar, 2002b Degertekin, 2002a Degertekin, 2002b Abizaid, 2002	**Colombo, 2002** *N* included 238 BMS 118 DES 120 **Beck, 2004** *N* randomised not explicitly stated	**Morice, 2002** *6 months* BMS 26.6% DES 0 (Angiographic follow-up available for 211 patients) *N* randomised 238 BMS 118 DES 120 **Regar, 2002** Not reported *N* randomised 238 BMS 118 DES 120

continued

TABLE 39 *DES review data extraction tables: binary restenosis (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
SCORE	Abstracts identified not reporting this outcome Kataoka, 2001a Kataoka, 2001b Honda, 2002 Kataoka, 2002 **Lansky, 2002** 6 months BMS 38/103 (36.9) DES 10/99 (10.1) *N* randomised 260 BMS 134 DES 126	**Grube, 2002a** *6 months* BMS 36.9% DES 10.1% Angiographic following available for 202 patients. Denominators not stated *Report on first 260* BMS 126 DES 134 **Grube, 2002b** *N* randomised 266 (of 400) BMS 138 DES 128	**Stone, 2002** *6 months: 202 patients* BMS 36.9% DES 6.4% Denominators not stated *N* randomised 266 (of 400) BMS 138 DES 128	**Grube, 2002** Not reported *N* randomised 266 (of 400) BMS 138 DES 128		**Grube, 2004** *6 months* BMS 35/107 DES 7/94
SIRIUS	**Ako, 2002** (Interim IVUS analysis of 63 patients)	**Moses, 2002** *N* randomised (550 per group) 1101	**Leon, 2002a** *In-stent binary stenosis* *8 months* BMS 31.1% DES 2.0% Denominators not stated Interim analysis of first 400 patients (SIRIUS 400)	**Leon, 2002b** BRR reported for subgroups *N* randomised (all) 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered	**Moses, 2002** *In-stent binary stenosis* *8 months* BMS 125/353 DES 11/348 *N* randomised 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered Incorrectly stated on 'study design' slide: BMS 556 DES 545	**Moses, 2003** *In-stent binary stenosis* *8 months* BMS 125/353 (35.4%) DES 11/350 (3.2%) *N* randomised 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered **Holmes, 2004** Reference made to Moses *et al.* *N* randomised 1101 BMS 545 (–20*) DES 556 (–23*) * Deregistered

continued

TABLE 39 *DES review data extraction tables: binary restenosis (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
TAXUS I	**Grube, 2001** BRR not reported *N* randomised 61	**Grube, 2001** *6 months* BMS 10% DES 0% *N* enrolled 61 BMS 30 DES 31 **Grube, 2002** *6 months* BMS 10% DES 0 % *N* randomised 61 BMS 30 DES 31	**Stone, 2002** *6 months* BMS 10.3% DES 0 % *N* randomised 61 BMS 30 DES 31	**Grube, 2003** Not reported *N* randomised 61 BMS 30 DES 31	**Grube, 2003** *6 months* BMS 3/29 (10%) DES 0/30 (0%) *N* randomised 61 BMS 30 DES 31
TAXUS II		**Gruberg, 2002** *(presented by Colombo)* *In-stent binary stenosis* *6 months* BMS combined 26/129 DES SR 3/130 MR 6/128 *N* randomised not explicitly stated	**Colombo, 2003a** *In-stent binary stenosis* *6 months* BMS combined 50/263 (19.0) DES SR 3/128 (2.3) MR 6/128 (4.7) *N* randomised not explicitly stated	**Colombo, 2003b** *In-stent binary stenosis* *6 months* BMS combined 19.0% DES SR 2.3% MR 4.7% *N* randomised 536 BMS combined 270 SR 136 MR 134 DES 266 SR 131 MR 135	**Colombo, 2003** *In-stent binary stenosis* *6 months* BMS SR 17.9% MR 20.2% DES SR 2.3% MR 4.7% Denominators unclear (only 98% and 96% follow-up in SR and MR groups, respectively) *N* randomised 536 BMS combined 270 SR 136 MR 134 DES 266 SR 131 MR 135

BRR, binary restenosis rate.

Case study 3: DES review:[39] data discrepancies

TABLE 40 *DES review: data discrepancies in reporting event rate*

Study name	Abstracts	Presentations			Full paper(s)
ACTION	Not available	**Linnemeier, 2002**	**Serruys, 2002**		**Serruys, 2004**
		BMS	*BMS*		*BMS*
		30 days 1/**121**	30 days 1/**119**		30 days 1/**119**
		DES	*DES*		*DES*
		30 days	30 days		30 days Unclear
		Low dose **3**/120	Low dose **1**/120		*1 year*
		High dose **1/119**	High dose **4/121**		BMS 14/104
		1 year	*1 year*		DES 90/239
		Not reported	Not reported		
ASPECT		**Park, 2001**	**Lee, 2002**		**Park, 2003**
		BMS	*BMS*		*BMS*
		30 days 1/59	30 days 1/**59**		30 days 1/**58**
		6 months 3/**59**	6 months 3/**59**		6 months 3/**58**
		DES	*DES*		*DES*
		30 days	30 days		30 days
		Low dose **3**/58	Low dose **2**/58		Low dose **2**/58
		High dose 4/**60**	High dose 4/**60**		High dose 4/**59**
DELIVER	**Knopf, 2002**	**O'Neill, 2003**	**Knopf, 2003a**	**Knopf, 2003b**	**Lansky, 2004**
	MACE at 30 days	*MACE*	*BMS*	MACE not reported	MACE not reported
	Group A 6/524	*BMS*	30 days 2/512		
	Group B 2/519	*30* days 2/512	9 months **44**/512		
		9 months **68**/512	*DES*		
		DES	30 days 5/517		
		30 days 5/517	9 months **34**/517		
		9 months **53**/517			

continued

TABLE 40 *DES review: data discrepancies in reporting event rate (cont'd)*

Study name	Abstracts	Presentations				Full paper(s)
ELUTES		**Gershlick, 2002**		**Chevalier, 2002**		**Gershlick, 2004**
		BMS		*BMS*		*BMS*
		6 months	**4**/38	6 months	**4**/38	6 months **5**/38
		DES		*DES*		*DES*
		6 months		6 months		6 months
		0.2 μg mm^{-2}	**2**/37	0.2 μg mm^{-2}	**2**/37	0.2 μg mm^{-2} **1**/37
		0.7 μg mm^{-2}	**2**/39	0.7 μg mm^{-2}	**2**/39	0.7 μg mm^{-2} **1**/39
		1.4 μg mm^{-2}	**1**/39	1.4 μg mm^{-2}	**1**/39	1.4 μg mm^{-2} **3**/39
		2.7 μg mm^{-2}	4/37	2.7 μg mm^{-2}	4/37	2.7 μg mm^{-2} 4/37
FUTURE I		**Grube, 2002**		**Grube, 2003a**	**Grube, 2003b**	**Grube, 2004**
		BMS		*BMS*	*BMS*	*BMS*
		30 days	0/**15**	6 months 1/**13**	30 days 0/**13**	30 days 0/**15**
		DES		*DES*	6 months 1/**12**	6 months 1/**14**
		30 days	0/27	6 months 2/26	*DES*	*DES*
					30 days 0/27	30 days 0/27
					6 months 2/26	6 months 2/26
RAVEL	**Colombo, 2002**	**Beck, 2004**				**Morice, 2002**
	BMS	*BMS*				*BMS*
	1 year **34**/118	1 year	**22**/118			1 year **34**/118
	DES	*DES*				*DES*
	1 year 7/120	1 year	7/120			1 year 7/120
SCORE				**Grube, 2002**		**Grube, 2004**
				1 year		*1 year*
				BMS **42/138**		BMS **35/140**
				DES **63/128**		DES **37/126**
				Cardiac deaths included MACE (reported non-hierarchically)		Cardiac deaths included MACE (reported cumulatively)

continued

TABLE 40 *DES review: data discrepancies in reporting event rate (cont'd)*

Study name	Abstracts		Presentations				Full paper(s)	
TAXUS I	**Grube, 2001**				**Stone, 2002**		**Grube, 2003**	
	30 days				*1 year*		1 year	
	MACE	0/61			BMS	**4/30**	BMS	**3/30**
	N randomised	61			DES	**1/31**	DES	**1/30**
TAXUS II			**Gruberg (Colombo), 2002**		**Colombo, 2003a**	**Colombo, 2003b**	**Colombo, 2003**	
			30 days		*30 days*		*30 days*	
			BMS		BMS		BMS	
			SR	**5**/136	SR	**6**/136	SR	**6**/136
			MR	5/134	MR	**6/136**	MR	**6/134**
			DES		DES		DES	
			SR	**2**/131	SR	**3**/131	SR	**3**/131
			MR	3/135	MR	3/135	MR	3/135

Data discrepancies identified between conference abstracts/presentations and their subsequent full publications are highlighted in bold.

TABLE 41 *DES review: data discrepancies in reporting mortality*

Study name	Abstracts	Presentations						Full paper(s)	
ACTION	Not available	**Linnemeier, 2002**		**Serruys, 2002**				**Serruys, 2002**	
		BMS		*BMS*				*BMS*	
		30 days	0/**121**	30 days	0/**119**			30 days	0/**119**
				6 months	**0**/88			6 months	**1**/101
		DES		*DES*				*DES*	
		30 days		6 months				6 months	
		Low dose	0/120	Low dose	1/120			Low dose	0/120
		High dose	0/**119**	High dose	0/**121**			High dose	0/**121**
ASPECT		**Park, 2001**		**Lee, 2002**				**Park, 2003**	
		BMS		*BMS*				*BMS*	
		30 days	0/**59**	30 days	0/**59**			30 days	0/**58**
		6 months	0/**59**	6 months	0/**59**			6 months	0/**58**
		DES		*DES*				*DES*	
		30 days		30 days				30 days	
		Low dose	1/58	Low dose	1/58			Low dose	1/58
		High dose	0/**60**	High dose	0/**60**			High dose	0/**59**
		6 months		6 months				6 months	
		Low dose	1/58	Low dose	1/58			Low dose	1/58
		High dose	0/**60**	High dose	0/**60**			High dose	0/**59**
DELIVER		**O'Neill, 2003**		**Knopf, 2003a**		**Knopf, 2003b**		**Lansky, 2004**	
		All deaths reported		*Cardiac deaths reported*		*All deaths reported*		Not reported	
		BMS		*BMS*		*BMS*			
		9 months	**5**/512	9 months	**4**/512	9 months	**6**/512		
		DES		*DES*		*DES*			
		9 months	**5**/517	9 months	**1**/517	9 months	**5**/517		

continued

TABLE 41 *DES review: data discrepancies in reporting mortality (cont'd)*

Study name	Abstracts	Presentations			Full paper(s)
FUTURE I	**Grube, 2002** 24 patients recruited Death not reported No in-hospital MACE (i.e. deaths)	**Grube, 2002** *30 days** BMS 0/**12** DES 0/**24** *Early findings: 30-day event-free survival 0/36	**Grube, 2003a** *BMS* 6 months 0/**13** *DES* 6 months 1/**26**	**Grube, 2003b** *BMS* 30 days 0/**13** 6 months 0/**12** *DES* 30 days 0/27 6 months 1/**26**	**Grube, 2004** *BMS* 30 days (MACE) 0/**15** 6 months 0/**15** *DES* 30 days (MACE) 0/27 6 months 1/**27**
SCORE	**Grube, 2002b** *Cardiac deaths* *6 months* BMS 0/**138** DES **5**/**128**	**Stone, 2002** *6 months* BMS 0/**138** DES **5**/**128**	**Grube, 2002** *Cardiac deaths* *1 year* BMS 0/**138** DES 5/**128**		**Grube, 2004** *Cardiac deaths* *6 months* BMS 0/**140** DES **3**/**126** *1 year* BMS 0/**140** DES 5/**126**
TAXUS II		**Colombo, 2002** *6 months* BMS Combined 1/**270** DES SR 0/**131** MR 0/**135**	**Colombo, 2003a** *6 months* BMS Combined 1/**270** DES SR 0/**131** MR 0/**135**	**Colombo, 2003b** *6 months* BMS Combined 1/**270** DES SR 0/**131** MR 0/**135** *1 year* BMS Combined 2/**270** DES SR 0/**131** MR 0/**135**	**Colombo, 2003** *6 months* BMS SR 1/**133** MR 0/**130** DES SR 0/**130** MR 0/**129** *1 year* BMS SR 2/**132** MR 0/**131** DES SR 0/**129** MR 0/**131**

Data discrepancies identified between conference abstracts/presentations and their subsequent full publications are highlighted in bold.

TABLE 42 *DES review: data discrepancies in reporting any MI*

Study name	Abstracts	Presentations						Full paper(s)	
ACTION	Not available	**Linnemeier, 2002**		**Serruys, 2002**				**Serruys, 2004**	
		BMS		*BMS*				*BMS*	
		30 days	**0/121**	30 days	**1/119**			30 days	Unclear
		DES		6 months	1/88			6 months	Unclear
		30 days		*DES*				*DES*	
		Low dose	**3**/120	30 days				30 days	Unclear
		High dose	**1/119**	Low dose	**0**/120			6 months	Unclear
				High dose	**3/121**				
ASPECT		**Park, 2001**		**Lee, 2002**				**Park, 2003**	
		BMS		*BMS*				*BMS*	
		30 days	1/**59**	30 days	1/**59**			30 days	1/**58**
		6 months	1/**59**	6 months	1/**59**			6 months	1/**58**
		DES		*DES*				*DES*	
		30 days		30 days				30 days	
		Low dose	1/58	Low dose	1/58			Low dose	1/58
		High dose	2/**60**	High dose	2/**60**			High dose	2/**59**
		6 months		6 months				6 months	
		Low dose	1/58	Low dose	1/58			Low dose	1/58
		High dose	2/**60**	High dose	2/**60**			High dose	2/**59**
DELIVER		**O'Neill, 2003**		**Knopf, 2003a**		**Knopf, 2003b**		**Lansky, 2004**	
		BMS		*BMS*		*BMS*		MI not reported	
		9 months	5/512	9 months	5/512	9 months	5/512		
		DES		*DES*		*DES*			
		9 months	**6**/517	9 months	**6**/517	9 months	**5**/517		

continued

TABLE 42 *DES review: data discrepancies in reporting any MI (cont'd)*

Study name	Abstracts	Presentations						Full paper(s)	
ELUTES				**Gershlick, 2002**		**Chevalier, 2002**		**Gershlick, 2004**	
				BMS		*BMS*		*BMS*	
				6 months	**1**/38	6 months	**0**/38	6 months	**0**/38
				DES		*DES*		*DES*	
				6 months		6 months		6 months	
				0.2 μg mm^{-2}	0/37	0.2 μg mm^{-2}	0/37	0.2 μg mm^{-2}	0/37
				0.7 μg mm^{-2}	1/39	0.7 μg mm^{-2}	1/39	0.7 μg mm^{-2}	1/39
				1.4 μg mm^{-2}	0/39	1.4 μg mm^{-2}	0/39	1.4 μg mm^{-2}	0/39
				2.7 μg mm^{-2}	1/37	2.7 μg mm^{-2}	1/37	2.7 μg mm^{-2}	1/37
FUTURE I	**Grube, 2002**	**Grube, 2002**		**Grube, 2003a**		**Grube, 2003b**		**Grube, 2004**	
	24 patients recruited	*BMS*		*BMS*		*BMS*		*BMS*	
	MI not reported	30 days	0/**12**	6 months	0/**13**	30 days	0/**13**	30 days (MACE)	0/**15**
						6 months	0/12	6 months	0/14
		DES		*DES*					
		30 days	0/**24**	6 months	0/26	*DES*		*DES*	
						30 days	0/**27**	30 days (MACE)	0/**27**
						6 months	0/26	6 months	0/26
SCORE				**Grube, 2002**				**Grube, 2004**	
								6 months	
								BMS	3/140
								DES	20/126
				1 year				*1 year*	
				BMS	4/**138**			BMS	4/**140**
				DES	**27**/**128**			DES	**24**/**126**

continued

TABLE 42 *DES review: data discrepancies in reporting any MI (cont'd)*

Study name	Abstracts	Presentations						Full paper(s)	
TAXUS II		**Colombo, 2002**		**Colombo, 2003a**		**Colombo, 2003b**		**Colombo, 2003**	
		6 months		*6 months*		*6 months*		*6 months*	
		BMS		BMS		BMS		BMS	
		Combined	14/**270**	Combined	14/**270**	Combined	14/**270**	SR	7/**133**
								MR	7/**130**
		DES		DES		DES			
		SR	2/**131**	SR	2/**131**	SR	2/**131**	DES	
		MR	3/**135**	MR	3/**135**	MR	3/**135**	SR	2/**130**
								MR	3/**129**
						1 year			
						BMS		*1 year*	
						Combined	14/**270**	BMS	
								SR	7/**132**
						DES		MR	7/**131**
						SR	3/**131**		
						MR	5/**135**	DES	
								SR	3/**129**
								MR	5/**131**

Data discrepancies identified between conference abstracts/presentations and their subsequent full publications are highlighted in bold.

TABLE 42 *DES review: data discrepancies in reporting binary restenosis*

Study name	Abstracts	Presentations				Full paper(s)	
ACTION			**Serruys, 2002**			**Serruys, 2004**	
			6 months			*6 months: in-stent restenosis*	
			BMS	7/**64**		BMS	7/**65**
			DES			DES	
			Low dose	28/113		Low dose	28/113
			High dose	20/115		High dose	20/115
ELUTES			**Gershlick, 2002**		**Chevalier, 2002**	**Gershlick, 2004**	
			In-stent restenosis		*In-stent restenosis*	*In-stent restenosis*	
			6 months		*6 months*	*6 months*	
			BMS	7/34	BMS 7/34	BMS	7/34
			DES		DES	DES	
			0.2 μg mm^{-2}	7/**35**	0.2 μg mm^{-2} 7/**35**	0.2 μg mm^{-2}	7/**34**
			0.2 μg mm^{-2}	**4/34**	0.7 μg mm^{-2} **4/34**	0.7 μg mm^{-2}	**5/35**
			0.2 μg mm^{-2}	5/37	1.4 μg mm^{-2} 5/37	1.4 μg mm^{-2}	5/37
			0.2 μg mm^{-2}	1/**32**	2.7 μg mm^{-2} 1/**32**	2.7 μg mm^{-2}	1/**31**
SIRIUS		**Leon, 2002a**			**Moses, 2002**	**Moses, 2003**	
		In-stent binary stenosis			*In-stent binary stenosis*	*In-stent binary stenosis*	
		8 months			*8 months*	*8 months*	
		BMS	**31.1%**		BMS 125/353	BMS	125/353 **(35.4%)**
		DES	**2.0%**		DES 11/**348**	DES	11/**350 (3.2%)**
		Denominators not stated					
		Interim analysis of first 400 patients (SIRIUS 400)					

Data discrepancies identified between conference abstracts/presentations and their subsequent full publications are highlighted in bold.

Appendix 6

DES case study[39] meta-analysis forest plots

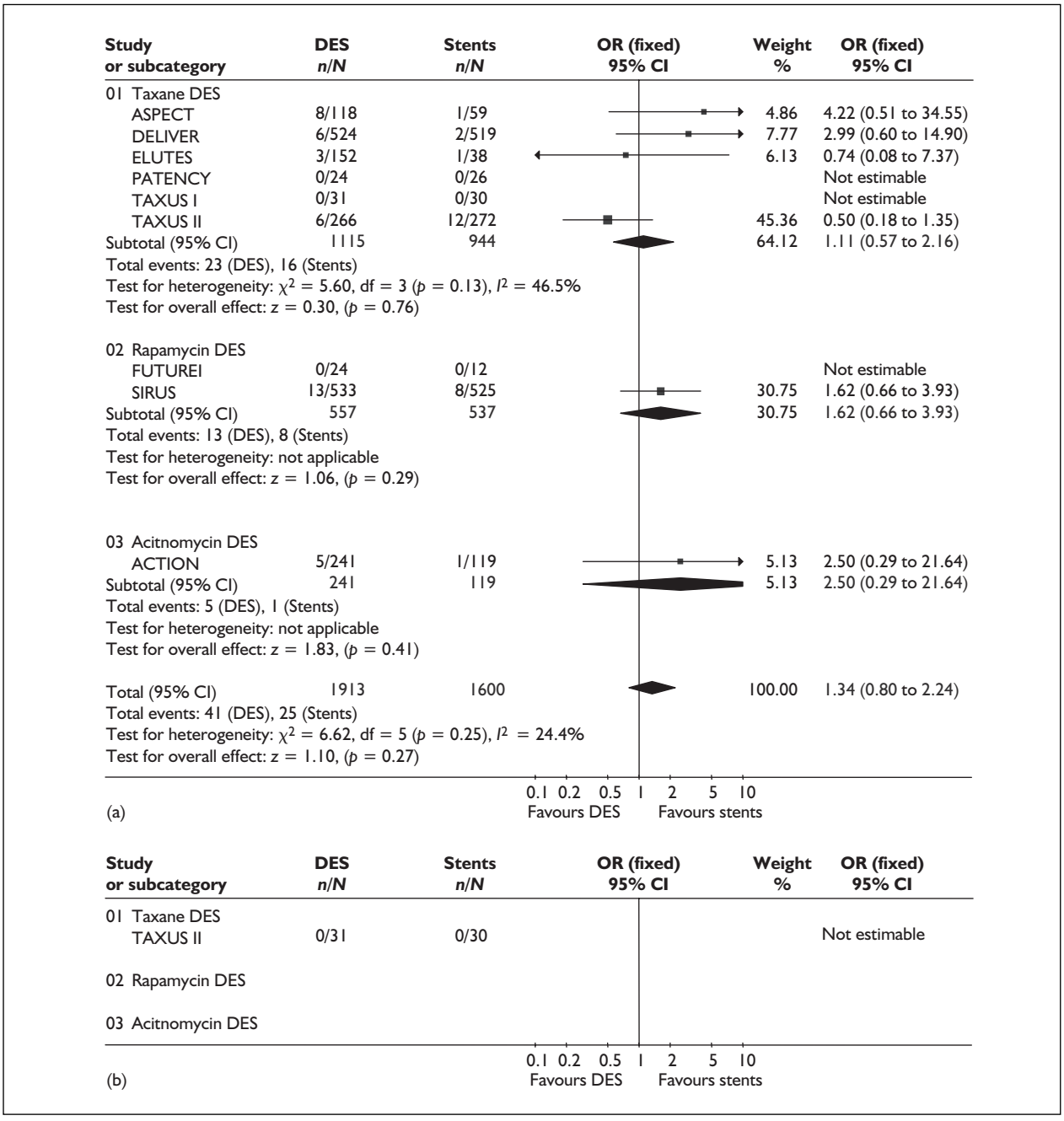


FIGURE 2 *Meta-analysis of event rates up to 36 days: (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e.* excluding *abstracts/presentations); (c) including* only *full papers published* to date

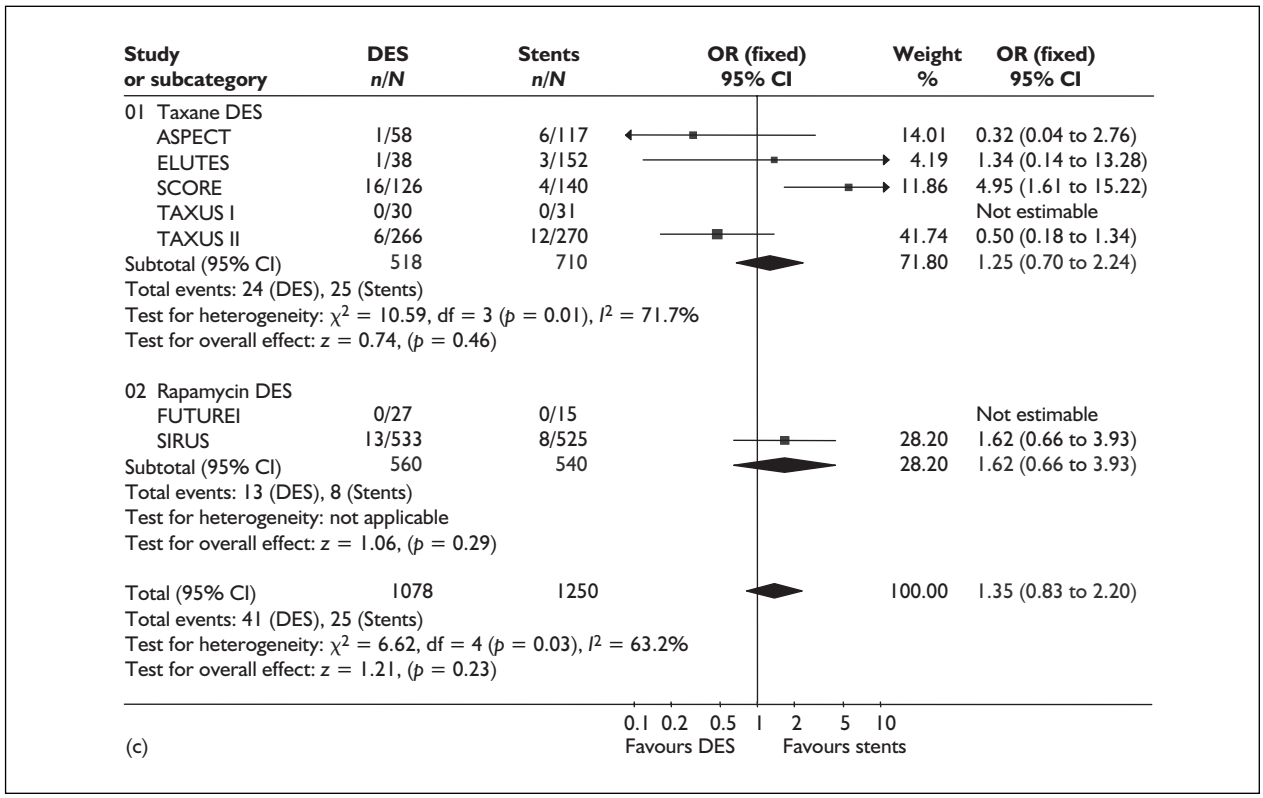


FIGURE 2 *(cont'd)*

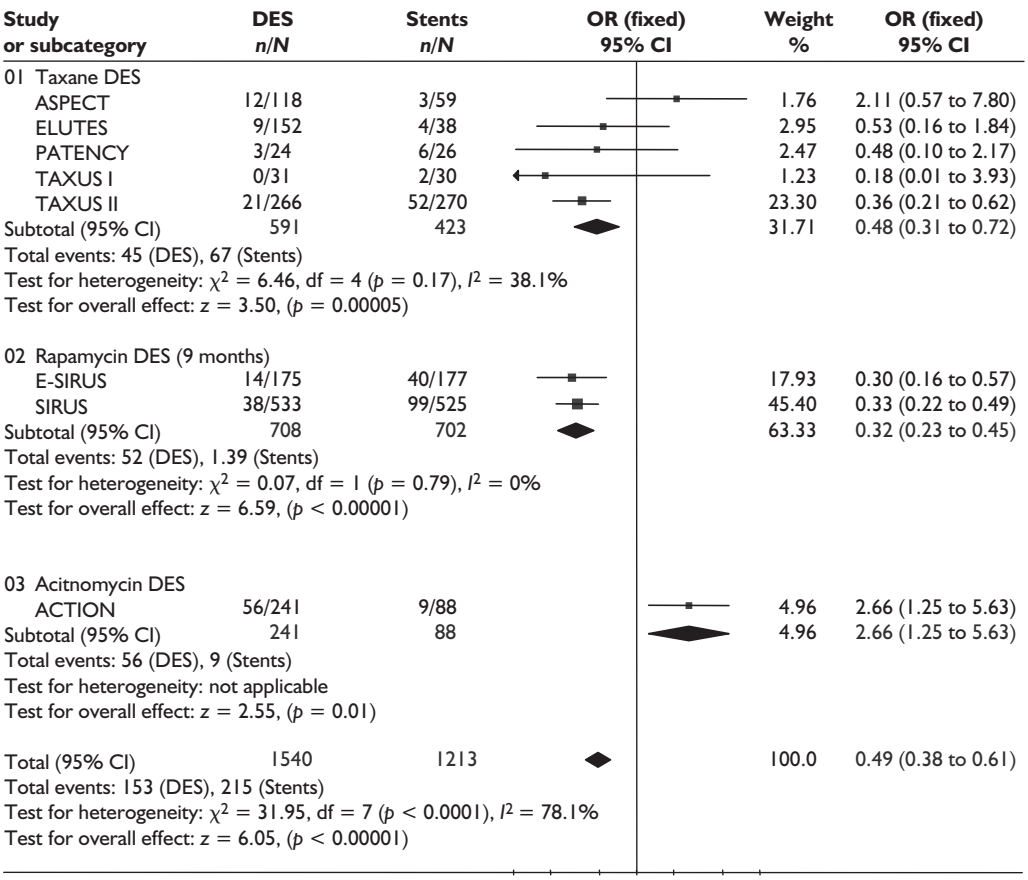


FIGURE 3 *Meta-analysis of event rates up to 6 months: (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e.* excluding *abstracts/presentations); (c) including* only *full papers published* to date

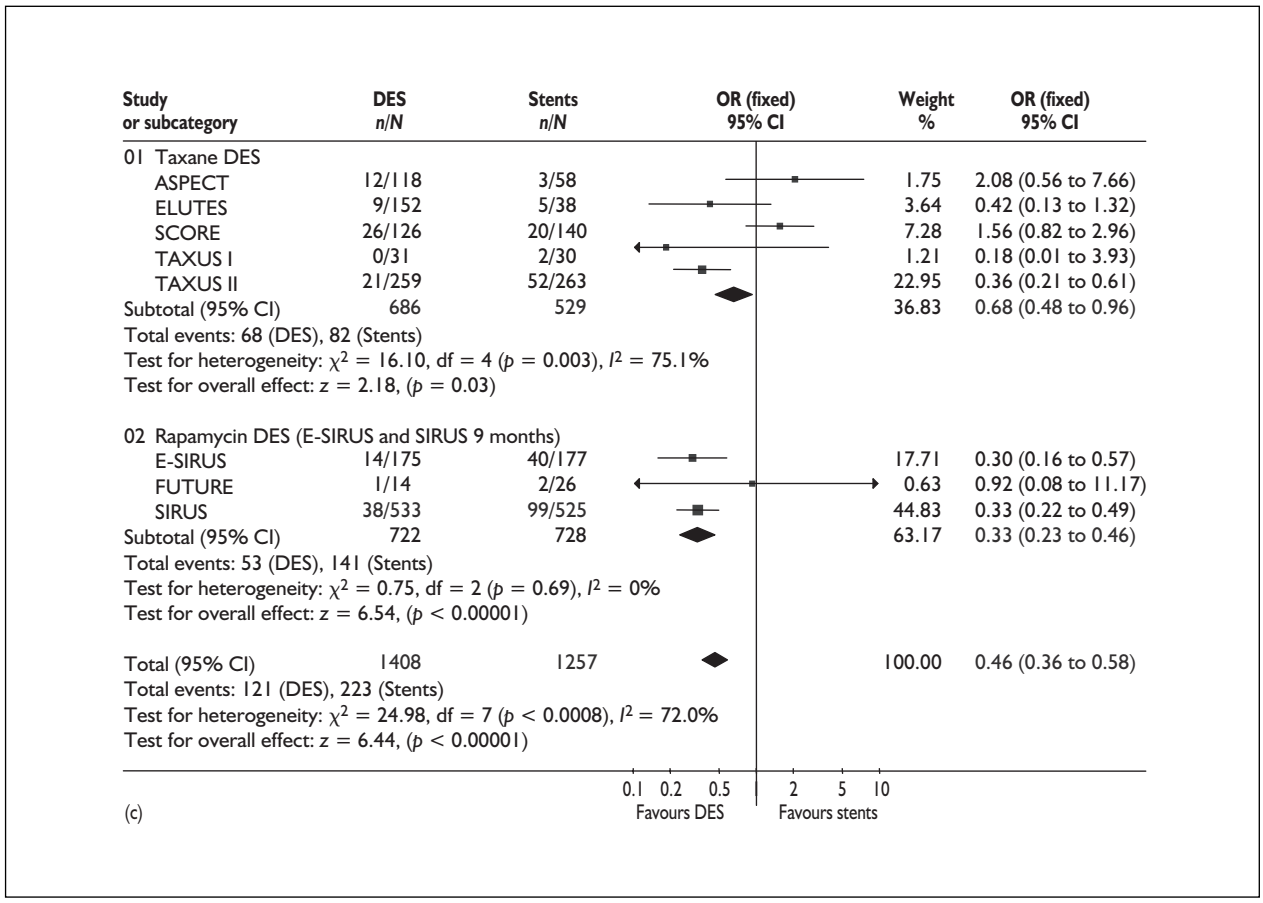


FIGURE 3 *(cont'd)*

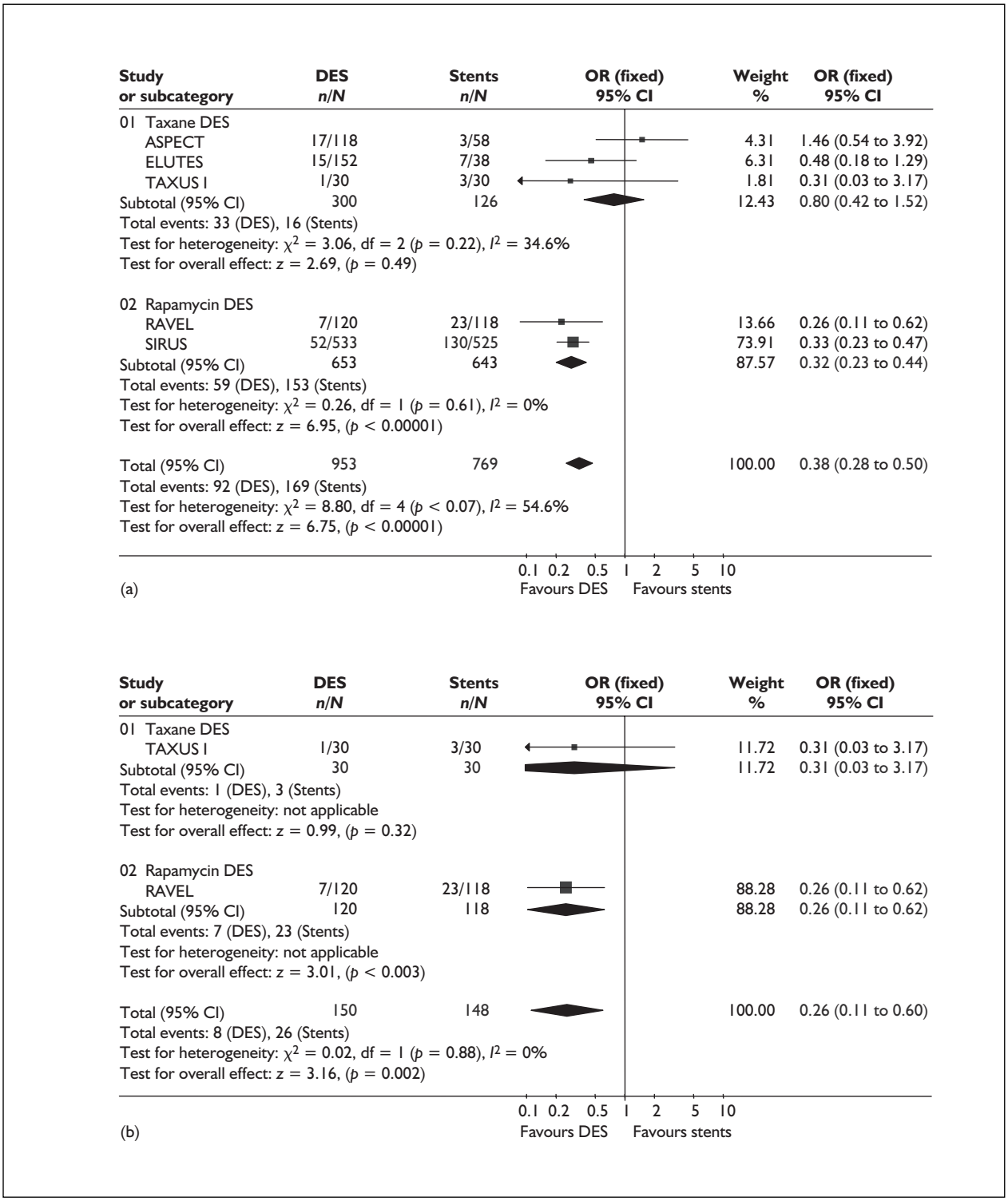


FIGURE 4 *Meta-analysis of event rates up to 12 months: (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e.* excluding *abstracts/presentations); (c) including* only *full papers published* to date

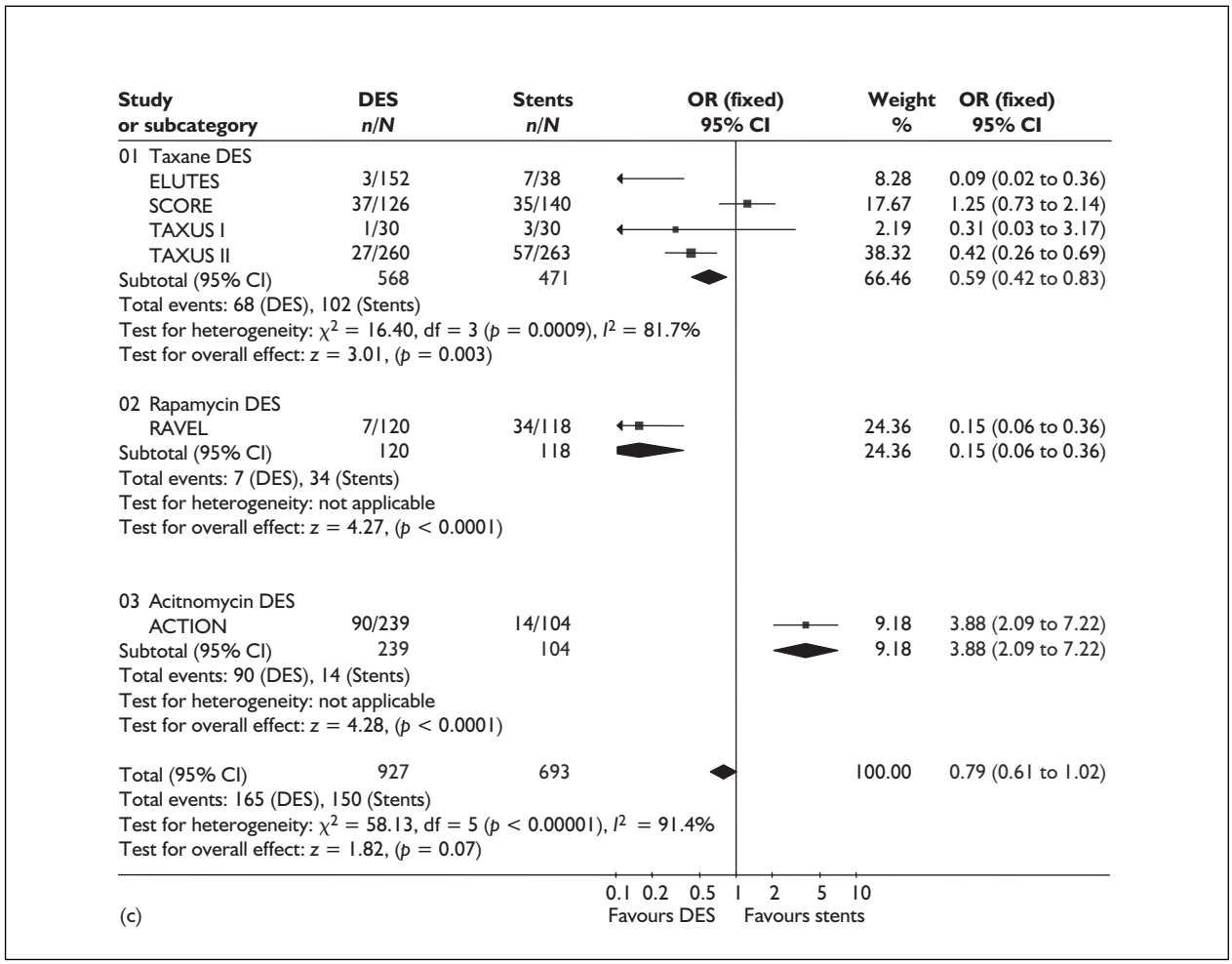


FIGURE 4 *(cont'd)*

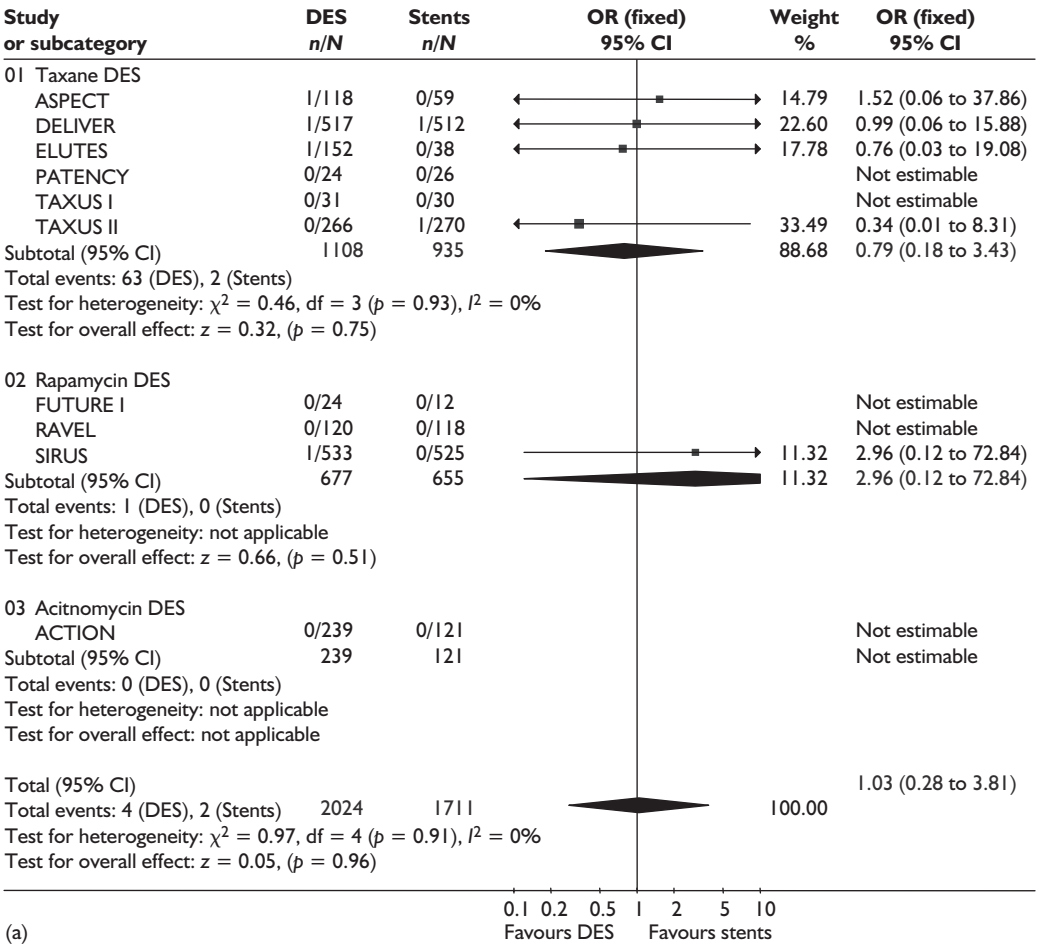


FIGURE 5 *Meta-analysis of mortality up to 36 days; (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e.* excluding *abstracts/presentations); (c) including* only *full papers published* to date

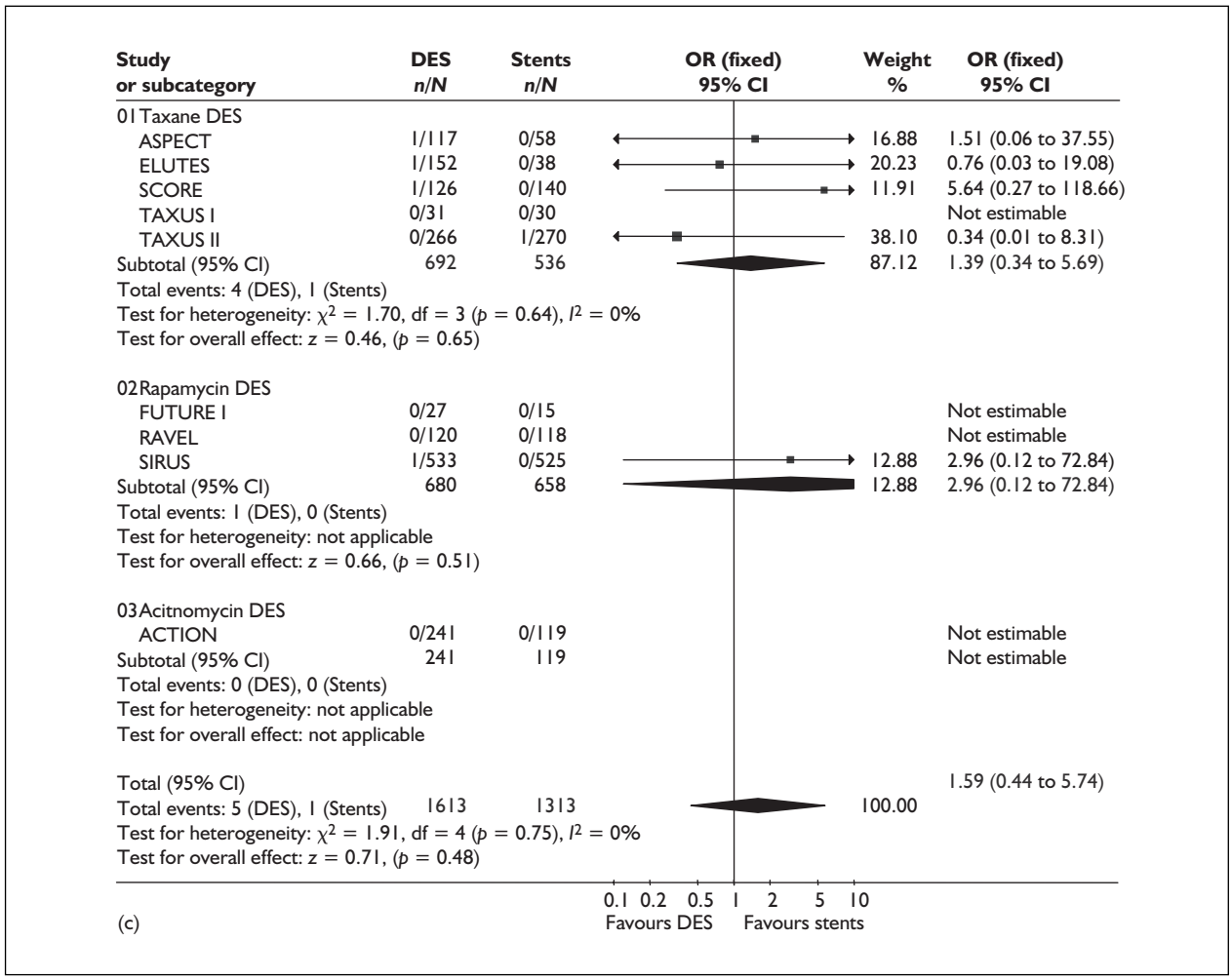


FIGURE 5 *(cont'd)*

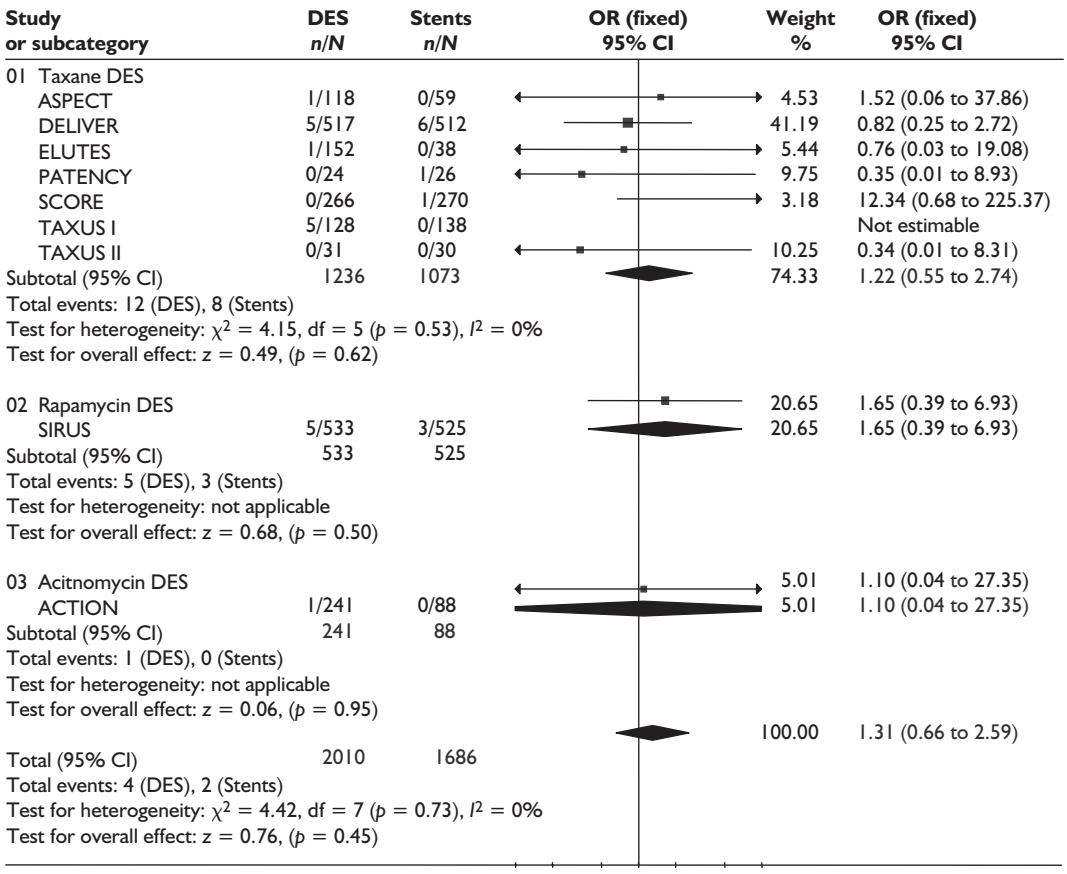


FIGURE 6 *Meta-analysis of mortality up to 6 months: (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e. excluding abstracts/presentations); (c) including* only *full papers published* to date

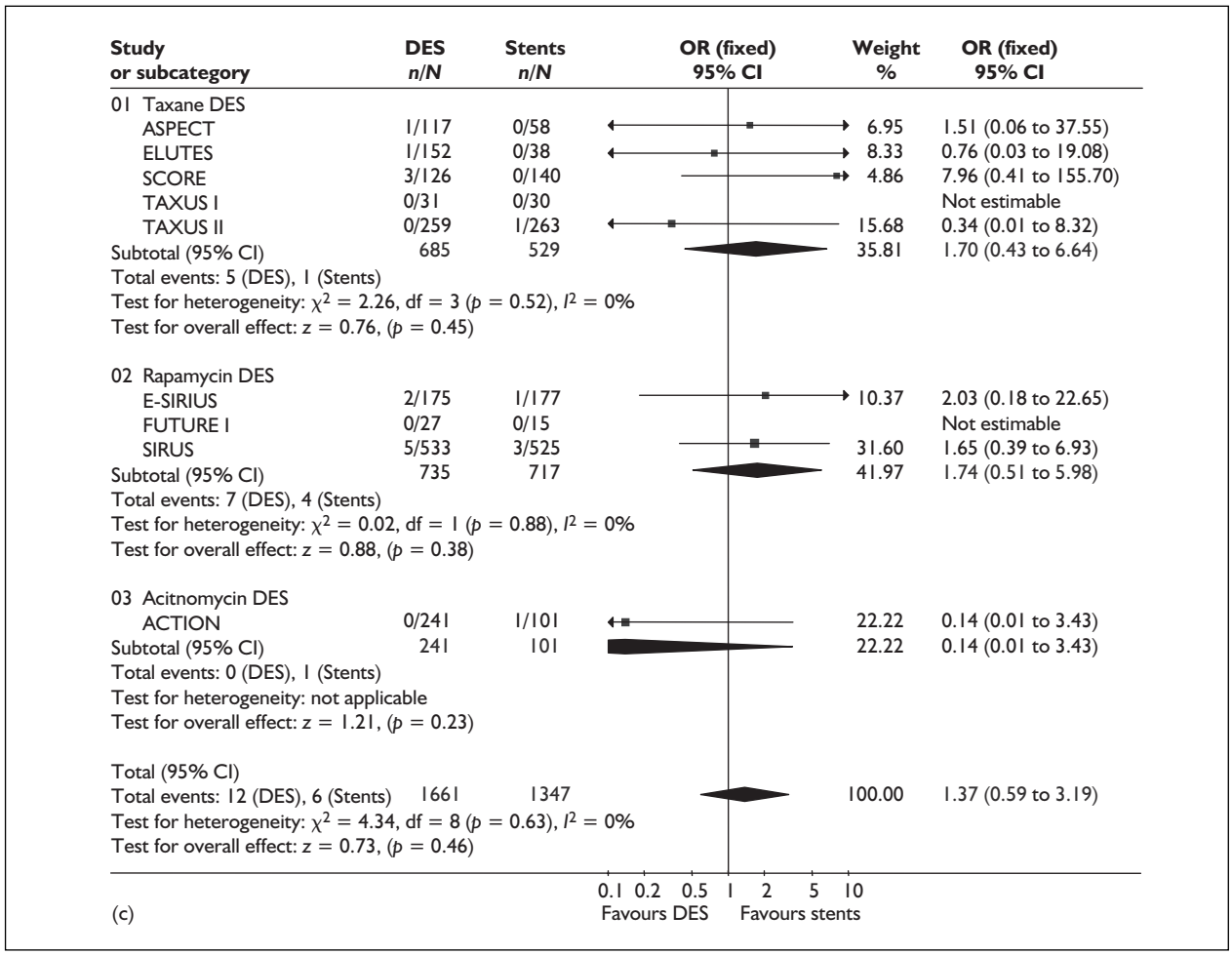


FIGURE 6 *(cont'd)*

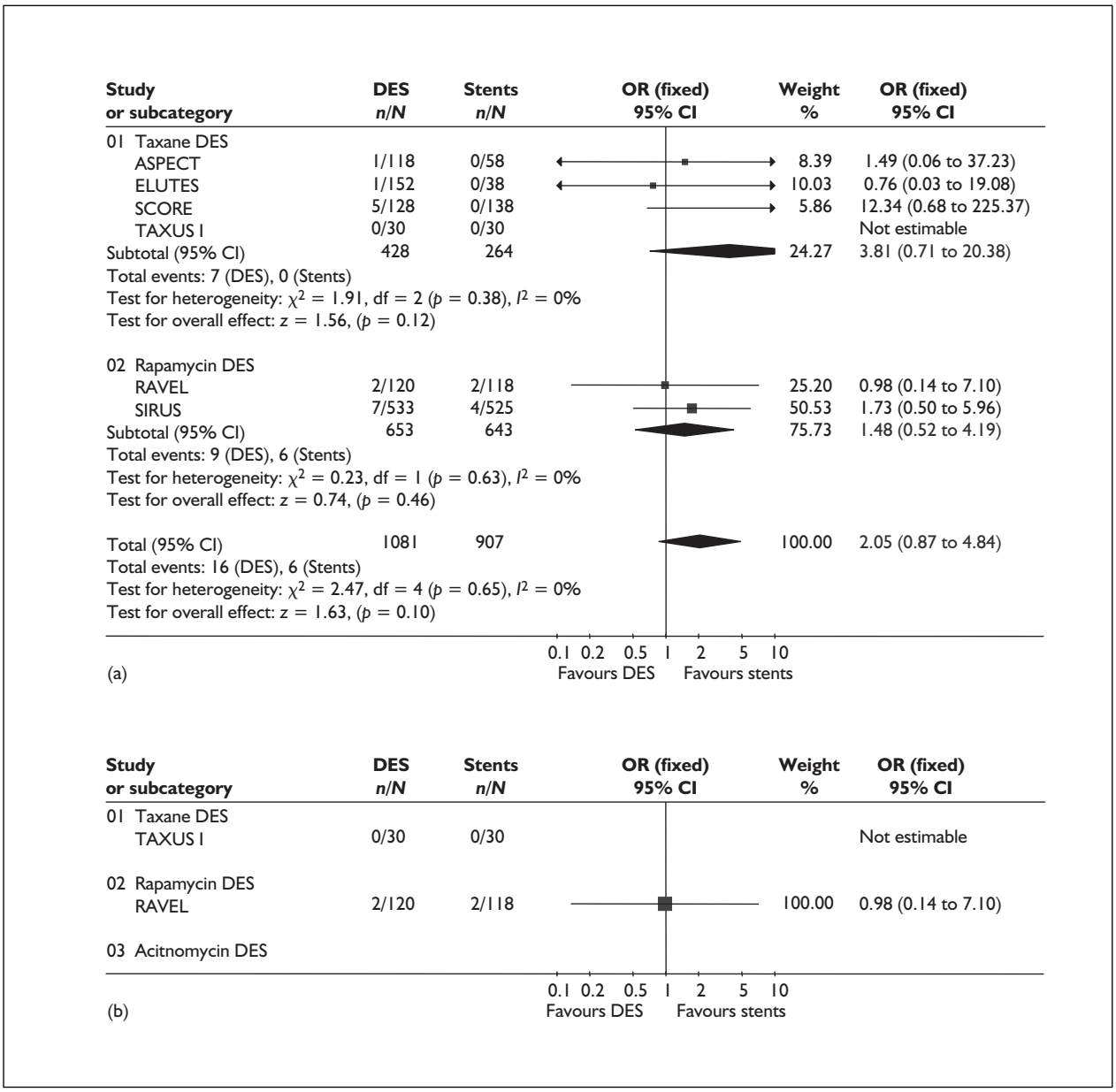


FIGURE 7 *Meta-analysis of mortality up to 12 months: (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e. excluding abstracts/presentations); (c) including* only *full papers published* to date

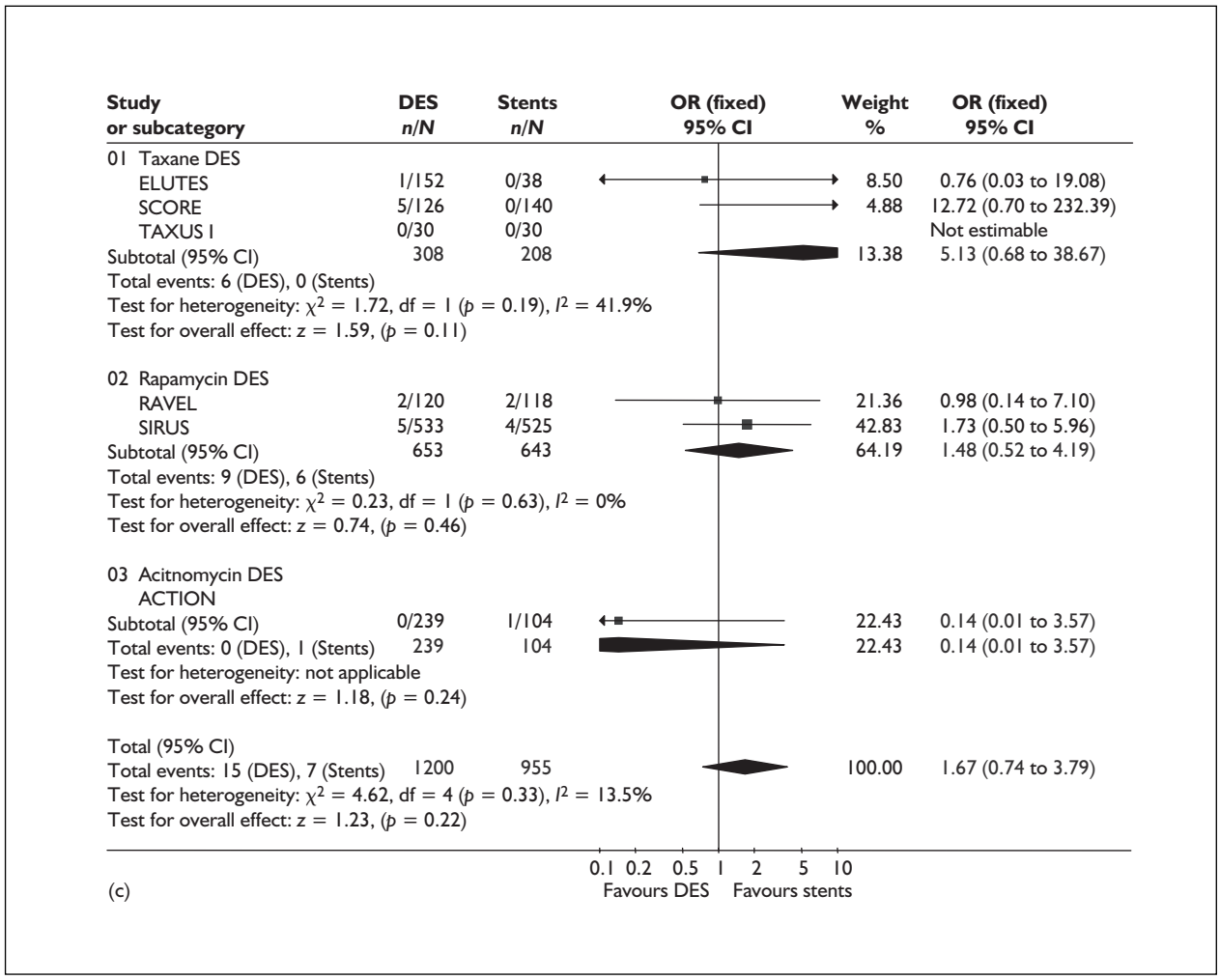


FIGURE 7 *(cont'd)*

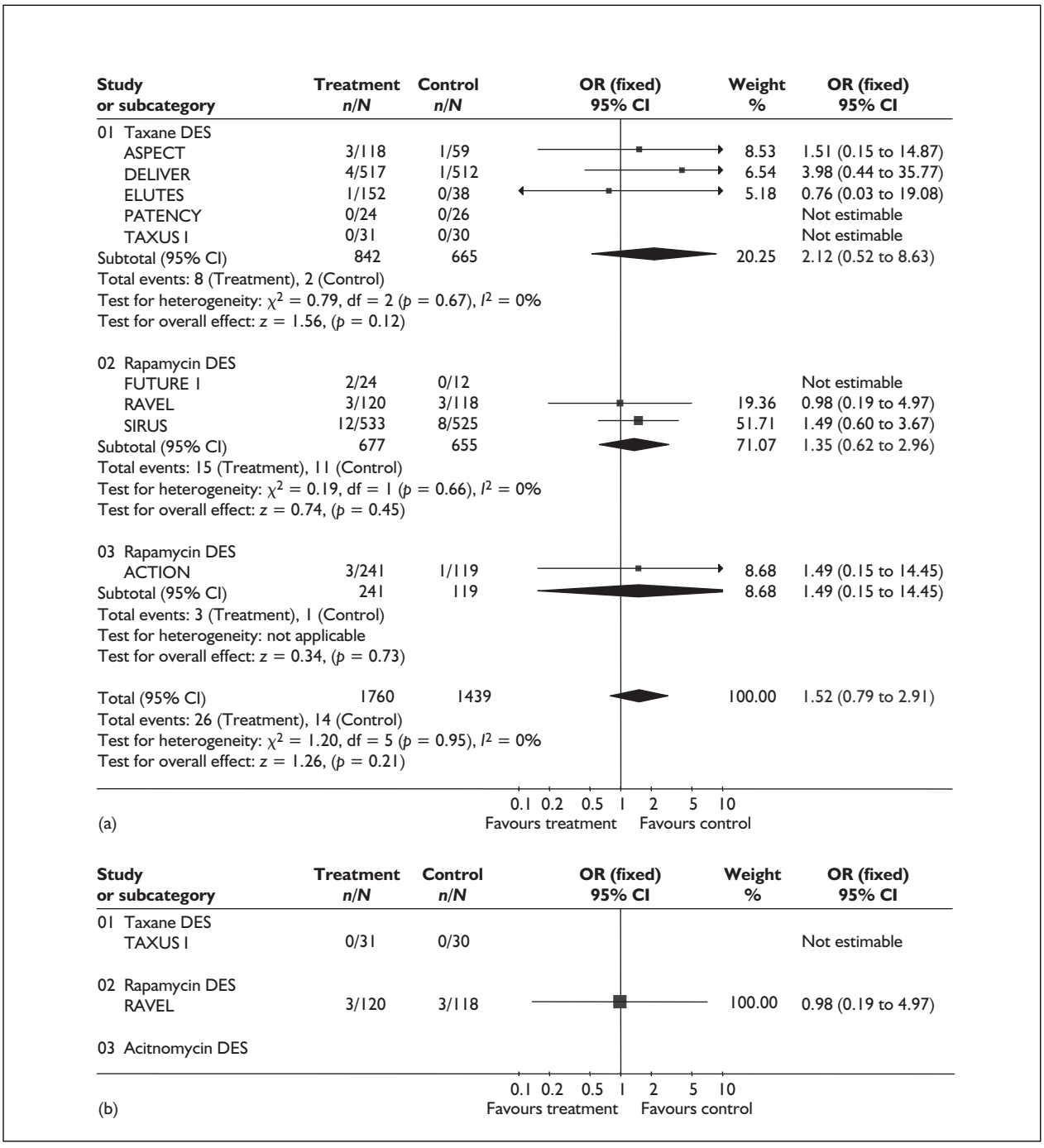


FIGURE 8 *Meta-analysis of any MI up to 36 days: (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e. excluding abstracts/presentations); (c) including* only *full papers published* to date

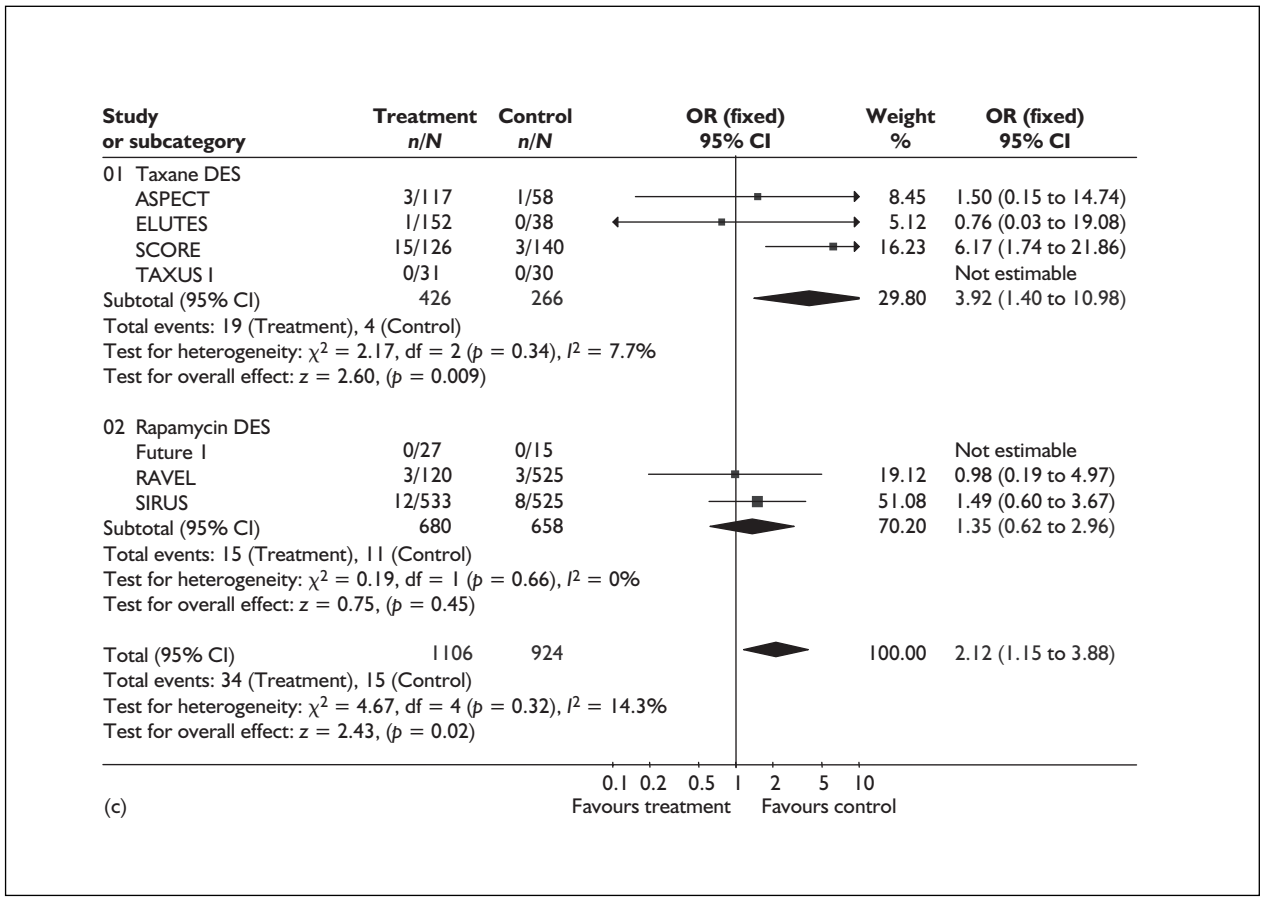
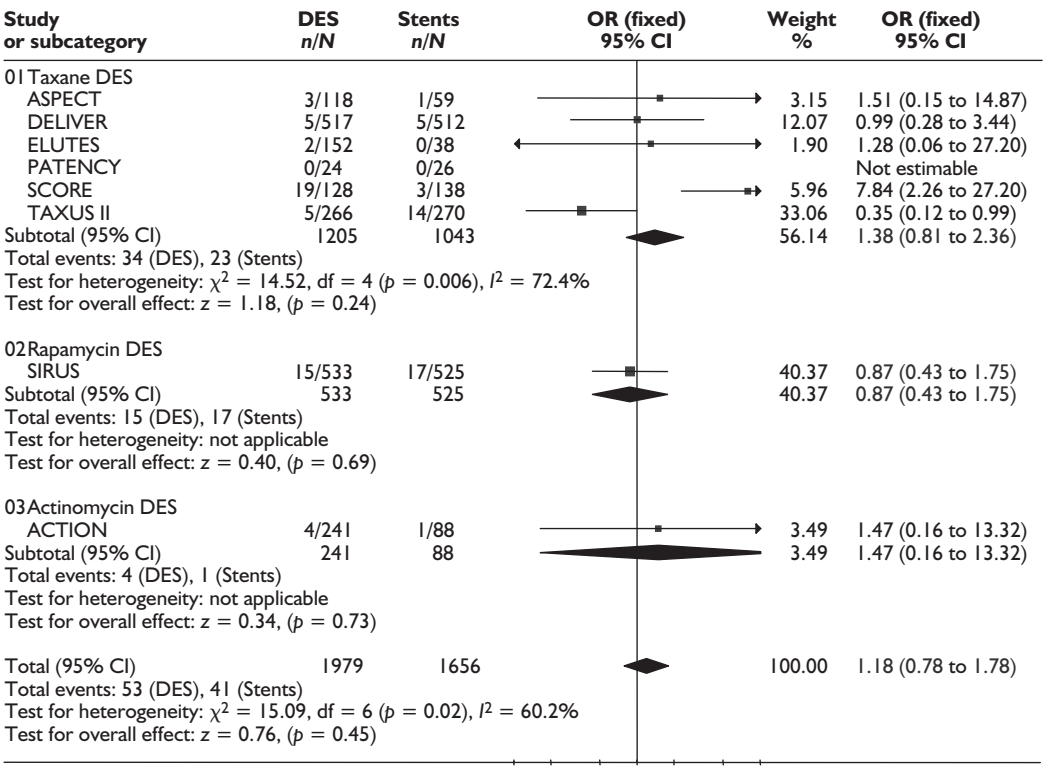


FIGURE 8 *(cont'd)*



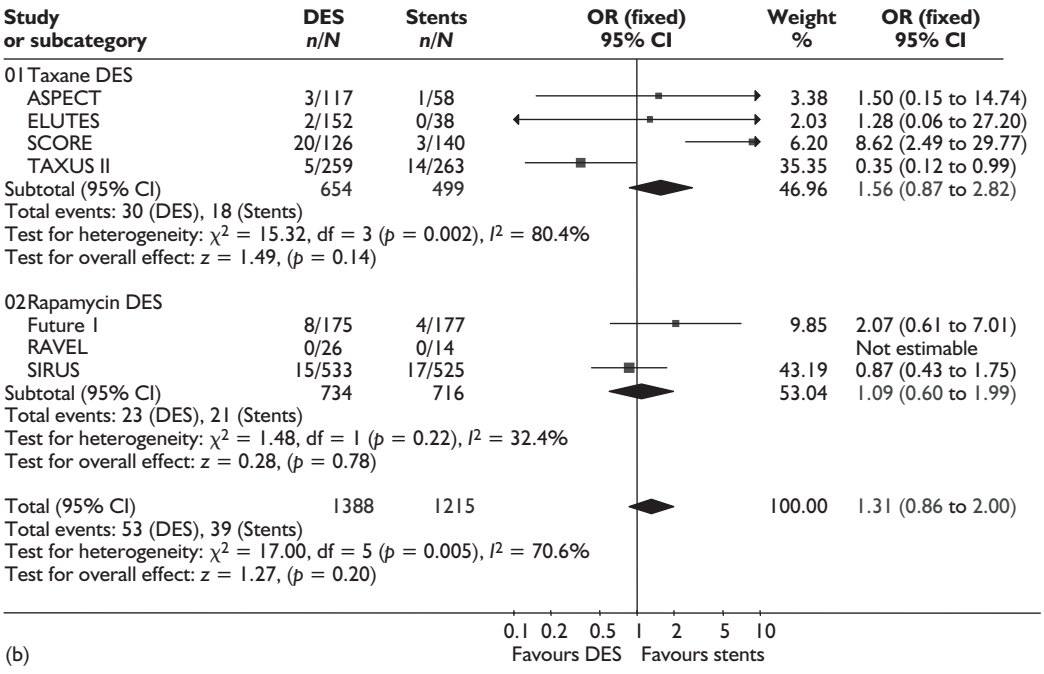


FIGURE 9 *Meta-analysis of any MI up to 6 months: (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers published* to date

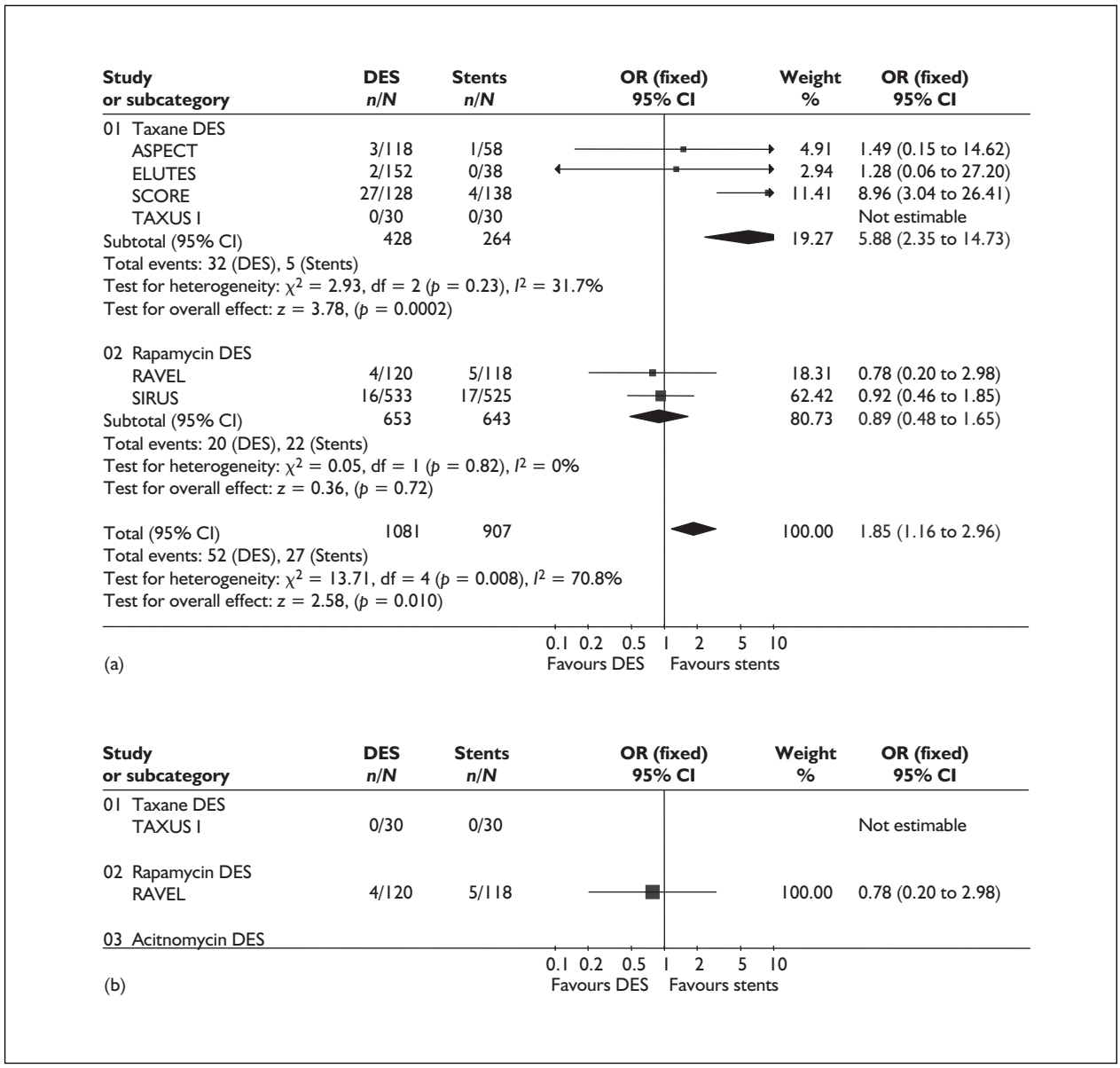


FIGURE 10 *Meta-analysis of any MI up to 12 months: (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e. excluding abstracts/presentations); (c) including* only *full papers published* to date

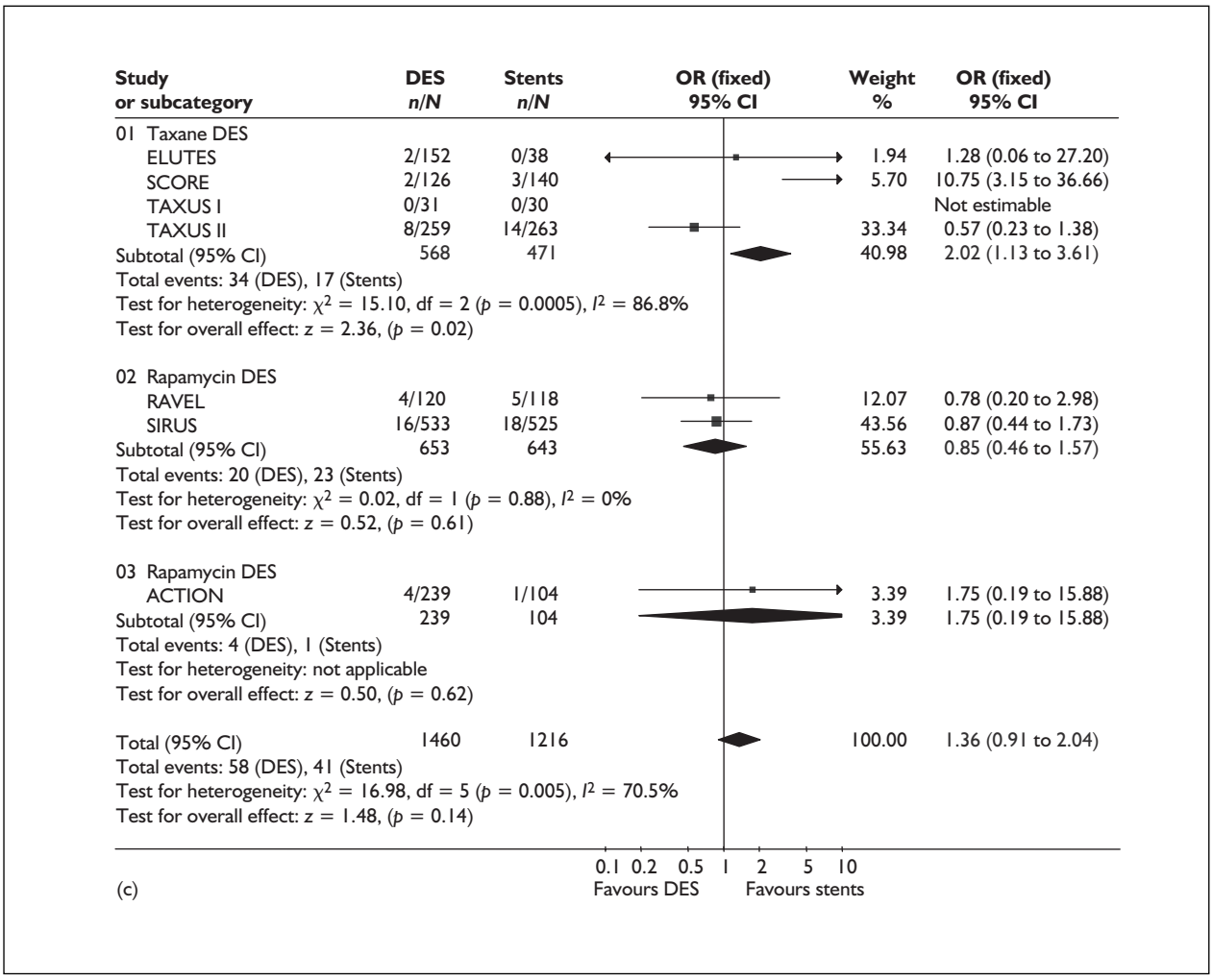


FIGURE 10 *(cont'd)*

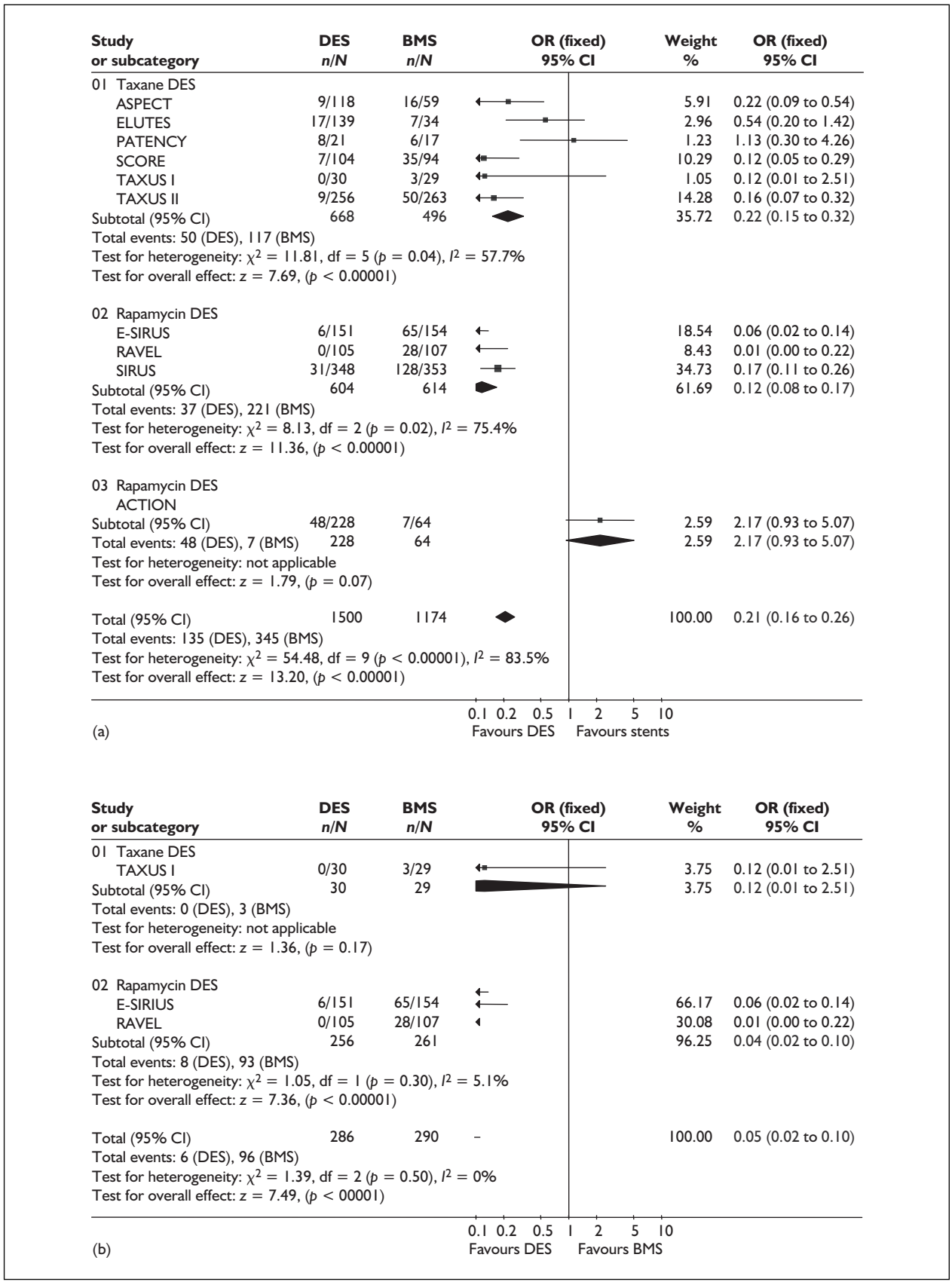


FIGURE 11 *Meta-analysis of binary restenosis (6-9 months): (a) including* both *abstracts/presentations* and *full papers (as presented in the DES review); (b) including* only *full papers* available *at the time of the DES review (i.e. excluding abstracts/presentations); (c) including* only *full papers published* to date

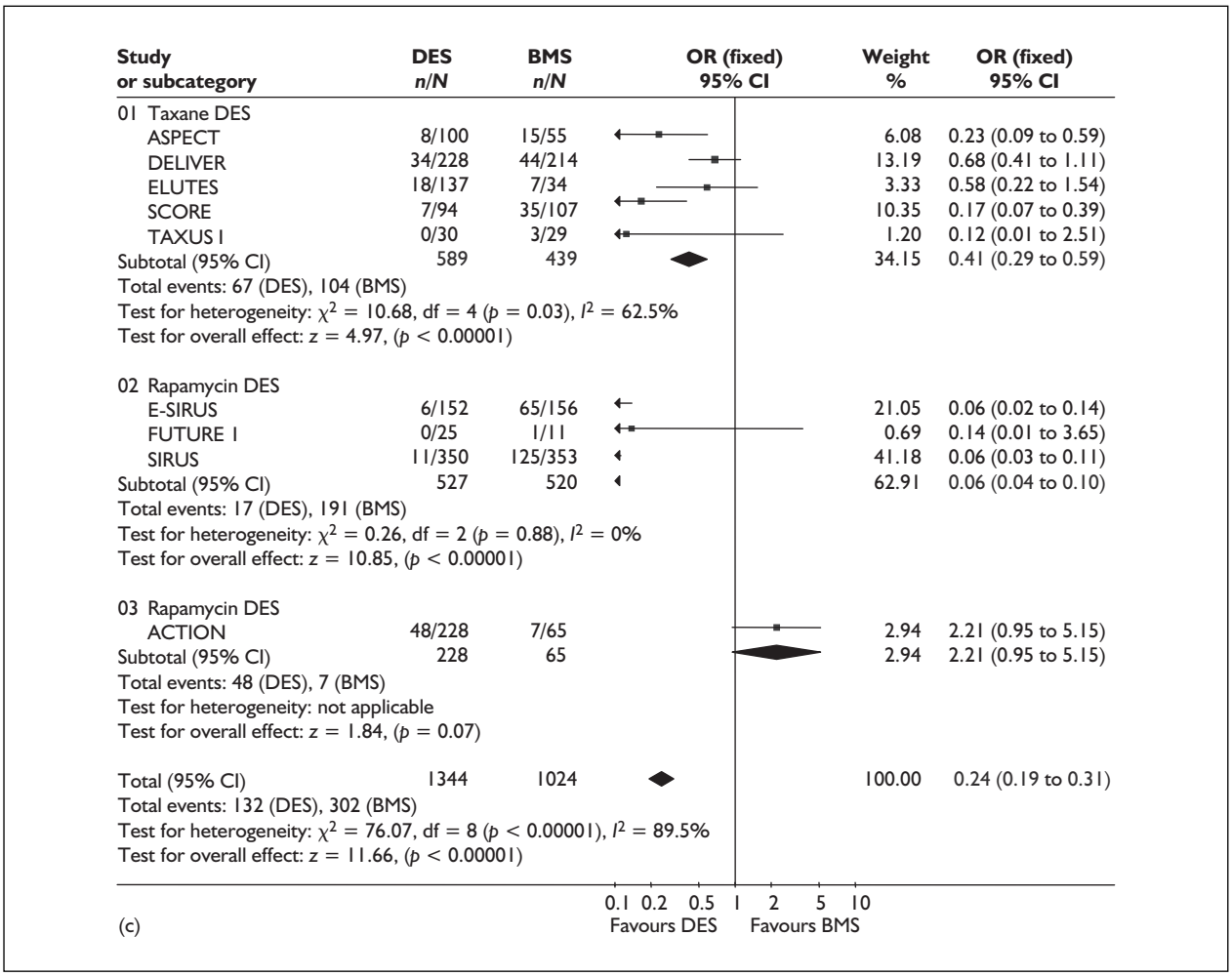


FIGURE 11 *(cont'd)*

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Feedback

The HTA Programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (http://www.ncchta.org) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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