



Rapid Appraisal Protocol Internet Database

RAPid

User Guide



THE JOANNA BRIGGS INSTITUTE

JBI RAPid

Rapid Appraisal Protocol Internet Database

User Guide Version 1.2



THE JOANNA BRIGGS INSTITUTE

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Preface

Welcome to The Joanna Briggs Institute – Rapid Appraisal Protocol internet database (JBI-RAPid). This instrument is designed for online critical appraisal of evidence to assist universities to promote critical appraisal skills and research utilisation in health care practice.

RAPid is a single point of entry resource that teaches students to critically appraise evidence using established data collection tools, and offers them the possibility of publishing this appraisal in the form of a refereed report in the RAPid Library.

Developed specifically for students of medicine, nursing, midwifery, physiotherapy, occupational therapy, podiatry, medical radiation, dietetics and other health sciences, RAPid is based on the CATmaker program developed by the Centre for Evidence Based Medicine in Oxford, UK, by Douglas Badenenoch, David Sackett and Sharon Straus.

Like CATmaker, RAPid is designed to organise, conduct and archive an evidence summary of a single study of an intervention or professional activity or of specific findings of a completed systematic review.

Unlike CATmaker, RAPid is designed to include processes to appraise and summarise evidence from a wide range of sources, including the results of quantitative and qualitative studies.

RAPid is designed to assist individual practitioners and undergraduate and postgraduate students to acquire the skills of posing relevant questions about the feasibility, appropriateness, meaningfulness or effectiveness of an intervention or professional activity, and to pursue this question through applying the following basic steps of the comprehensive systematic review process:

- Topic identification and rigorous question development
- Searching for the evidence
- Critically appraising the evidence
- Summarising the evidence
- Reporting the results of this process in an accessible format to maximise knowledge transfer to practice.

SECTION 1

The RAPid program

The RAPid program has two major components: RAP Maker and the RAP Library.

1.1 RAP Maker

RAP Maker is the software component of RAPid; it is where the type of paper (systematic review or single study) is selected.

Once the type of paper is chosen, RAPpas are prompted to define the type of study or review that the selected paper represents, and are then expected to use the program to appraise the paper, critiquing the study type, its methods, findings and applicability.

Each aspect of appraisal and data entry is conducted in real time in RAP Maker. RAP Maker facilitates study type recognition, data extraction and construction of a final report, which may then be submitted online to the RAP Library for independent critique, followed by uploading for worldwide access.

1.2 The RAP Library

The RAP Library (an internet database) is a readily available resource, accessible 24 hours a day via the Internet. The RAP Library promotes the transfer of knowledge, increases the pool of resources available to health care professionals and students, and is frequently updated with new RAP sheets. Students can view completed RAP sheets or create new RAPs.

The benefits of the RAP Library are that university lecturers and facilitators of continuing education in health services can readily identify areas of practice not currently covered by the library. Students can then be directed to address gaps, conduct updates or contribute on a similar topic using a different study design, thus facilitating a coordinated approach to education.

RAP sheets are only loaded in the library after undergoing appraisal via the Institute, and the criteria used in the appraisal process can be made available to lecturers, thus facilitating the marking process and promoting the quality of each RAP sheet.

The RAP Library is fully indexed and can be searched by title or author. For students, acceptance for publication may motivate them to become active in the publication of their work so that they experience the benefits of disseminating knowledge.

SECTION 2

Why RAP?

2.1 Integrating RAPid into undergraduate and postgraduate teaching

Health sciences students are expected to acquire knowledge of research and of critical appraisal, and to develop the skills required to access resources that inform their practice at undergraduate, postgraduate or higher degree levels.

RAPid is a flexible program that can be used at both the undergraduate and postgraduate level, and lecturers can specify what study types and degree of analysis they expect from their students. The final report each student generates follows a consistent format for its study type, and the information is readily viewed and appraised by lecturers via the RAP Library.

Uploading a RAP sheet only occurs after the student's work has been appraised for quality and relevance by trained JBI appraisers, thus giving lecturers an independent opinion on the RAP sheet, and giving students high quality feedback on their work. This process of review and appraisal by the JBI reviewers does not constitute an assessment or grading process for students. This is primarily a learning tool for students, while assessment and grading remain the responsibility of course coordinators.

SECTION 3

History and development of evidence-based health care

Evidence-based practice stems from A.L. Cochrane's work in relation to evidence-based medicine, and is increasingly being adopted by most health professions and in most health systems in most Westernised countries. Cochrane drew attention to the lack of information about the effects of health care, with particular reference to medicine, and suggested that:

[it] is surely a great criticism of our profession that we have not organised a critical summary by specialty or subspecialty adapted periodically of all relevant randomised controlled trials.¹

He argued that as resources for health care are limited, they should be used effectively to provide care that has been shown, in valid evaluations, to result in desirable outcomes. He emphasised the importance of randomised controlled trials in providing reliable information on the effectiveness of medical interventions.

Evidence-based health care practice thus focuses on the need for all health professionals to base their interventions and activities on the most up-to-date evidence or knowledge available. The evidence-based approach acknowledges the difficulties faced by busy practitioners in keeping up to date with an ever-growing body of literature in health care, and emphasises the importance of providing them with condensed information gathered through systematic review of the international literature on a given topic.

Although there is an international focus on a multidisciplinary approach to reviews and dissemination, until 1996 most activities focused on medicine, and even now evidence-based practice is often largely an acronym for evidence-based medicine.

Evidence-based medicine

Professor David Sackett of the University of Oxford has led the rapid development of evidence-based medicine in the past ten years. Evidence-based medicine (EBM) has been defined by Sackett and colleagues as:

The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.²

Sackett and Rosenberg³ argue for the need to base medical practice on the best possible evidence, to critically appraise research reports for validity and usefulness and to incorporate the rapidly growing body of evidence into medical practice. They suggest that EBM is concerned with 5 linked ideas:

- Clinical and other health care decisions should be based on the best patient-, population- and laboratory-based evidence
- The nature and source of the evidence to be sought depends on the particular clinical question
- Identification of the best available evidence requires the application of epidemiological, economic and biostatistical principles plus pathophysiology and personal experience
- This identification and appraisal of the evidence must be acted upon
- There should be continuous evaluation of performance

This evidence-based approach to medicine draws on the activities of numerous specialist groups from across the world, linked together to form the Cochrane Collaboration.

SECTION 4

Critical appraisal

What exactly is critical appraisal, and what is the difference between 'appraising' an article and simply reading it? If you have been conscientious enough to organise a literature search, go to the library and copy a promising article, why can't we leave you alone to read it over a coffee? Why do you need to put it through some complex process called *critical appraisal*?

Appraisal is a technique that offers a discipline for increasing the effectiveness of your reading, by enabling you to quickly exclude papers that are of inadequate quality to inform practice, and to systematically evaluate those that pass muster to extract their salient points.

Critical appraisal provides solutions to three major problems in medical informatics:

- the sheer volume of material now being published (*information overload*): there are about 20,000 worldwide biomedical journals, publishing about 6 million articles per annum!
- the fact that much of this is of limited relevance and utility in providing daily clinical care, and so the information you need resides in only a small fraction of this huge volume (*the '80/20' rule*)
- the notion that all studies are flawed to some extent, or are too 'ivory tower' to make much difference to real life (*nihilism*).

SECTION 5

Accessing JBI-RAPid

JBI-RAPid is designed to run on the following web browsers:

- Microsoft Internet Explorer 6.0 on Windows 95 or later
- Apple Computer Safari 1.2.3 on Macintosh OS 9 or later
- Microsoft Internet Explorer 5.2 on Macintosh OS 9 or later.

This range of platforms and browsers is designed to ensure that the majority of users will have easy access to JBI-RAPid, and it is anticipated that JBI-RAPid will run on later versions of these web browsers. However, note that Safari v 1.2.3 is recommended for use on Macintosh computers due to a caching issue with earlier versions of Safari and MS Internet Explorer 5.2.

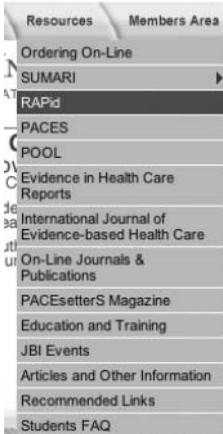
You will need a network or Internet connection to access the JBI-RAPid server. JBI-RAPid can be accessed through a firewall as it uses standard web protocols (i.e. HTTP on port 80). JBI-RAPid will operate on low bandwidth connections such as a dial-up modem.

SECTION 6

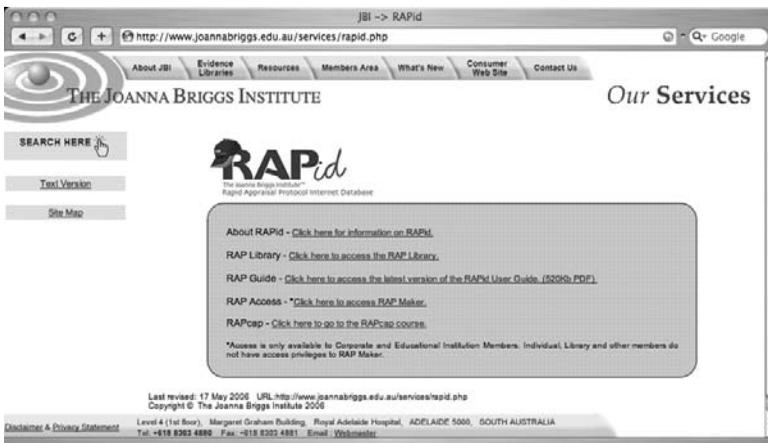
Getting started

6.1 Logging on

Access to JBI-RAPid is via the JBI web site at www.joannabriggs.edu.au.



Click on **<RAPid>** under **<Resources>** on the menu bar.



From this screen, you will be presented with the following options:

- *About RAPid* – this will provide you with an information page on the RAPid program, with a link to information about becoming a member. Press **<Click here for information on RAPid>**

- *RAP Library* – provides the link to enter the RAP Library, to search for existing RAP Sheets. Press **<Click here to access RAP Library>**
- *RAP Guide* – where this RAPid user guide is found. Press **<Click here to access the RAPid User Guide>**
- *RAP Access* – Click here to enter RAPid by entering your username and password (see Section 7: RAP access)
- *RAPcap Course* – where you can register to become a RAP reviewer, a peer reviewer of submitted RAP sheets

6.2 Logging off

Once you have entered RAPid you can log out at any time by clicking the **<RAPid LogOut>** button at the top of the screen. After a quick confirmation to log out the session will end.

6.3 Time out

To keep the system secure from accidental changes by unauthorised users, the system will log you out after 15 minutes of inactivity. Return to the home page and log in again (see 6.1) if you are timed out. A pop-up window will give a warning 2 minutes before timing out.

SECTION 7

RAP access

Press **<Click here to access RAP Maker>**. You will see the JBI-RAPid logon screen. This screen prompts you to enter your username and password. Enter these and click logon to connect.

RAPid
The Joanna Briggs Institute™
Rapid Appraisal Protocol Internet Database

RAPid
Rapid Appraisal Protocol Internet Database

If you are first time user of RAPid please use your organisations JBI Username and Password.

If you are a registered RAppa use your own RAP Username and Password.

Username

Password

Joanna Briggs Institute

If this is your first time logging into RAPid you will be required to enter your organisation's JBI username and password. You will then be required to create your own individual username and password (create a new RAP username).

To create your individual username and password, fill in the blank fields. Click the **<Add Me>** button. You will then be required to enter this new username and password at the log on screen, as above. Please ensure that the email address entered is correct, as correspondence related to the RAP review will be sent to this address.

Create a new Rap username.

You need to create a Rap username and password.
To create a RAP you will be required to log in again using this new username.
* Indicates information must be provided.

Username (Full Name e.g John Doe)

Password

University or Health Service

Course enrolled in/Dept

Email Address

You will need to log in again using the username you just created.

Existing users will be directed to a similar screen to this after entering their username and password, but a **<Create RAP>** button will replace the **<Add Me>** button. This screen is also for verifying the user's details. To start the RAP process, click **<Create RAP>**. See Section 10: Step-by-step guide to conducting a RAP.

SECTION 8

RAP Library

The RAP Library contains a menu bar with five links.

Clicking **<Index page>** will direct you to an alphabetical list of all RAP Sheets included in the RAP Library. You can search by clicking on the appropriate letter, or use the scroll function to conduct a manual search.

To open a RAP Sheet, click on the title.

You can return to the top of the page by clicking **<Back to index>**.

To search the RAP Library using a key word, click **<Search>**. Enter the key word into the free text box provided and click **<Submit>**.

The **<Help>** feature provides an information page about the RAP Library.

Clicking **<RAP maker>** links you to the log-in page of RAPid.

A link is also provided to the JBI homepage. To access, click **<JBI website>**.

SECTION 9

User guide

This user guide has been developed for students and healthcare professionals and academics to assist them in practicing or promoting critical appraisal of evidence.

The user guide is available to download in PDF format. On the open page of RAPid, click on **<Click here to access RAPid User Guide>**. This requires that you have Adobe Acrobat installed on your computer.

SECTION 10

Step-by step guide to conducting a RAP

Once you have entered your individualised username and password, a screen will appear showing your details. Ensure these details are correct. Make any changes as necessary.

To begin conducting a RAP, click **<Create a RAP>**. This will open up in a new window.

Create New Rap

Verify your details before creating Rap

Name	Jane Doe
University or Health Service	Royal Adelaide Hospital
Course Enrolled In / Dept	Nursing
Email Address	J.Doe@mail.com
Create a new RAP	Create RAP

The screen that appears requires you to enter details of the paper being critiqued. Click on the free text boxes to type in this information. Use the tab button to move between data entry boxes. Mistakes can be edited at this stage or everything entered can be deleted by clicking **<Reset>**. The * asterisk next to the text box indicates that the field is mandatory. Please note changes cannot be made once the RAP has been submitted.

10.1 Details of paper

10.1.1 RAP question/topic

The elements of the question under investigation will differ depending on the focus of your interest. Questions should be structured according to the particular area of interest.

The RAP question should clearly state the following information (each study type is defined further below):

For risk, intervention and cost RAP questions, the population, intervention, comparison (if applicable) and outcome being queried should be described. Example questions are:

- *What is the effectiveness of propofol versus midazolam in maintaining sedation in adult ventilated patients in the intensive care unit?* For this question the population is defined as adult ventilated patients in the intensive care unit, the intervention and comparison are propofol versus midazolam, and the outcome is maintaining sedation.

- *Which moist wound dressing is most cost effective in healing venous leg ulcers in adult diabetic patients living in residential care facilities?*
In this question the population is adult diabetic patients living in residential care facilities, the intervention is moist wound dressings, and the outcome is healing venous leg ulcers.

For **prognostic** RAP questions, the population and outcome being queried should be described. For example:

- *In adult patients with second stage renal failure who maintain a high protein diet, what is the likelihood of developing end stage renal failure within 10 years?* In this example the population is patients in second stage renal failure that maintain a high protein diet, and the outcome is the patients who develop end stage renal failure within 10 years.

For **Qualitative (experiential)** RAP questions, the population, phenomena of interest and outcome being queried should be stated. For example:

- *What are the experiences of women less than 45 years old following mastectomy?* In this example the population is women less than 45 years old, the phenomena of interest is the mastectomy and the outcome is the experiences of the women.

10.1.2 Evidence source

Requires the entry of authors' names, title of the paper, year of publication, name of journal, the volume number, and page numbers. Issue number is not compulsory, but should be entered if present.

10.1.3 Study type

Use the drop down box to choose the study type - prognosis, risk, intervention, cost, experience, diagnosis, or systematic review of intervention.

The screenshot shows the 'RAP' logo and navigation links 'The Guide', 'About', and 'Logout'. Below is the 'Details of Paper Retrieved' form. The form has the following fields:

- RAP Question: [Text input field]
- Evidence Source: [Section header]
- Author/s: [Text input field]
- Study / Review Title: [Text input field]
- Year: [Text input field]
- Journal: [Text input field]
- Volume: [Text input field]
- Issue: [Text input field]
- Page Number/s: [Text input field]
- Study Design: [Dropdown menu]

The dropdown menu for Study Design is open, showing the following options:

- Choose a category
- Prognosis
- Risk
- Intervention
- Cost
- Experience
- Diagnosis
- Systematic Review of Intervention

Below the dropdown menu, there is a note: 'Additional information must be entered.'

Each study type that is chosen has its own critical appraisal and data extraction tool; thus it is essential the correct study type is selected.

To determine the category for your RAP review, see the following category definitions, largely taken from Miller-Keane's Encyclopedia and Dictionary of Medicine, Nursing and Allied Health.

Prognosis

Definition: forecast of a probable cause or outcome of a disease/illness and the prospects of recovery as indicated by the nature of the disease or symptoms. The possible outcomes of a disease and the frequency with which they can be expected to occur.

Example: *in adult patients with second stage renal failure who maintain a high protein diet, what is the likelihood of developing end stage renal failure within 10 years?*

Risk

Definition: the probability of suffering harm.

Example: *what is the likelihood of developing cancer of the lung in adults with prolonged exposure to second hand cigarette smoke?*

Intervention

Definition: an action or activity that is undertaken to address a specific client problem and to improve, maintain or restore health to prevent illness.

Example: *what is the clinical effectiveness of hydrocolloid dressings in comparison to dry dressings, on healing rates of leg ulcers in adult patients?*

Cost

Definition: examines the cost minimisation, effectiveness, benefit, or utility of an action or activity.

Example: *what is the potential economic benefit of using hydrocolloid dressings over dry dressings to prevent infection in hospitalised patients?*

Experience

Definition: studies that fall in the interpretive and critical paradigms, examining the meaningfulness, appropriateness or feasibility of phenomena of interest on an individual or group. Study methods used are commonly phenomenology, ethnography, or grounded theory.

Example: *what is the lived experience of women being informed of a diagnosis of breast cancer?*

Diagnosis

Definition: a concise description of the cause, nature, or manifestations of a condition, situation, or problem. The efficacy of a diagnostic tool is in comparison with the gold standard. 'Two level' refers to a study when the person may or may not have the disease, whereas the 'multi-level' considers the gradation/levels of the disease, such as renal failure.

Example: *what is the efficacy of using spiral CT in diagnosing thrombus in comparison to pulmonary angiography?*

Systematic Review of Intervention

Definition: studies that provide comprehensive and unbiased summaries of the research on a single topic, by bringing together large numbers of individual studies in a single document.

Example: *The Effectiveness of Solutions, Techniques and Pressure in Wound Cleansing: A Systematic Review.*

When all information has been correctly entered, click **<Next>** to move to the critical appraisal stage.

SECTION 11

Critical appraisal

A critical appraisal tool will be chosen depending on the category selected in the previous stage. This tool is used to judge the quality of the study being examined. A three-point scale is used to appraise the paper. Click on the buttons on screen to indicate <Yes> <No> or <Unclear> for each critical appraisal statement for the study.

- To click <Yes>, there must be a clear statement within the paper in response to that critical appraisal statement, affirming that it did occur.
- To click <No>, there must be a clear statement within the paper affirming that it did not occur.
- To click <Unclear>, there is no statement within the paper in relation to that critical appraisal statement, and thus the appraiser is unable to make this judgment.

11.1 Critical appraisal tool for a prognostic study

This section describes features of high quality prognostic studies. For each statement, click on <Yes>, <No> or <Unclear>. Use the indicators to assist your decision making process.

The choice of study method is appropriate

Indicators: usual types of studies include cohort/survival studies.

The population studied is appropriate

Indicators: the population is sufficiently broad in representation. Relevant variables include age, sex, ethnicity, culture, and socio-economic status.

The comparison group used was appropriate

Indicators: if a comparison group is receiving an alternative therapy, this group is otherwise sufficiently similar so as to act as a control for the comparison.

All possible effect explanations are acknowledged

Indicators: the study addresses any additional factors that may impact on the outcomes. Do events unfold similarly for both control and intervention group throughout the study – i.e. were there any uncontrolled factors that influenced one group differently to the other group?

The outcomes are objectively measured

Indicators: where possible, those measuring the outcome(s) were blinded to the subject's clinical characteristics or treatment group. An even more rigorous approach is 'double-blinding', when both subject and investigator do not know to which treatment group the subject is allocated.

The duration of follow-up was adequate

Indicator: the follow-up was for a period that would allow the outcomes to occur.

The effect was sufficiently long term

Indicator: the effect or outcome measures are not inconsequential.

The dropout rate was not significant.

Indicator: generally a drop out rate of 5% or less is considered insignificant. A drop out rate of 20% or greater is considered to significantly impact on the validity of the study.

The rate of patient follow up was adequate.

Indicator: at least 80% of patients were followed up.

In reflecting upon my critical appraisal I believe that this paper is...

In considering the appraisal you have conducted for the study, indicate your overall assessment using the drop down box. There are three choices – of good quality, of poor quality and to be used with caution.

If you choose either 'of good quality' or 'to be used with caution' you will progress to the data extraction page.

If you choose 'of poor quality' you will progress to the conclusions page.

When questions or statements have been answered, this portion of the critical appraisal is complete.

Click **<Submit>** to move to the next stage.

11.2 Critical appraisal tool for a risk study

This section describes features of high quality risk studies. For each statement, click on **<Yes>**, **<No>** or **<Unclear>**. Use the indicators to assist your decision making process.

The choice of study method is appropriate

Indicators: usual types of studies include cohort or case control.

The population studied is appropriate

Indicators: the population was sufficiently broad in representation.

The control group used was appropriate

Indicators: the comparison group was determined to be sufficiently similar at baseline.

All possible effect explanations are acknowledged

Indicators: the study addresses any additional factors that may have impacted on the outcomes.

The outcomes are objectively measured

Indicators: those measuring the outcome were, where possible, blinded to the patient's clinical characteristics.

The duration of follow-up was adequate

Indicators: the follow-up was for a period that would allow the outcomes to occur.

The effect was sufficiently long term

Indicators: the effect or outcome measures were not inconsequential.

The dropout rate was not significant

Indicators: Generally a drop out rate of 5% or less is considered insignificant. A rate of 20% or greater is considered to significantly impact on the validity of the study.

The rate of patient follow up was adequate

Indicators: At least 80% of patients were followed up.

In reflecting upon my critical appraisal I believe that this paper is...

In considering the appraisal you have conducted for the study, indicate your overall assessment using the drop down box.

If you choose either 'of good quality' or 'to be used with caution' you will progress to the data extraction page.

If you choose 'of poor quality' you will progress to the conclusions page.

Choose the type of risk study from the drop down menu. Cohort is a study in which one group is followed over a period of time. Case Control is a study in which two separate groups are compared. Click **<Submit>** to move to the next stage.

11.3 Critical appraisal tool for an intervention study

This section describes features of high quality intervention studies. For each statement, click on <Yes>, <No> or <Unclear>. Use the indicators to assist your decision making process.

The patients were randomised to study groups

Indicator: the method of patient allocation is detailed sufficiently to demonstrate that it was without bias. Note that in some cases, full randomisation might be either unfeasible or inappropriate for the intervention of interest.

Allocation to treatment groups was concealed from the allocator

Indicators: the person allocating each participant to treatment groups was unaware of which participant was allocated to which group, in an attempt to eliminate selection bias.

Other than for the intervention/s of interest, participants were treated the same

Indicators: there were no additional treatments given to one group in comparison to another, apart from that treatment being tested.

The groups were comparable at entry

Indicators: there were no measurable differences in the characteristics of the different treatment groups. For example, in the examination of a new wound dressing, it is not appropriate to have a treatment group of young, healthy participants, and a control group of elderly participants with peripheral vascular disease.

The outcomes were measured in the same manner for all participants

Indicators: There was no difference in the way participant outcomes were measured. Participants cannot be compared if outcomes are measured differently between the groups.

Those assessing outcomes were blinded to the treatment allocation

Indicators: those assessing participant outcomes were unaware of the treatment group that the participants were allocated to. Concealing allocation from the assessors further reduces the chances of bias. In certain situations it may be impossible to blind the assessor to the treatment allocation.

The outcomes were measured in a reliable manner

Indicators: a recognised, validated tool was used for measuring the outcomes. For example, when measuring a patient's level of consciousness, the Glasgow Coma Scale is a widely recognised tool.

The statistical analysis used was appropriate for the data presented

Indicators: there are a variety of statistical analyses available; the one(s) chosen were appropriate to the data being presented.

The dropout rate was not significant

Indicators: generally a drop out rate of 5% or less is considered insignificant. A rate of 20% or greater is considered to significantly impact on the validity of the study.

The rate of patient follow up was adequate

Indicators: at least 80% of patients were followed up.

In reflecting upon my critical appraisal I believe that this paper is...

In considering the appraisal you have conducted for the study, indicate your overall assessment using the drop down box.

If you choose either 'of good quality' or 'to be used with caution' you will progress to the data extraction page.

If you choose 'of poor quality' you will progress to the conclusions page.

Click **<Submit>** to move to the appropriate page.

11.4 Critical appraisal tool for a cost study

This section describes features of high quality cost studies. For each statement, click on **<Yes>**, **<No>** or **<Unclear>**. Use the indicators to assist your decision making process.

The question is well defined

Indicators: is it clear what interventions/programs and outcomes will be examined in terms of cost effectiveness? Many economic studies are conducted in conjunction with clinical trials. The economic evaluation may relate to all or only part of the trial conducted. The research question stated in the paper often relates to the primary clinical trial and not the economic evaluation.

There is a comprehensive description of alternatives

Indicators: all interventions subject to the economic evaluation must be comprehensively described. Some interventions can be administered in a variety of ways that will impact on cost. Consider issues of duration and frequency of the intervention and mode of delivery, including level and type of practitioner. Consider if a 'do nothing' alternative is appropriate.

All important and relevant costs and outcomes for each alternative are identified

Indicators: in delivering even a single simple intervention there are a variety of direct and/or indirect costs incurred. An intervention may also result in benefit that reduces cost. An example of an 'avoided' cost is an intervention that reduces the rate of infection and subsequently reduces the cost of managing the infection. Consider costs to the health provider, the individual receiving the intervention and potentially the individual's family also.

Clinical effectiveness has been established

Indicators: any measure of clinical effectiveness used in the economic evaluation of clinical effectiveness. It may be that one alternative clinical intervention is more effective than another or that both are equally effective. Either way, examine the evidence to support this position. If this evidence is based on a concurrently run clinical trial then the report should provide enough information to appraise the quality of the trial. If the evidence is derived from a systematic review, then make a judgment about the quality of the review if possible.

Costs and outcomes are measured accurately

Indicators: a description is given of how costs were derived. Any items included in the costing should have the 'price' or cost per unit reported separately from quantities used. This will assist in making judgments about the accuracy of measures. Consider the appropriateness of the physical units costed. Were they actual costs or estimates based on modeling? If costs were estimated, is the method logical?

Costs and outcomes are valued credibly

Indicators: the value of a cost or an outcome may vary depending on the perspective used to derive the value. In considering the outcome of pain, for example, this may be valued in terms of the cost of analgesia (provider's perspective). For the patient the emphasis is more likely to relate to the physical and emotional impact of pain.

Costs and outcomes are adjusted for differential timing

Indicators: some interventions are ongoing and can incur costs into the future. Costs may be expected to change over time and therefore must be adjusted or 'discounted' to their value at the time of the intervention.

There is an incremental analysis of costs and consequences

Indicators: in some cases it is appropriate to use the average cost of an intervention, and in other cases the marginal (additional) cost of providing the intervention is more appropriate. The incremental cost is determined by establishing the difference between the marginal costs and consequences of the alternative interventions. If this approach is taken it must be justified.

Sensitivity analyses were conducted to investigate uncertainty in estimates of cost or consequences

Indicators: in some economic evaluations, certain costs and consequences are estimated on values that may vary over a range or have some degree of uncertainty. These elements in the evaluation are estimated using various assumptions. A sensitivity analysis is conducted to test the robustness of the result of the evaluation by varying these underlying assumptions.

Study results include all issues of concern to users

Indicators: this issue in part relates to perspective, and the interests of all stakeholders must be considered. There may be important ethical and cultural considerations.

The results are generalisable to the setting of interest in the review

Indicators: economic evaluations are conducted within a given context, taking into account a given population, healthcare setting, time and other elements that can impact on the generalisability of the results. In considering the clinical question that prompted the review of the economic evaluation, these elements must be considered in determining how widely the results can be used.

In reflecting upon my critical appraisal I believe the paper is...

In considering the appraisal you have conducted for the study, indicate your overall assessment using the drop down box.

If you choose either 'of good quality' or 'to be used with caution', you will progress to the data extraction page.

If you choose 'of poor quality', you will progress to the conclusions page.

What type of cost study is it?

Choose the type of cost study from the drop down menu.

Cost Minimisation is a study where the only the costs of alternative interventions are compared.

Cost Effectiveness is a study where the costs of alternative interventions and their effects are compared.

Cost Utility is more complex than cost effectiveness evaluations, and the end result of the intervention is quantified and compared to the cost. QALYs (quality adjusted life years) is a common measure used.

Cost Benefit is similar to cost effectiveness studies in that the objective is to compare the cost against the outcome. The outcome, however, is also converted to monetary terms, resulting in an overall monetary value for the intervention.

Click **<Submit>** to move to the next stage.

11.5 Critical appraisal tool for an experience study

This section describes features of high quality experience studies. For each statement, click on **<Yes>**, **<No>** or **<Unclear>**. Use the indicators to assist your decision making process.

There is congruity between the stated philosophical perspective and the research methodology

Indicators: the report clearly states the philosophical or theoretical premise on which the study is based. The report clearly states the methodological approach adopted on which the study is based. There is congruence between the two.

There is congruity between the research methodology and the research question or objectives

Indicators: the study methodology is appropriate for addressing the research question. For all studies there will be one methodology that is most appropriate to answer the research question being posed.

There is congruity between the research methodology and the methods used to collect data

Indicators: studies that fall in the interpretive paradigm cover a variety of approaches and methods of data collection. The methods of data collection are appropriate to the study methodology.

There is congruity between the research methodology and the representation and analysis of data

Indicators: the data is analysed and represented in ways that are congruent with the stated methodological position.

There is congruity between the research methodology and the interpretation of results

Indicators: the research methodology is consistent with the methods used to interpret the data. For example, if the research methodology of phenomenology is used, the interpretation of the results is in line with traditional methods within phenomenology.

There is a statement locating the researcher culturally or theoretically

Indicators: the researcher's cultural or theoretical background is clearly stated if it may have an influence on the study.

The influence of the researcher on the research, and vice versa, is addressed

Indicators: does the researcher have an effect on the results of the research? A statement on their position must be made.

Participants and their voices are adequately represented

Indicators: the authors use direct quotes of the participants to validate points that have been made.

The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body

Indicators: there is a statement regarding the attainment of ethical approval.

Conclusions drawn in the research do appear to flow from the analysis, or interpretation of the data

Indicators: what is being concluded from the research is consistent with the data presented.

In reflecting upon my critical appraisal I believe the paper is...

In considering the appraisal you have conducted for the study, indicate your overall assessment using the drop down box.

If you choose either 'of good quality' or 'to be used with caution', you will progress to the data extraction page.

If you choose 'of poor quality', you will progress to the conclusions page.

Click **<Submit>** to move to the next stage.

11.6 Critical appraisal tool for diagnosis two-level and multi level studies

This section describes features of high quality diagnosis two-level and multi-level studies. For each statement, click on <Yes>, <No> or <Unclear>. Use the indicators to assist your decision making process.

The choice of study method is appropriate

Indicators: in a diagnosis study the test results from a group of subjects affected by a clinical condition are compared to the test results from a normal group of subjects. The aim of a diagnosis study is to determine how readily the test results confirm the presence of the condition.

The population is appropriate

Indicators: the population is sufficiently broad in representation.

The control group used was appropriate

Indicators: if a comparison group is receiving an alternative therapy, this group is otherwise sufficiently similar. The most important feature of the control group is that they are free from the condition. The control group must be matched to the affected group in terms of known risk factors predisposing them to the condition.

A type 1 and/or type 2 error and bias has been acknowledged

Indicators: any Type 1 error is acknowledged and justified. Due consideration is given to the selection of the Type 1 error. A power analysis was conducted, using sample sizes large enough to detect differences that actually occur between the control and affected group.

All possible effect explanations are acknowledged

Indicators: the study addresses any additional factors that may impact on the outcomes. For example, in studies where a cut-off in a diagnostic value is used, is the calculation of the cut-off value objectively or subjectively assigned? Also, consideration must be given as to how each population was derived. If the affected population consists of people that are severely affected by the disease, the findings may not be applicable over a wide range of patients.

The outcomes are objectively measured

Indicators: Those measuring the outcome are where possible blinded to the patient's clinical characteristics. Both study groups undergo the same treatment; i.e. both receive the diagnostic test and the reference standard evaluation. The diagnostic test is conducted and interpreted in ignorance of the results of reference standard and vice versa, i.e. the comparison is 'blinded'.

The duration of follow-up was adequate

Indicators: the follow-up was for a period that would allow the outcomes to occur.

The effect was sufficiently long term

Indicators: the effect or outcome measures were not inconsequential.

The drop out rate was not significant

Indicators: generally a drop out rate of 5% or less is considered insignificant. A rate of 20% or greater is considered to significantly impact on the validity of the study.

The rate of patient follow-up was adequate

Indicators: at least 80% of patients were followed up.

In reflecting upon my critical appraisal I believe this paper is...

In considering the appraisal you have conducted for the study, indicate your overall assessment using the drop down box.

If you choose either 'of good quality' or 'to be used with caution' you will progress to the data extraction page.

If you choose 'of poor quality' you will progress to the conclusions page.

Click **<Submit>** to move to the next stage.

11.7 Critical appraisal tool for systematic review of interventions

This section describes features of high quality systematic reviews of interventions. For each statement, click on <Yes>, <No> or <Unclear>. Use the indicators to assist your decision making process.

Question

Well formulated

Indicators: the question gives a clear understanding of what the review was trying to achieve.

Clearly documented in the report

Indicators: the question is clearly visible within the review report. This guides the review, and must be evident.

Search Strategy

Two-phase search strategy is described

Indicators: a two-phase search strategy is the minimum requirement, and includes an initial search to establish appropriate search terms and a second search of all relevant databases.

Phase 1 search terms appropriate

Indicators: the search terms are specific to the topic in review.

Phase 2 was relevant and exhaustive

Indicators: the search strategy covers all aspects of the topic in review.

Accessed a broad number of databases

Indicators: the databases match the area of practice that is of concern, including all the major (broad) and minor (topic specific) databases.

References and bibliographies were searched

Indicators: this is clearly documented.

Unpublished literature was sourced

Indicators: the strategy for accessing unpublished literature is clearly defined.

There is reference to languages searched

Indicators: if studies using languages other than the reviewer's first language are sourced, then they are documented. If not, then this is justified.

Inclusion Criteria

Describes who the target population were

Indicators: this includes relevant demographic, disease/condition and intervention characteristics.

Describes the intervention/s in detail

Indicators: it is clear what intervention/s were being reviewed, and that they are appropriate for the patient group.

Describes the outcomes in detail

Indicators: all outcomes are stated and relevant to the interventions reviewed.

States the study design/s

Indicators: it is clearly stated what study designs were to be included and what level of study was considered as unacceptable.

Describes the exclusion in detail

Indicators: the decisions about the inclusion criteria are justified in terms of the objectives of the review and any exclusions are also justified.

Critical Appraisal

Method was appropriate

Indicators: the criteria used are specific to the design of the included studies.

Method clearly reported

Indicators: the methods used in the report are stated.

Any checklists or tools used are reported

Indicators: all tools used are documented; this is often in the appendices.

Determined by two independent reviewers

Indicators: two independent reviewers have performed the critical appraisal process in an attempt to maintain consistency and eliminate bias.

Data Extraction

Methods were used to minimise errors

Indicators: a recognised and agreed upon data extraction tool is used in an attempt to minimise errors, often in the appendices.

Methods were clearly reported

Indicators: all tools used are documented; this is often in the appendices.

Double data entry by two independent reviewers

Indicators: two independent reviewers have performed the data extraction process in an attempt to maintain consistency and eliminate bias.

Data Synthesis

Results from individual studies are reported in a narrative, tabular or statistical summary

Indicators: if studies could not be pooled statistically, the results are clearly reported.

The review question has been answered

Indicators: the results of studies provide evidence that directly informs the review question.

If meta-analysis was undertaken

It was appropriate to combine studies

Indicators: if studies were combined the study samples, interventions and outcomes are very similar (clinical homogeneity).

The methods were appropriate

Indicators: there are a variety of statistical methods available; their use is logical and appropriate.

The methods were reported

Indicators: the above methods used in meta-analysis are reported.

Studies were tested for heterogeneity

Indicators: this determines that the studies combined were sufficiently statistically similar.

For All Studies

Summarises major findings of review

Indicators: any major findings of the review are summarised and included in the report.

All issues of importance are addressed

Indicators: the report includes all issues that are seen to be of importance.

Limitations are acknowledged

Indicators: the review includes a list of what are seen to be the limitations of the study. This then acknowledges what is lacking in the study, and makes the reader aware of these areas.

All issues arising from review addressed

Indicators: everything that was discovered from the review is included. If there are particular issues, it could disclose the need for further work.

Implications for Practice

Implications for practice identified

Indicators: any recommendations for practice that have resulted from the review have been included

Recommendations are clear and unambiguous

Indicators: any recommendations that have resulted from the review are stated in a manner that is easy to understand, with little room for misinterpretation.

Recommendations are supported by findings

Indicators: the recommendations that have resulted from the review are clearly congruent with the findings presented.

No major areas omitted

Indicators: no area of the findings was left out of the recommendations for practice.

Implications for Research

Recommendations are clear and unambiguous

Indicators: any suggestion for further research as a result of the review is clearly and explicitly stated.

No major areas omitted

Indicators: no area of the review was left out of the implications for further research.

In reflecting upon my critical appraisal I believe that this paper is...

In considering the appraisal you have conducted for the review, indicate your overall assessment using the drop down box.

If you choose either 'of good quality' or 'to be used with caution' you will progress to the data extraction page.

If you choose 'of poor quality' you will progress to the conclusions page.

Click **<Submit>** to move to the next page.

SECTION 12

Data extraction

When critical appraisal has been performed, and the paper has been determined to be of good quality or to be used with caution, the next stage is data extraction.

An appropriate data extraction tool will be used depending on the study type selected. If the paper is appraised to be of poor quality, then the data extraction stage is not necessary, and the user will move to the conclusions page (Section 13).

12.1 Data extraction for prognostic study

Please complete the following steps:

- Describe the study participants and include all relevant characteristics such as number, gender, co-morbidities and study setting.
- Detail the disease/condition of interest and the outcomes to be predicted. If more than one disease/condition use the additional text boxes.
- Name the disease/condition and the relevant outcome. Include the time to the event if relevant and the percentage of patients with the outcome.
- State the 95% confidence interval if known. Indicate for each of the outcomes if they are independent.

When you have completed your extraction, click **<Submit>** to move to the conclusions page.

12.2 Data extraction for risk (cohort) study

Please complete the following steps:

- Describe the study participants and include all relevant characteristics, such as number, gender, co-morbidities and study setting.
- Detail in 'exposure' the risk factor of interest and in 'outcome' the disease or condition relating to the exposure.
- In the outcomes box name the disease/condition.
- Fill in the results of the study as far as possible. As a minimum you must have the number of subjects exposed that had the disease/condition present and those who did not and those that were not exposed to the risk factor and again had the disease/condition present and those who did not.

When you have completed your extraction, click <Submit> to move to the conclusions page.

12.3 Data extraction for risk (case control) study

Please complete the following steps:

- Describe the study participants and include all relevant characteristics such as number, gender, co-morbidities and study setting.
- Detail in 'exposure' the risk factor of interest and in 'outcome' the disease or condition relating to the exposure.
- In the outcomes box name the disease/condition.
- Fill in the results of the study as far as possible. As a minimum you must have the number of subjects exposed that had the disease/condition present and those who did not and those that were not exposed to the risk factor and again had the disease/condition present and those who did not.

When you have completed your extraction click **<Submit>** to move to the conclusions page.

12.4 Data extraction for intervention studies

Please complete the following steps:

- Describe the type of study eg. RCT, pseudo RCT etc.
- Describe the total number of study participants and include all relevant characteristics such as number, gender, co-morbidities and study setting.
- Describe the interventions being compared; up to three interventions can be documented. A range of outcomes can be detailed.
- In the box titled 'dichotomous data', details of outcomes where an event rate is provided should be documented; that is, there is a number that had the outcome present/number that received the specific intervention. For example if 30 patients received intervention 1, and 5 had the outcome of infection, then 5/30 would be documented in the box for the first outcome and intervention 1.
- For continuous data a mean and standard deviation are required with the number receiving that intervention in brackets. Document p values for each outcome measure.

When you have completed your extraction click **<Submit>** to move to the conclusions page.

12.5 Data extraction for cost studies

Please complete the following steps:

- Describe the study participants and include all relevant characteristics such as number, gender, co-morbidities and study setting.
- All economic evaluations are taken from a given perspective, e.g. the patient, the service provider etc; this should be documented.
- Document the currency and the study date. Up to three interventions can be listed.
- The source of the effectiveness data is documented, and may be derived from a primary concurrent study or even a meta-analysis combining a number of studies.
- The measure of benefit should be included if this is available (lower level studies may not have a measure of benefit).
- Details of the clinical effectiveness of the intervention/s should be documented.
- Items that were included in direct and indirect costs should be described.
- In the outcomes table the comparative costs should be listed and the benefits where appropriate.
- Details of cost benefit synthesis should be given as appropriate.

When you have completed your extraction, click <Submit> to move to the conclusions page.

12.6 Data extraction for experience studies

Please complete the following steps:

- Describe the study in terms of the following elements: the methodology, method of data collection and data analysis used to derive findings or themes.
- Describe in detail the study setting and any relevant geographical and/or cultural issues.
- Document the number of participants and describe the group.
- Interventions/Phenomena of interest should be described.
- All major findings of themes should be described in Outcomes.

When you have completed your extraction click <Submit> to move to the conclusions page.

12.7 Data extraction for diagnosis two level studies

Please complete the following steps:

- Describe the study participants, and include all relevant characteristics such as number, gender, co-morbidities and study setting.
- Describe the disease/disorder that is being diagnosed.
- Document the 'gold standard', the measure or criteria that determines a true diagnosis. Describe the test of tool being tested.
- In the outcomes table, as a minimum include the number of subjects that had the disease/disorder present and were tested as positive or negative, and also those who did not have the disease/disorder.
- Complete in the boxes provided any additional results you can.

When you have completed your extraction click **<Submit>** to move to the conclusions page.

12.8 Data extraction for diagnosis multi-level studies

Please complete the following steps:

- Describe the study participants and include all relevant characteristics such as number, gender, co-morbidities and study setting.
- Describe the disease/disorder that is being diagnosed.
- Document the 'gold standard', the measure or criteria that determines a true diagnosis. Describe the test or tool being tested.
- In the outcomes table document the different levels of diagnosis up to four levels.
- For each level document the proportion of patients diagnosed and the associated sensitivity, and the proportion that did not have the disease/disorder and the associated specificity. Include any other data available.

When you have completed your extraction click **<Submit>** to move to the conclusions page.

12.9 Data extraction for systematic review of intervention

Please complete the following steps:

- Enter the type of study that has been used in the systematic review e.g. Randomised controlled trial, or quasi-experimental design.
- Describe the type of study e.g. RCT, pseudo RCT etc., and then describe the study setting in detail (institution, city, country).

- Describe the intervention and the control or placebo being compared.
- There is room to enter five outcomes. Only enter outcomes that are relevant to your RAP question. For example, if your RAP question is: *What is the effectiveness of propofol versus midazolam in maintaining sedation in adult ventilated patients in the intensive care unit?* Only include outcomes specifically about sedation. The studies may also be examining the effects of these two medications on haemodynamics, but that is not of relevance to the question, so does not need to be included as one of the outcomes.
- For each relevant RAP question outcome, enter one or more outcome measures. For the above example, an outcome measure might be the Ramsey sedation scale. There are two different categories into which data can be entered; dichotomous, the sort of data that is either one or the other, i.e. yes/no, or continuous, the sort that uses a scale for its outcome, such as weight, blood pressure, pulse. Here, the Ramsey sedation scale would be entered as continuous data, as it is a scale.
- For dichotomous data enter the number that had the outcome present/number that received the specific intervention. For example if 30 patients received intervention 1 and 5 had the outcome of infection then 5/30 would be documented in the box for the first outcome and under Intervention. The same needs to be done for Control/Placebo. You will also need to extract further data from the systematic review (if it is present). Enter the Peto Odds Ratio, Confidence Interval (CI-%), Chi Square (degrees of Freedom), and the P value.
- For continuous data, enter the Weighted Mean Difference (WMD), Confidence Interval (CI-%), Chi Square (degrees of Freedom), and the P value.

When you have completed your extraction click **<Submit>** to move to the conclusions page.

SECTION 13

Concluding a RAP

13.1 Conclusions for all extracted studies

- In 'authors' conclusions' provide a concise summary of the conclusions documented in the study.
- In 'your conclusions' give your overall assessment of what the evidence in the study indicates.
- If you chose 'use with caution' after your appraisal, indicate why you made this decision.
- If you chose 'of poor quality' after your appraisal, indicate why you made this decision.

Click **<Take me to my RAP sheet>** to move to the RAP Sheet.

RAP Title	A Randomised Crossover Study of Silver-Coated Urinary Cath
Authors Conclusions	
Your Conclusions	
If you selected 'poor study' or 'use with caution' during your appraisal give reasons why	
Take me to my RAP sheet	

SECTION 14

RAP Sheet

The RAP sheet provides a summary of the information the user has entered on the paper, the data extraction, as well as the conclusions made, in an easy to read table form.

To submit this RAP Sheet for review and possible inclusion into the RAP Library, click **<Submit for review>**. After the user submits the RAP Sheet, a confirmation screen will appear.

Rap review

Zuben Florence Your Rap Sheet has been submitted for Review
You can access the Rap Sheet [Here](#)

Clicking **<Here>** will take the user to their RAP Sheet, where they are able to print, by accessing the top menu under file. To save the RAP Sheet, click on **<View as PDF>**.

This will open the RAP Sheet as a PDF file, where the user can then save to their computer.

SECTION 15

Where to now?

After the completion of the RAP Sheet, the user has several options.

- The user can simply log out by clicking the **<Log out>** button, or closing the window.
- If they wish to conduct another RAP sheet, the user closes the current window, and the window from Section 7 will still be present. To commence the process again, press **<Create RAP>**, and follow from Point 10.

References

¹Cochrane AL. 1931-1971: a critical review, with particular reference to the medical profession. In: Medicines for the year 2000. London: Office of Health Economics, 1979, p 1-11.

²Sackett DL, Straus S, Richardson SR, Rosenberg W, Haynes RB: Evidence-Based Medicine: How to Practice and Teach EBM. 2nd ed. London: Churchill Livingstone; 2000.

³Sackett DL, Rosenberg WMC. On the need for evidence-based medicine. Health Economics. 1995;4:249-254.

⁴Miller-Keane, O'Toole MT. Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing and Allied Health, 7thEd., Elsevier. 2005.

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