Module 105
Writing and reviewing epidemiological papers

Study guide and Reader
These study materials for the distance learning Epidemiology course have been prepared by the London School of Hygiene & Tropical Medicine (LSHTM).

**Dean of Studies:** Sharon Huttly  
**Course Directors:** Anne Tholen and James Hargreaves (Course Content Director)  
**Head, Distance Education & Professional Development Office:** Sue Horrill

---

**Acknowledgements**

LSHTM would like to thank all the staff and associates of the School who developed and wrote these materials.

Any comments on this study pack, favourable or unfavourable, would be most welcome and should be addressed to:

**Head, Distance Education & Professional Development Office**  
London School of Hygiene & Tropical Medicine  
Keppel Street  
London WC1E 7HT  
United Kingdom

Telephone: +44 (0)20 7299 4658  
Email: dlsupport@lshtm.ac.uk
Contents

Writing and reviewing epidemiological papers

Information
Module introduction
Module specification

Sessions
Session 1 Overview of an epidemiological paper
Session 2 Searching the medical literature
Session 3 Evaluating the epidemiological literature
Session 4 Critical evaluation of original papers
Session 5 Systematic reviews and evidence-based medicine
Session 6 Peer review of epidemiological research papers
Session 7 Writing an outline of an epidemiological research paper
Session 8 Writing the first draft
Session 9 Revising drafts and preparing the final manuscript
Session 10 Dealing with the journal

Reader
Reader contents
Reader articles
Module Introduction

The London School of Hygiene & Tropical Medicine welcomes you to:

EPM105 Writing and Reviewing Epidemiological Papers

We hope you enjoy studying this module.

Contents
Finding out about the module ................................................................. 1
The module in context ............................................................................. 2
Module calendar .................................................................................... 2
Study guide ............................................................................................ 3
Readings ................................................................................................. 3
Assignments and additional exercise ..................................................... 5
Web conferencing .................................................................................. 5
Website .................................................................................................. 6
Accessing the LSHTM library ............................................................... 7
Acknowledgments .................................................................................. 9

Finding out about the module

Before you start going through the module materials you may want to get an overview of this module and how it is run. All of this information is stored in a single place for your convenience - in the Module Specification document. This document is provided with your course materials and on the course website. It provides an at-a-glance source of key information about the module such as:

- The title and course code for the module (sections 1 and 2).
- The overall aim of the module and its learning objectives (sections 10 and 11).
- The module content (section 12).
- The learning methods used (section 13).
- The recommended books, software and LSHTM materials you will need to complete the module (section 14).
- How learning is assessed (section 15).
It is worth spending some time acquainting yourself with this information before you start the sessions in detail. It is also useful to check the introductory message for this module posted on the web conferencing forum for key information.

**The module in context**

This, the last of the epidemiology core EPM1 modules, covers the skills needed to find, interpret and criticise information in the scientific literature, and for writing skills needed for the publication of research findings in peer-reviewed journals. It pre-supposes basic knowledge of epidemiology, acquired in the first three core EPM1 modules.

The module aims at providing the basic skills for writing research papers and searching and evaluating the scientific literature. A researcher’s good reputation (and promotion prospects) are dependent not only on rigorous research, but also on the ability to write and have published peer-reviewed research papers. Such papers are read around the world, particularly by other scientists, but in some cases also by informed members of the lay public. The importance of being able to select and critically evaluate the overwhelming amount of published literature cannot be overemphasised, and is a key skill for epidemiologists.

**Module calendar**

<table>
<thead>
<tr>
<th>September</th>
<th>Study materials sent out.</th>
</tr>
</thead>
<tbody>
<tr>
<td>October</td>
<td>Tutoring support begins (web conferencing, email queries). Formative Assignments may be submitted from this time.</td>
</tr>
<tr>
<td>31 March</td>
<td>First submission date for the Formative Assignments (FAs) if submitting the Assessed Assignment (AA) by the May deadline.</td>
</tr>
<tr>
<td>March-May</td>
<td>Interactive sessions (dates to be decided).</td>
</tr>
<tr>
<td>31 May</td>
<td>Final submission date for the FAs if submitting the AA by the August deadline. First submission date for the Assessed Assignment (AA).</td>
</tr>
<tr>
<td>31 August</td>
<td>Final submission date for the Assessed Assignment (AA).*</td>
</tr>
</tbody>
</table>

*Students submitting the EPM105 AAs by the August deadline should note that results for these assignments will be available in November and so, if EPM105 is needed to proceed to EPM2 and elective modules’ study, this will delay the start of these modules by at least two months.
Study guide

This forms the basic learning material. It consists of ten sessions:

- Session 1 provides an overview of the main features of an epidemiological paper.
- Sessions 2-6 concern literature searching, guidance on how to read papers to evaluate them, first for use in preparing your own research and analysis, and secondly for reviewing manuscripts and helping authors to improve their manuscripts.
- Sessions 7-10 provide a step-by-step guide to writing an epidemiological research paper. You will learn how to plan your paper, how to write an outline and a first draft, what to look for when you revise early drafts, and how to prepare and submit a final manuscript. You will also learn how the editorial team are likely to assess your paper, and how to respond appropriately to the editor’s decision.

In the study guide you will find several activities for you to do, followed by feedback. Often we ask you to use your existing knowledge and common sense to answer some questions before reading an article or other material to build on that knowledge.

Many of the exercises for writing use the same material (the Saxena paper in your reader). Thus, to obtain the most benefit from these, it is best to complete them all so that you build up a paper sequentially.

Readings

Throughout the study guide there are references to guidelines and articles and textbooks. Most of these are to be accessed via the internet. The urls for the internet are given wherever possible and were correct at the time of writing but there is a possibility that they will change. For those without good access to journals via the institution or organisation where you work or live, you can access these via the LSHTM library (see below). Items that are not accessible via the internet are given in the module Reader.

You have been provided with one textbook for this module:


There is one online e-book which you can access via LSHTM library but cannot be downloaded. Make sure you can access it. This is used mainly in Session 1, and Sessions 7-10:

- *Winning the Publications Game* by T Albert – available as an e-book from the LSHTM online Library –
One other textbook is used and there are four articles which are required for several exercises in the module. It is advised that you download these before you start the module.

- *How to Survive Peer Review* by E Wager, F Godlee and T Jefferson [http://resources.bmj.com/bmj/pdfs/wager.pdf](http://resources.bmj.com/bmj/pdfs/wager.pdf)
- OR

You will also find references to the *Academic Writing Handbook*, available on the Student Website under ‘General Resources’ [http://dl.lshtm.ac.uk/programme/epp/docs/Misc%20Docs/Academic%20Writing%20handbook%202010-11.pdf](http://dl.lshtm.ac.uk/programme/epp/docs/Misc%20Docs/Academic%20Writing%20handbook%202010-11.pdf).

**Further reading**

- See also the EQUATOR network site ([http://www.equator-network.org/home/](http://www.equator-network.org/home/)) to learn the latest guidelines on writing various types of paper. Internet technology and increasing expectation of transparency in writing mean that the details required for writing and reviewing papers are continually changing. In this module our aim is to teach you the main principles of telling and critiquing a research story but when writing or reviewing a paper in your work you will need to check both the general guidelines for that kind of paper and the journal’s specific requirements.
Assignments and additional exercise

- Formative Assignment
  We recommend that you complete the two assignments (known as Formative Assignments - FAs). These test your understanding and the feedback given by tutors (and specimen answer) enables you to see how you are progressing. They will also help you prepare for the Assessed Assignment (AA). The FA submission deadline is 31st March if submitting your AA in May or 31st May if you plan to submit your AA in August.

- One additional self assessment exercise is also provided.

- Assessed Assignment
  The Assessed Assignment (AA) consists of two parts i) a paper critique and ii) writing sections of a scientific paper. This is the only assessed element of the module, comprising 100% of the final module grade. There is no exam. See the Module calendar for deadlines.

- Accessing the assignments and exercise
  Assignments should be downloaded from the module page on the course website: http://dl.lshtm.ac.uk/programme/epp/docs/modules/ep105.htm (see website section at the end of this document). Assignments are subject to change each year for all modules so you must ensure you download the assignments corresponding to the year in which you are submitting your assignment for marking. Assignments from previous years will not be accepted.

  Full details of how and when to submit assignments, can be found in Chapter 8 of the Student Handbook.

Web conferencing

- The ‘WebBoard’ is our current web-based conference system* and an integral part of this course, putting you in touch with other students and with tutors on relevant modules. The WebBoard will be open from 1 October onwards until the module exam.

- It is used for:
  - Discussion of module content and queries
    We strongly recommend that you make use of the EP web conferencing system (WebBoard) to discuss issues relating to the course material. This gives an opportunity for you to ask questions and to take part in discussions initiated by fellow students. The conferences are monitored by tutors who will contribute to the discussions.

    There are conferences for use as you work through the study guide, together with a General EPM105 conference, and conferences for discussing FAs and AAs. You may also find the LSHTM Library
Module introduction

support conference helpful in getting advice on accessing and using the online information resources available to you.

You may also email specific queries to the Distance Learning Support Office (dlsupport@lshtm.ac.uk) who will refer your queries to one of the EPM105 tutors.

- **Messages from your Module Organiser and Distance Learning Support Office.** We use WebBoard as the primary means of communication of important messages between students and staff, and in early October, the Student Support Office will subscribe you to the mailing lists for the **EPM105 NoticeBoard (Students).** This conference will be ‘read-only’ with only Course Directors, Module Organisers and Student Support Office staff posting messages in these and it is essential that you read all messages posted there. **Please log on regularly to WebBoard to view this module NoticeBoard, and check you are receiving these messages by email.** Please do this at least once by the end of October at the latest. If you see NoticeBoard messages for this module on WebBoard that have not reached you by email, please contact the Distance Learning Support Office (dlsupport@lshtm.ac.uk).

  * **Accessing WebBoard.**
    Access is via the student website http://dl.lshtm.ac.uk/ (then click on EP). All students studying EP modules should have their own unique username and password to access the EP WebBoard. Please contact the Distance Learning Support Office (dlsupport@lshtm.ac.uk) if you do not have this. For information about using WebBoard in general, please see Chapter 7 of the Student Handbook.

*Please note that we may be upgrading our web conferencing software over the next few months. We will keep you informed of any changes.*

**Website**

- Assignments and additional resources such as list of module tutors, student evaluations etc can be downloaded from the **EPM105 module page** on the student website http://dl.lshtm.ac.uk/programme/epp/docs/modules/ep105.htm.

- There is also a **General Resources page** which includes documents such as the Student Handbook, list of course materials, general exam guidance and some basic maths resources. http://www.lshtm.ac.uk/dl/programme/student/ep/student/general.htm.

- **Accessing the student website.** You will be provided with the username and password to access the website at the beginning of the academic year. Please email dlsupport@lshtm.ac.uk if you do not know these.
Module introduction

Accessing the LSHTM library

A brief introduction is given here. There is also information on accessing materials at the end of Session 2.

If you are looking for a journal article, you first need to search the catalogue (http://unicorn.lshtm.ac.uk/) for the journal then see if we have the publication year or volume you need.

Click on Journal Search option, and then enter the full journal title (not an abbreviation) into the search box. Click search.

Quick Search

Journal Title

A list of journal titles with those words in the title are returned.

Journal of infectious diseases
Infectious Diseases Society of America

Click the Details button to see which volumes we have available and to click through to the electronic journal. Note that the volumes and years available for the print and electronic versions may differ.

EPM105 Writing and reviewing epidemiological papers
Click the link under Electronic access to access TDNet. TDNet is our e-journals portal and it gives you access to all of the Library’s e-journal subscriptions. Click the tick under full-text access to access the School’s subscription.

You will be prompted to enter your username and password.

Use the login you have been provided by the University of London International Programmes. It is the same as you use to access the Student Portal. If you have not received a login, please contact uolia.support@london.ac.uk.
This will take you to the homepage of the journal. Browse the journal archive to find the details of the article you need and open up the full text.

Sometimes you may need to login again on the journal webpage. Look for the institutional login option, select UK Access Management Federation and then LSHTM. You should then be prompted to provide a username and password, again you should use the login information provided by the University of London International Programmes.

Access to databases is also through the Library website http://www.lshtm.ac.uk/library/databases/. You can find guides to individual resources as well as general literature searching guidance at www.lshtm.ac.uk/library/help/help.html.

For further help, there is lots of information online at www.lshtm.ac.uk/library/help/ and a WebBoard conference that you can post questions or comments to.

Finally, a reminder that we are here to help! Do let us know if you have any queries at all – either by posting in the relevant WebBoard conference, or emailing dlsupport@lshtm.ac.uk.

Acknowledgments

Thanks are due to Dr Sonia Saxena, for permission to use her research report entitled ‘Do consultations for childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’

Thanks also to tutors and members of the Library staff who contributed to the Study Guide. The guide was substantially amended for 2011-12.
# Module Specification (Distance Learning)

In collaboration with University of London International Programmes

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Title:</td>
<td>Writing and Reviewing Epidemiological Papers</td>
</tr>
<tr>
<td>2. Module code:</td>
<td>EPM105</td>
</tr>
</tbody>
</table>
| 3. Institution: | Faculty of Epidemiology and Population Health  
London School of Hygiene & Tropical Medicine  
Keppel Street  
London  
WC1E 7HT  
http://www.lshtm.ac.uk/eph/ |
| 4. Module Organisers: | Elizabeth Breeze, Pauline Brocard |
| 5. Mode of study: | Distance learning |
| 6. Type: | Core module |
| 7. Duration and dates: | Deadlines if taken as part of a formal award:  
Application deadline: 30 June each year  
Registration deadline: 31 August each year  
Course registration duration: Up to 5 years  
Course starts: 1 October each year  
Assessment submission by: 31 May or 31 August each year  
Deadlines if taken as an individual module (i.e. not registered for formal award):  
Application deadline: 31 August each year  
Registration deadline: 30 November each year  
Registration duration: 2 years  
Module study starts: 1 October each year  
Assessment submission by: 31 May or 31 August each year. |
| 8. Credit points: | 15 credit points will be awarded on successful completion of this module at Masters level (Level 7). |
| 9. Notional Learning Hours (NLH): | The module should take about 150 hours to complete. On average students will divide these learning hours as follows:  
Directed self-study: 60 hours  
Self-directed learning: 40 hours  
Assessment, review and revision: 50 hours. |
| 10. Aim: | The module aims to provide basic skills for writing epidemiological research papers and searching and evaluating the scientific literature. |
| 11. Learning objectives: | By the end of this module students should be able to:  
1. outline strategies for writing good-quality epidemiological research papers  
2. search and manage the literature and other sources of information in preparation for addressing a specific research question as part of study design, writing a paper, or undertaking a review  
3. specify the principles of systematic reviews and the importance of conducting them, and describe the concept of evidence-based medicine  
4. critically appraise research papers and other sources of information by:  
   - checking the scientific clarity and reproducibility  
   - evaluating the methodological quality  
   - assessing the quality of the presentation  
5. demonstrate the main skills required to act as a referee for a research paper once s/he has the topic and epidemiological knowledge  
6. write a draft of a research paper with appropriate contents and format to demonstrate understanding of the quality and structure required for submission to a peer-reviewed journal. |
### 12. Content:
Module content is structured around the self-study sessions listed below:

<table>
<thead>
<tr>
<th>Session</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Overview of an epidemiological paper</td>
</tr>
<tr>
<td>2</td>
<td>Searching the medical literature</td>
</tr>
<tr>
<td>3</td>
<td>Evaluating the epidemiological literature</td>
</tr>
<tr>
<td>4</td>
<td>Critical evaluation of original papers</td>
</tr>
<tr>
<td>5</td>
<td>Systematic reviews and evidence-based medicine</td>
</tr>
<tr>
<td>6</td>
<td>Peer review of epidemiological research papers</td>
</tr>
<tr>
<td>7</td>
<td>Writing an outline of an epidemiological research paper</td>
</tr>
<tr>
<td>8</td>
<td>Writing the first draft</td>
</tr>
<tr>
<td>9</td>
<td>Revising drafts and preparing the final manuscript</td>
</tr>
<tr>
<td>10</td>
<td>Dealing with the journal</td>
</tr>
</tbody>
</table>

### 13. Learning methods:
Learning is self-directed against a detailed set of learning objectives using the materials provided. The key learning methods are:

- Reading and reflecting on paper-based materials which introduce, explain and apply the principles and methods covered in the module.
- Accessing academic support which is available from the module tutors through the web-based discussion forum in which students are encouraged to participate.
- Completing formative assignment(s) and reflecting on written feedback from module tutors.
- Completing the assessed assignment and reflecting on written feedback from module tutors.

### 14. Study resources provided:
EPM105 Writing & Reviewing Epidemiological Papers, Study Guide & Reader.

**Textbooks:**
- The Pocket Guide to Critical Appraisal (Crombie)
- Winning the Publications Game (Albert) – available as an e-book only.

Registered students have access to the School’s online library resources.

### 15. Assessment procedures:
You will be assessed wholly by the assessed assignment, consisting of two written exercises.

### 16. Prerequisites:
Students should have completed EPM101, EPM102 and EPM103 or have equivalent experience.

Those wishing to study this module must be able to access the internet on average at least once a week to benefit from library facilities, participate in web-based conference discussions and submit assignments.

Students must meet the standard of English required to study this course. See [http://www.lshtm.ac.uk/prospectus/english.html](http://www.lshtm.ac.uk/prospectus/english.html).

### 17. Attendance:
No maximum number

### 18. Selection, if applicable:
This module is compulsory for students registered on the PG Certificate/PG Diploma/MSc Epidemiology courses; alternatively, it can be taken as an Individual Module.

### 19. Fees:
For current schedule of fees see [http://www.londoninternational.ac.uk/fees/schedules/lshtm.pdf](http://www.londoninternational.ac.uk/fees/schedules/lshtm.pdf).

### 20. Scholarships:
None available

### 21. External accreditation:
None

### 22. Application process:
Applications are managed by the University of London International Programmes (website: [http://www.londoninternational.ac.uk/](http://www.londoninternational.ac.uk/)).

### 23. Further enquiries:
Enquiries may be emailed to distance@lshtm.ac.uk.
Overview of an epidemiological paper

Overview

When you sit down to write a research paper, it is often tempting to write a detailed essay on the subject you are addressing, along with descriptions of all the tests you carried out and all the data you collected. However, a scientific research paper is not an unstructured account of everything that you have done and found in a particular study. Rather, a research paper is a tightly structured document with a clear purpose, style and format. This session will discuss the purpose and structure of a scientific research paper. You will also learn the main points that you must clarify before you start to write a paper. Although many of the principles in this study guide are applicable to scientific research papers in general, the emphasis is on the use of reviewing and writing skills in an epidemiological context.

Learning objectives

After working through this session you will be better able to:

- define the purpose of a scientific research paper
- describe the structure of a research paper and explain why this structure is important
- define the main question for a specific research paper
- identify the data relevant to answering the main question for a specific research paper
- define the audience and select the target journal for a specific research paper
- establish authorship for a specific research paper.

Planning your study

For this session you will be reading from one of your textbooks and the documents or websites listed below, and you will carry out a number of activities related to your reading. You will make notes for the paper you will draft in sessions 7-10. To complete the work in this session, you need:

From your module reader:

- Saxena S. Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales;
Session 1: Overview of an epidemiological paper

From websites:


- BMJ information for authors: [http://resources.bmj.com/bmj/authors](http://resources.bmj.com/bmj/authors)

- URM: Uniform Requirements for Manuscripts Submitted to Biomedical Journals:  
  For ethical considerations, including authorship, follow the links within the website  
  [http://www.icmje.org](http://www.icmje.org)

- The LSHTM academic writing handbook  
  [http://dl.lshtm.ac.uk/programme/epp/docs/Misc%20Docs/Academic%20Writing%20handbook%202010-11.pdf](http://dl.lshtm.ac.uk/programme/epp/docs/Misc%20Docs/Academic%20Writing%20handbook%202010-11.pdf)

From ebook via the LSHTM library:

  Library reference:  

Websites for four journals to look at the kinds of articles they contain:

- The British Medical Journal: [http://www.bmj.com/articlearchive/](http://www.bmj.com/articlearchive/)

- The International Journal of Health Services:  

- The International Journal of Epidemiology:  
  [http://ije.oxfordjournals.org/content/by/year](http://ije.oxfordjournals.org/content/by/year)

- Journal of the American Medical Association (JAMA):  
  [http://jama.ama-assn.org/content/by/year](http://jama.ama-assn.org/content/by/year)

You will find that the British Medical Journal (BMJ) is used many times as an example in this study guide. This is mainly because they abide by the ICMJE guidelines and give extensive information on their website. Also, despite ‘British’ in the title it is an international journal.

You should allow yourself approximately seven hours to complete this session. You may want to do the session in more than one sitting. A suitable point to take a break is shown.
**Key terms**

**Impact factor:** A score based on citations of papers in a journal by authors of other papers. It is commonly used as an indicator of prestige of the journal.

**IMRaD:** The acronym for the order in which information is presented in a typical epidemiological paper: Introduction, Methods, Results, and Discussion.

**Peer review:** Process whereby a piece of academic work (manuscripts submitted for publication, grant applications or abstracts submitted for presentation at scientific meetings) is judged for scientific and technical merit by other scientists who are considered knowledgeable about the subject.

In **open peer review** the authors and reviewers are identified to each other. In **closed peer review** the reviewers’ identity is concealed from the authors and sometimes the authors’ identity is concealed from the reviewers.

**Why publish?**

When you have finished collecting and analysing the data in an epidemiological study, you feel ready for a well-earned rest. However, the scientific process is not over yet. Your research will not contribute to epidemiological knowledge nor be applied to the solution of health problems if it remains in a filing cabinet or on a computer disk. Science is a social activity. So, if you want your research to have an impact, you must now communicate your findings to your peers.

You need to decide the purpose and scope of each communication you make, whatever form it takes. Of course a major part of the planning of a data collection exercise – indeed often a prerequisite of funding – is specification of the purpose of the study. However, it is rare that all the findings from one study are put in one communication or targeted at the same audience – which aspects of your study do you want to talk about, (and, once analysed) which message do you want to convey on a particular occasion?

There are several acceptable ways of communicating epidemiological research: you could give a presentation at a conference, write a report for the organization that funded your work, give a briefing to practitioners or policymakers, or publish a research paper in a scientific journal. You can use any of these formats to inform people of your basic findings. However, only publication in a peer-reviewed journal will enable a large audience to critically evaluate your work and assess its importance and applicability. Publishing your research in a peer-reviewed journal is therefore an essential part of the epidemiological process.

There is, of course, another very practical reason for wanting to publish your work. In contemporary academic life, publication is one of the main criteria used to evaluate an epidemiologist’s work. So your career prospects will be influenced by how often you manage to publish papers in high-impact, peer-reviewed journals.
What is a scientific research paper?

Before we begin to look in detail at how to write a research paper, it is important that you have a clear understanding of what an epidemiological research paper is. There are two main types of research paper: primary (or original) research papers and secondary research papers:

- A primary research paper reports original research that has not previously been published.
- A secondary research paper reviews data from a number of studies, many of which have previously been published; a secondary research paper may take the form of an overview, a systematic review, or a meta-analysis. This is to be distinguished from secondary analysis which can use one data set but undertake analyses to look at research questions for which that data set was not primarily designed. This often happens with large data sets such as the WHO demographic surveys or birth cohort surveys that collect information on a wide variety of topics.

In this section, you will concentrate on how to write a primary research paper, and the term ‘epidemiological research paper’ refers only to primary research papers.

ACTIVITY 1

1. First write down what you consider to be the purpose of an epidemiological research paper

2. Turn to Albert and read the section ‘The Scientific Article as Truth’ pages 3-5.

After you have finished reading, briefly note what criteria are used to judge a paper.

Feedback

Your answers should be similar to the ones that follow:

1. The purpose of a scientific paper is to provide:
   (a) an answer to a question or a solution to a problem
   (b) sufficient evidence to enable the reader to assess the validity of the answer and the conclusion.

2. The criteria are broadly-speaking: Original: does the work add anything to knowledge or understanding? Significant: does it represent an important advance? Disclosure: has it appeared in print elsewhere? Is it reproducible: can the work be repeated? Ethical: has it met the agreed standards?” (See Albert page 5.)

The structure of a research paper

For most journals epidemiological research papers are presented in a particular ordered format known as IMRaD. However, authors do not necessarily write in this order – it depends on the way they have been taught and the method they find easiest. In this study guide, you will consider the particular writing order that the
LSHTM authors have found useful; Sessions 7-9 provide a step-by-step guide to writing a research paper in this way.

The basic, conventional format of a research paper is summarized by the acronym IMRaD:

**Introduction** – justifying and specifying the question that you are addressing – “why you are addressing your particular research question”

**Methods** – telling how the answer was sought – “what you did”

**Results** – giving the findings – “what you found”

and

**Discussion** – saying what the findings mean and giving your answer to the study question – “what it means”.

## Preparing to write

**Before** you sit down to write a research paper, it is worth spending some time clarifying what you have to say and to whom you have to say it. If you do not address these issues before you start, then your paper is unlikely to have a clear focus and you may waste considerable time and effort.

The first step in planning your paper is to clarify the following points:

- What main **question** will the paper address?
- What evidence is there to **answer** the main question?
- Who is the **audience**?
- Which is the right **journal**?
- Who are the **author(s)**?

Optional reading: Albert “Winning the Publications Game” section “when to stop researching and start reading” pages17-19.

You will now consider each of these questions in turn.

## What main question will the paper address?

People read research papers to look for answers to specific questions. Ideally, a research paper should only address one main question. If you try to include several very different questions in one research paper, it will be difficult for your readers to separate out the answer to the individual question that they are interested in. Establishing the research question that you aim to answer in this paper is critical because it guides you in data collection, analysis, and writing up. Once you have the data and have analysed it to address that question you should then work out the main message that you wish to get across.
Studies addressing several questions of equal weight

Many epidemiological studies address several different questions of equal importance. Because of this, it may be necessary for you to write several papers, all based on one particular research study, with each paper addressing a different study question.

It is appropriate to write more than one paper about a particular study if each paper addresses a separate question which, on its own, is likely to be of interest to a specific audience.

Example  Mother-to-child transmission of HIV

A study on the mother-to-child transmission of HIV may address the following three questions, each of which would probably merit a separate paper:

- What is the sensitivity and specificity of salivary testing for HIV infection in children born to infected mothers?
- Is breastfeeding a risk factor for mother-to-child transmission of HIV infection?
- Is there an association between mode of delivery and the risk of mother-to-child transmission of HIV infection?

Studies where the main question is multi-faceted

You may find that your main study question can be broken down into a number of more specific sub-questions. If each sub-question is likely to be of interest to the same audience, then you should include them all in a single paper, provided it does not make that paper too long or too complex.

If you write several different papers in these circumstances, then interested readers will have to search for each separate paper to find an overall answer to the main question. However, as each specific question may have a different answer, you should break the main study question down into its component parts when planning your paper.

Example  Nutritional intake during pregnancy

A study on nutritional intake during pregnancy may address the following main study question:

- Does maternal nutrition during pregnancy influence birthweight at term?

This general question can be broken down into the following, more specific questions, all of which could be addressed in a single paper:

- Does fat intake during pregnancy influence birthweight at term?
- Does carbohydrate intake during pregnancy influence birthweight at term?
- Does protein intake during pregnancy influence birthweight at term?
Studies with a main question and a number of related subsidiaries

You may find that you have one main study question and a number of subsidiary questions which address different, but related, issues. If the subsidiary questions will clearly be of interest to the same audience as the main study question but do not merit a paper of their own, you should probably include them in the same paper. In these circumstances, the main study question will provide the focus for the paper.

Example: Specific hormone replacement therapy

A clinical trial on the use of a specific hormone replacement therapy in post-menopausal women might address the following questions, all of which could be addressed in a single paper:

- Main question
  - Does this hormone replacement therapy reduce the incidence rate of coronary heart disease in post-menopausal women?

- Subsidiary questions
  - What are the minor side-effects of this hormone replacement therapy in postmenopausal women?
  - What are the major side-effects of this hormone replacement therapy in postmenopausal women?

ACTIVITY 2

Read: Albert ‘Winning the Publications Game’ section “only one message per article” pages 20-22.

ACTIVITY 3

Turn to the Saxena paper in your reader. Read the ‘Summary’ on pages 5 and 6, and Section 2.1 ‘Aims’ on page 14.

You should also browse through Chapter 1 ‘Background’ on pages 7–13, although you do not need to read this section in detail. While you are reading, concentrate on identifying the main question(s) addressed by the study. Now answer the following questions:

1. What are the main question(s) addressed by this study?
2. Do you think that this study should be written up in more than one paper?
Feedback

1. You may have identified one main study question such as: Does the rate of consultations with a General Practitioner differ for children of different social classes?

   Alternatively, you may have identified three or four more specific questions, such as:

   (a) Does the rate of consultations with a General Practitioner for episodes of common childhood illnesses differ for children of different social classes?
   (b) Does the rate of consultations with a General Practitioner differ according to the severity of the illness for children of different social classes?
   (c) Does the rate of consultation with a General Practitioner for preventive care differ for children of different social classes?
   (d) Does the rate of home visits by a General Practitioner differ for children of different social classes?

   Do not worry if you have stated the questions in a slightly different way.

2. Even if you identified three or four specific questions like the ones above, they can all be encompassed under the main study question: Does the rate of consultations with a General Practitioner differ for children of different social classes?

   Readers would probably prefer all these sub-questions to be addressed in a single paper.

What evidence is there to answer the main question?

You should now be able to identify the new data produced by your study that support an answer to your main study question. Although your study may have collected a wide variety of data relevant to a number of different questions, at this stage you are only interested in the data directly relevant to the main study question that your paper will address. However, if your main study question can be broken down into a number of more specific questions, you should identify the data relevant to answering each specific sub-question. Do not, at this stage, identify the data that answer any subsidiary questions.

You should try to condense the data you identify here into two or three key tables. Do not worry too much at this stage about the presentation of the tables. You will learn how to construct tables suitable for publishing when you write the first draft of your paper (Session 8).

ACTIVITY 4

Turn again to the Saxena paper in your reader. Read Chapter 3 ‘Results’, starting on page 20 and look through the tables in Chapter 4.

You are going to start the preparatory work for a paper ‘Childhood consultation rates in General Practice’, so while you are reading Saxena’s research report, concentrate on trying to identify the data directly relevant to answering the main study question:
‘Does the rate of consultations with a General Practitioner differ for children of different social classes?’

Now undertake the following tasks:

1. Find the tables in the report containing data directly relevant to answering the main study question. Include tables that contain data relevant to each of the sub questions given in Activity 3 feedback 1.

2. Condense the data from these tables into four main tables.

Feedback

1. The relevant tables are:

   Table 4 Consultation rates for any reason by social class
   Table 5a Consultation rates for all illness episodes by social class
   Table 5b Consultation rates for serious illness by social class
   Table 5c Consultation rates for moderate illness by social class
   Table 5d Consultation rates for minor illness by social class
   Table 6 Consultation rates for preventive health care by social class
   Table 7 Consultation rates for infectious episodes by social class
   Table 8 Consultation rates for respiratory illness episodes by social class
   Table 9 Consultation rates for injuries and poisonings by social class
   Table 10 Consultation rates for asthma episodes by social class
   Table 11 Consultation rates for home visits by social class.

2. These tables can be condensed into the following four tables:

Table 1 Mean annual consultation rates per child per year for any reason by social class

<table>
<thead>
<tr>
<th>Social class*</th>
<th>Mean rate</th>
<th>Difference in mean rates</th>
<th>95% Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-II</td>
<td>3.54</td>
<td>ref</td>
<td></td>
</tr>
<tr>
<td>III non-manual</td>
<td>3.95</td>
<td>0.41</td>
<td>(0.23, 0.60)</td>
</tr>
<tr>
<td>III manual</td>
<td>3.95</td>
<td>0.41</td>
<td>(0.27, 0.56)</td>
</tr>
<tr>
<td>IV-V</td>
<td>4.18</td>
<td>0.64</td>
<td>(0.49, 0.80)</td>
</tr>
<tr>
<td>Other</td>
<td>4.15</td>
<td>0.61</td>
<td>(0.33, 0.88)</td>
</tr>
<tr>
<td>Not known</td>
<td>2.43</td>
<td>-1.12</td>
<td>(-0.12, -0.94)</td>
</tr>
</tbody>
</table>

*Registrar General Social Class as used in the UK prior to 2000
Table 2 Mean annual consulting rates and rate differences per child per year by social class for illness, prevention and home visits

<table>
<thead>
<tr>
<th>Social class</th>
<th>Illness</th>
<th>Prevention</th>
<th>Home visits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean rate</td>
<td>Difference in mean rate</td>
<td>P-value</td>
</tr>
<tr>
<td>I–II</td>
<td>2.88</td>
<td>ref</td>
<td>0.53</td>
</tr>
<tr>
<td>III non-manual</td>
<td>3.23</td>
<td>0.36</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>III manual</td>
<td>3.29</td>
<td>0.41</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>IV–V</td>
<td>3.53</td>
<td>0.65</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>other</td>
<td>3.37</td>
<td>0.49</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>not known</td>
<td>1.90</td>
<td>0.08</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 3 Mean annual consultation rates and rate differences per child per year by social class for illness episodes and severity of illness

<table>
<thead>
<tr>
<th>Social class</th>
<th>Minor illness</th>
<th>Moderate illness</th>
<th>Serious illness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean rate</td>
<td>Difference in mean rate</td>
<td>P-value</td>
</tr>
<tr>
<td>I–II</td>
<td>1.87</td>
<td>ref</td>
<td>1.45</td>
</tr>
<tr>
<td>III non-manual</td>
<td>2.13</td>
<td>0.17</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>III manual</td>
<td>2.07</td>
<td>0.14</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>IV–V</td>
<td>2.21</td>
<td>0.27</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>other</td>
<td>2.25</td>
<td>0.24</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>not known</td>
<td>1.39</td>
<td>−0.57</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 4 Mean annual consultation rates and rate differences per child per year by social class for infectious diseases, asthma and accidents and poisoning

<table>
<thead>
<tr>
<th>Social class</th>
<th>Infectious diseases</th>
<th>Asthma</th>
<th>Accidents and poisoning</th>
<th>Respiratory illness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean rate</td>
<td>Difference in mean rate</td>
<td>P-value</td>
<td>Mean rate</td>
</tr>
<tr>
<td>I–II</td>
<td>0.35</td>
<td>ref</td>
<td>0.18</td>
<td>ref</td>
</tr>
<tr>
<td>III non-manual</td>
<td>0.42</td>
<td>0.07</td>
<td>&lt;0.019</td>
<td>0.20</td>
</tr>
<tr>
<td>III manual</td>
<td>0.42</td>
<td>0.08</td>
<td>&lt;0.001</td>
<td>0.21</td>
</tr>
<tr>
<td>IV–V</td>
<td>0.50</td>
<td>0.15</td>
<td>&lt;0.001</td>
<td>0.20</td>
</tr>
<tr>
<td>other</td>
<td>0.48</td>
<td>0.13</td>
<td>0.002</td>
<td>0.18</td>
</tr>
<tr>
<td>not known</td>
<td>0.24</td>
<td>−0.10</td>
<td>&lt;0.001</td>
<td>0.08</td>
</tr>
</tbody>
</table>

This would be a good point to take a break if you wish.
Who is the audience?

Whenever you write anything, you do so with an intended audience in mind. You would not write for a group of neurologists or for patients in the same way as you would write for a group of epidemiologists, or health planners. So it is important that you clarify the potential audience that your paper is aimed at 

*before* you start writing.

To identify the audience that is likely to be interested in your paper, you should ask yourself who would be interested in the answer to your main study question. Your potential audience may be quite a small group of specialized professionals, or a large number of different groups of people with different professional and technical backgrounds.

ACTIVITY 5

For the paper you are preparing, ‘Childhood consultation rates in General Practice’, who do you think would be interested in the answer to the main study question:

‘Does the rate of consultations with a General Practitioner differ for children of different social classes?’

Feedback

The answer to this particular research question may be of interest to a wide audience, especially in England and Wales. Groups likely to be interested include:

- General Practitioners and other primary health care workers
- Public health professionals and other health planners
- Paediatricians
- Epidemiologists
- Social scientists
- Politicians.

Which is the right journal?

Once you have identified the potential audience for your paper, you should decide which journal is likely to reach your target audience. Again, it is extremely important that you decide which journal you plan to submit your paper to *before* you start writing. If you tailor the style and the content of your paper to the requirements of a specific journal, you will increase your chances of getting your paper accepted.
ACTIVITY 6


After you have finished reading, answer the following questions.

1. What questions should you ask when considering a journal?

2. How can you judge a journal’s quality and influence?

3. How can you obtain answers to these questions? (This is not addressed specifically in this article but one to which you may know the answer.)

Feedback

1. Two tables of checklists are given on p1076 of the article. The questions that you should ask when considering a potential journal can be rephrased to include:

   (a) Is the topic of the proposed paper within the scope of this journal?
   (b) Does the journal publish the type of paper you wish to write (e.g. review, short technical article, original research)?
   (c) Would this journal offer the best match of audience with that topic?
   (d) Does this journal publish an information-for-authors page?
   (e) Is the delay between submission and publication (if accepted) reasonable?
   (f) Is it costly to publish in the journal?

   Thompson also includes support of the sponsoring organisation of the journal but that is unlikely to be a major concern at present.

2. You can judge a journal’s quality and influence by looking up the ‘impact factor’ of the journal in the Journal Citation Reports (JCR). The impact factor indicates the average number of times a journal’s papers are cited in other journals covered by the Science Citation Index in a particular year.

   You should not necessarily choose to try to publish in the journal with the highest impact factor: competition for publication in these journals is likely to be particularly high. You should probably try to publish in a journal with a very high impact factor if you think that your paper is excellent and original, but aim for a lower impact journal for a less outstanding paper. If your institution is registered, you may be able to access the JCR on the Internet via http://wokinfo.com/products_tools/analytical/jcr/ (you should be able to access via LSHTM if your own institution is not registered). A pdf explaining the various metrics can be obtained (without institutional login) via http://wokinfo.com/media/pdf/jcrwebfs.pdf .

3. You can obtain answers to these questions by:
   (a) looking at recent issues of the journal (over the past year approximately)
   (b) looking at the information-for-authors web-pages of the journal.
**ACTIVITY 7**

Read the information about four journals (BMJ, IJE, IJHS, JAMA), given overleaf.

On the internet look at some recent contents pages of the same four journals (urls given at the beginning of this session) and also look to see if they have topics collections and, if so, the subjects of these.

Now answer the following questions.

1. For each of these journals:
   
   (a) Is the topic of the paper ‘Childhood consultation rates in General Practice’ within the scope of the journal?
   
   (b) Do you think that the journal is likely to reach the target audience groups defined in Activity 5?

2. To which of these journals would you submit this paper?

The following information is taken from the journal websites.

**British Medical Journal**

The BMJ (British Medical Journal) is an international peer reviewed medical journal and a fully “online first” publication. Our publishing model—“continuous publication”—means that all articles appear on bmj.com before being included in an issue of the print journal. The website is updated daily with the BMJ’s latest original research, education, news, and comment articles, as well as podcasts, videos, and blogs.

All the BMJ’s original research is published in full on bmj.com, with open access and no limits on word counts. The BMJ’s vision is to be the world’s most influential and widely read medical journal. Our mission is to lead the debate on health and to engage, inform, and stimulate doctors, researchers, and other health professionals in ways that will improve outcomes for patients. We aim to help doctors to make better decisions. The BMJ team is based mainly in London, although we also have editors elsewhere in Europe and in the US.

About 1.67 million unique users download 6.1 million pages from bmj.com each month (ABCe audit, October 2010).

*Under instructions for authors, they also add:*

The BMJ’s mission is to lead the debate on health, and to engage, inform, and stimulate doctors, researchers and other health professionals in ways that will improve outcomes for patients. We aim to help doctors to make better decisions.

To achieve these aims we publish original research articles, review and educational articles, news, letters, investigative journalism, and articles commenting on the clinical, scientific, social, political, and economic factors affecting health. We are delighted to consider articles for publication from doctors and others, and from anywhere in the world.

We can publish only about 7% of the 7000-8000 articles we receive each year, but we aim to give quick and authoritative decisions. For all types of article the average time from submission to first decision is two to three weeks and from acceptance to publication eight to 10 weeks. These times are usually shorter for original research articles. We reject about two thirds of all submissions without sending them for external peer review, but many authors tell us they appreciate quick decisions that allow them to submit their work elsewhere without delay.

We also audit the performance of BMJ research articles, using a wide range of indicators to assess their impact on readers, and their dissemination to the wider world.

**Impact factor 2010: 13.47**
International Journal of Epidemiology (IJE)
The *International Journal of Epidemiology* is an essential requirement for anyone who needs to keep up to date with epidemiological advances and new developments throughout the world. It encourages communication among those engaged in the research, teaching, and application of epidemiology of both communicable and non-communicable disease, including research into health services and medical care. Also covered are new methods, epidemiological and statistical, for the analysis of data used by those who practise social and preventive medicine. The *International Journal of Epidemiology* is published six times yearly.
Impact factor 2010: 5.759

International Journal of Health Services (IJHS)
The *Journal* contains articles on health and social policy, political economy and sociology, history and philosophy, ethics and law in the areas of health and health care. The *Journal* provides analysis of developments in the health and social sectors of every area of the world, including relevant scholarly articles, position papers, and stimulating debates about the most controversial issues of the day. It is of interest to health professionals and social scientists interested in the many different facets of health, disease, and health care.

Of the major English-language health policy journals, the *IJHS* ranks in the top five for frequency of citation of its articles in the scientific literature.
4 issues yearly
Impact Factor 2010: 0.869

JAMA – Journal of the American Medical Association

**Key Objective**
To promote the science and art of medicine and the betterment of the public health.

**Critical Objectives**
1. To maintain the highest standards of editorial integrity independent of any special interests.
2. To publish original, important, well-documented, peer-reviewed articles on a diverse range of medical topics.
3. To provide physicians with continuing education in basic and clinical science to support informed clinical decisions.
4. To enable physicians to remain informed in multiple areas of medicine, including developments in fields other than their own.
5. To improve health and health care internationally by elevating the quality of medical care, disease prevention, and research.
6. To foster responsible and balanced debate on issues that affect medicine and health care.
7. To anticipate important issues and trends in medicine and health care.
8. To inform readers about nonclinical aspects of medicine and public health, including the political, philosophic, ethical, legal, environmental, economic, historical, and cultural.
9. To recognize that, in addition to these specific objectives, THE JOURNAL has a social responsibility to improve the total human condition and to promote the integrity of science.
10. To achieve the highest level of ethical medical journalism and to produce a publication that is timely, credible, and enjoyable to read.

JAMA's acceptance rate is approximately 9% of the nearly 6000 solicited and unsolicited manuscripts it receives annually; its average time from submission to publication.
Impact factor 2010: 30.01
Feedback

1. Your answers should look something like the following:

British Medical Journal:
(a) Yes. This journal covers papers on social factors affecting health and publishes papers on this topic several times a year. It has topic collections on health services and on social conditions and disease (the latter within the public health heading).
(b) This journal is likely to be read by a wide range of health professionals including General Practitioners, public health professionals, paediatricians and epidemiologists. As the journal covers a wide range of issues, it is likely to reach people both with and without a prior interest in social inequalities and health. It has a very large readership in Britain.

International Journal of Epidemiology:
(a) Yes. This journal covers papers on health services and medical care and has published many papers on social factors affecting health.
(b) This journal is likely to be read by epidemiologists and public health professionals, especially those with an interest in methodological issues. It is likely to reach people both with and without a prior interest in social inequalities and health.

International Journal of Health Services:
(a) Yes. This journal covers papers on health and social policy, and often publishes papers on social implications of health services or on health inequalities.
(b) The readership of this journal is likely to include social scientists and health professionals who have a prior interest in the social and political issues surrounding health and health care.

but it has a low impact factor.

JAMA:
(a) Possibly. It has occasional articles on primary health care and has a topic collection on women’s health, implying some interest in inequalities but the social implications of health care do not seem to be a major focus.
(b) This journal is primarily aimed at medics.

Other points:

Its very high impact factor and its acceptance rate is slightly higher than the BMJ — but there is no point in submitting to a high impact journal if the topic is inappropriate.

As it is linked to the American Medical Association there may not be a great deal of interest in the UK health system.

2. There is no ‘right’ or ‘wrong’ journal for this paper. It would be reasonable to prepare this paper for submission to any of the first three journals. In real life, you would have to make a judgement about which journal to submit the paper to. When making your decision, you should take into account the following questions:
(a) How important is it for you to reach an audience of both clinicians and non-clinicians?
(b) Is the paper mainly research or policy orientated?
When you have decided on your target journal, you should study the information-for-authors pages of the journal website.

**ACTIVITY 8**

Why do you think you should read the information-for-authors pages before writing a paper? Give at least three reasons.

**Feedback**

There are at least four good reasons to read the information-for-authors pages before you start to write:

(a) to ensure that the topic and format of your paper are suitable for the journal
(b) to check any restrictions on the length of the paper and abstract and the numbers of tables, illustrations and references
(c) to check any additional requirements for the structure and content of the paper
(d) to learn the procedures for submitting the manuscript (usually online).

Sending your paper to an inappropriate journal will waste the time of you, your co-authors, and the journal editors.

This would be a good point to take a break if you wish
ACTIVITY 9

Suppose that you have now decided to prepare the paper on ‘Childhood consultation rates in General Practice’ for submission to the British Medical Journal (BMJ). Turn to the information-for-authors pages from the BMJ.

Read the part headed “How to submit your article to the BMJ” on http://resources.bmj.com/bmj/authors/article-submission

Read the first two sections under the heading “How to prepare BMJ original research articles (full versions)” within http://resources.bmj.com/bmj/authors/types-of-article/research

Finally, look at the section on “structured abstract” (you may have to scroll a long way down the page to find this). Answer the following questions:

1. How should articles be submitted?
2. Is there a maximum length for a research paper submitted to the BMJ?
3. What is the BMJ’s online policy?
4. How long should the abstract be?

Feedback

1. Articles are submitted electronically to the journal's web-based submission and manuscript tracking system. Most international medical and epidemiological journals now require electronic submission.

2. There is no maximum length (they used to have a 2000 word limit when there were only printed papers). Authors are encouraged to produce concise papers. The web is now the principal location of BMJ articles, the paper version contains abridged 1-page versions known as PICO.

3. Papers are put on the website as soon as they are accepted and edited. Many research articles are open access i.e. you do not need an institutional licence to access them.

4. The abstract should be no more than 250 words long.

Who are the author(s)?

You may have planned, carried out and analysed your research on your own. If you are also going to write your paper alone, you will be the sole author. This situation is rare. It is more common for several researchers to have been involved in the research process. In these circumstances, it is important that you decide who will be the authors of the paper before you start writing. Unless a paper is very long or detailed it is often most efficient for one person to prepare the first draft after discussion with co-authors about the content and what should be the main message that the paper is aiming to convey.

At this stage, you should also define the exact role of each co-author in the writing process.
ACTIVITY 10

Read the following about authorship [http://www.icmje.org/ethical_1author.html](http://www.icmje.org/ethical_1author.html) then answer the following question:

What are the main criteria that an author should fulfil?

**Feedback**

An author should be able to take public responsibility for the intellectual content of the paper and have participated in all the following:

- substantial contribution to the conception and design of the work, to the acquisition of data, or to the analysis and interpretation of the data, or combinations of these
- drafting the article or revising it for critically important content
- final approval of the version to be published.

Not all journals follow the International Committee of Medical Journal Editors (ICMJE) guidelines on authorship. Some journals have less strict rules, but may ask you to state explicitly the contribution of each author in the research and writing process. Consult the information-for-authors web-pages of your target journal to establish which rules to follow. The ICMJE rules are followed by the BMJ. The BMJ also lists contributors, giving details of how each contributed to the work.

ACTIVITY 11

The list below shows the contributions of five people who participated in a hypothetical research study. For each of these participants, state whether they should be included as an author of the paper, or only be mentioned as contributors or in the acknowledgements:

- **Dr A** – suggested the specific question to be answered, supervised the data analysis, made substantial changes to the first draft of the paper and approved the final version.
- **Mr B** – collected data, performed the laboratory assays, read the first draft of the paper and suggested changes in the way the data were presented.
- **Ms C** – carried out the statistical analysis.
- **Ms D** – collected and analysed the data, wrote the first draft of the paper and approved the final version.
- **Dr E** – suggested the research methods.
Feedback

Dr A and Ms D fulfilled the criteria for authorship (both participated in the three steps required of an author).

The other three participants should feature as contributors or in the acknowledgements: Mr B, Ms C, Dr E, (they did not participate in all the three steps required of an author). Note that Mr B and Ms C contributed significantly to the study and it is rather unfortunate that they may not appear as authors. In most situations they would be expected to be involved in writing and approving the manuscript and therefore appear as authors.

Managing co-authorship

Once you have identified who you think the co-authors should be, you should check that everyone involved agrees with your decision. At this stage, you should also make sure that all the co-authors agree on the following points:

- the order in which the authors’ names will appear
- the main study question that the paper will address
- the target journal
- the role of each co-author in the writing process
- the process for reading drafts, giving feedback and approving the final manuscript.

The order of authors matters more in some disciplines than others but, generally speaking, to be first author carries more credit that authors later in the list – and it is the first author who does most of the work on the paper. The last author is sometimes reserved for the principal investigator or most senior author who has a wider responsibility for the study or department from which this research comes. In between, authors are listed in order of importance of contribution, which the co-authors have to decide amongst themselves.

Some journals now also request that one or more authors take on the role of “guarantor”, i.e. that they take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information. This is not necessarily the first author – sometimes the senior author takes on this responsibility if the first author is a temporary member of the team or is in the very early stages of their career.

If these issues are clearly defined before you start writing, you are less likely to encounter difficulties later on.
**Ethical issues**

Ethical issues are as relevant to writing up as they are to the conduct of research.

One major issue that is a concern of all journals is plagiarism. Plagiarism is dealt with in detail in the *Academic Writing Handbook* that all students should read (available on the Student Website under “General Resources” [http://dl.lshtm.ac.uk/programme/cpp/docs/Misc%20Docs/Academic%20Writing%20handbook%202010-11.pdf](http://dl.lshtm.ac.uk/programme/cpp/docs/Misc%20Docs/Academic%20Writing%20handbook%202010-11.pdf)).

**ACTIVITY 12**

Think through any aspects of writing or reviewing papers that could, in your opinion, be done unethically. Note them down.

Then read the sections on Ethical Considerations from the URM (url at beginning of this session).

Amend your list in the light of this.

**Feedback**

Some of the issues are:

- Fulfilling authorship criteria
- Fair peer review – transparent procedures
- Conflicts of interest that could bias the writing
  - Author's links with commercial interests
  - Sponsors' interference
  - Peer reviewers and editors having no conflict of interest
- Privacy and confidentiality of participants
- Privacy of author and reviewer unless explicitly open peer review and parties agreed to this (see Session 6)
- Experimental procedures that accord with the Helsinki declaration.

Although not listed under the heading of ethical considerations the section "obligation to publish negative studies" under ‘Publishing and Editorial Issues) is also relevant.

Others not mentioned in the above reading:

- Releasing results before they have been critiqued by a competent body
- Withholding information of public health [or clinical] importance once it has been reviewed by a competent body
- selecting information to ‘agree’ with one’s point of view and withholding information that contradicts it
- conduct work with honesty, integrity and on the basis of respect, beneficence (doing good to others) and justice
- unnecessary duplication of work.

Conflict of interest can be subtle. The author should specify financial and personal relationships with commercial companies or with others who have an interest in the results even if they do not see them as biasing their views. Sometimes a strong belief in a hypothesis and enthusiasm for a subject can sway the way that findings are interpreted and authors need to be on guard against this.
The BMJ note the following in their editorial policy:

“Editorial appraisal of ethical issues goes beyond simply deciding whether participants in a study gave informed consent although this is, of course, one very important issue to consider. Editors should judge whether the overall design and conduct of each piece of work is morally justifiable, as summed up by the following questions:

- How much does this deviate from current normal (accepted, local) clinical practice?
- What is the (additional) burden imposed on the patients (or others)?
- What (additional) risks are posed to the patients (or others)?
- What benefit might accrue to the patients (or others)?
- What are the potential benefits to society (future patients)?”

Source: from [http://resources.bmj.com/bmj/authors/editorial-policies/guidelines](http://resources.bmj.com/bmj/authors/editorial-policies/guidelines)

To help fulfil ethical criteria, there are institutions in many countries that vet projects and there are registers of clinical trials.

**Writing style**

Session 9 of this study guide includes some advice on prose and writing style e.g. appropriate wording, keeping sentences short, correct tense. There are also some tips in Chapter 1 of the LSHTM *Academic Writing Handbook*. However, neither of these claim to be comprehensive and you may wish to look at other sources. There are many websites with examples of poor and good use of words, sentence construction etc e.g.

- BMJ House style on [http://resources.bmj.com/bmj/authors/bmj-house-style](http://resources.bmj.com/bmj/authors/bmj-house-style)
- The Plain English Campaign [http://www.plainenglish.co.uk/](http://www.plainenglish.co.uk/). There are various free leaflets on grammar and punctuation to download.
Summary

The purpose of a scientific paper is to provide:
- an answer to a question or a solution to a problem
- sufficient evidence to enable the reader to assess the validity of the answer and the conclusion.

To achieve this purpose, the author of a scientific research article must first state the question the paper addresses. A clear question is essential for a good paper. The author should then provide appropriate evidence to convince the reader that the answer to the question and the conclusions drawn are correct.

The structure and basic format of a research paper is summarized by the acronym IMRaD:

- **I**ntroduction (What question did you ask? Why did you ask it?)
- **M**ethods (How was the answer sought?)
- **R**esults (What were the findings?)
- and
- **D**iscussion (What do the findings mean? What is the answer to the study question?)

Before starting to write, you should clarify the following five points:
- What main **question** will the paper address?
- What evidence is there to **answer** the main question?
- Who is the **audience**?
- Which is the right **journal**?
- Who are the **author(s)**?

Additional references

The additional references given at the end of sessions are for your use should you wish to explore a topic further.

- Guidance from the BMJ as to why it is not always appropriate to submit there. [http://resources.bmj.com/bmj/authors/authors/checklists-forms/is-bmj-the-right-journal-for-my-research-article](http://resources.bmj.com/bmj/authors/authors/checklists-forms/is-bmj-the-right-journal-for-my-research-article)
- IEA’s (International Epidemiological Association) *Good Epidemiological Practice*, available via [www.ieaweb.org](http://www.ieaweb.org)
- Roig M (2006) *Avoiding plagiarism, self-plagiarism, and other questionable writing practices: a guide to ethical writing*. [http://facpub.stjohns.edu/~roigm/plagiarism/Index.html](http://facpub.stjohns.edu/~roigm/plagiarism/Index.html). There is a link to Roig on the Equator network website as well as other documents on ethics.
Session 2

Searching the medical literature

Overview

An important component of any scientific research project is the literature review. A literature review is a systematic search and interpretation of the literature on a specific topic. You need a thorough knowledge of the existing literature in order to identify study questions that require answering, develop feasible methods for answering them, interpret the meaning of the results of your study and write a research paper.

In order to conduct a literature review, you must first do a literature search. In this session, you will learn how to carry out a literature search to identify literature relevant to your specific topic.

Learning objectives

By the end of this session, you should be able to:

- state when and why you should carry out a literature search
- define a search question and the extent of a specific literature search
- select the appropriate sources of data for a specific literature search and know where to find information on how to use these sources
- choose appropriate keywords and subject headings to search on your chosen topic
- conduct a comprehensive search on your topic, using one of your selected sources
- find the full-text of relevant items identified in your search
- record your literature search.

Planning your study

In this session, you will be working through thirteen activities related to searching the literature. To carry out these activities, you will have to become familiar with the search resources that you have available to you. You will be able to use your University of London password to access the LSHTM Library e-resources.
To complete the work in this session, you need:

- Access to the LSHTM Library webpages, particularly the Online Help-sheets and Tutorials pages (www.lshtm.ac.uk/library/help/help.html).
- Pubmed and other sources of information.
- Your University of London portal username and password.

The time you take to complete this session will depend on the search resources you have decided to use and how long it takes you to access them. You should expect to take at least six hours to complete this session. You may take much longer but it is worth pursuing as these skills will be needed time and again in epidemiological research. A suitable stopping point is indicated if you want to do it in two parts.

**Key terms and acronyms**

**Boolean Operators:** Boolean logic is a system of logic that symbolically represents the relationships between search terms. The Boolean operators AND, OR and NOT indicate how you want terms treated in relation to each other in a search. (The term Boolean comes from the British mathematician and logician Charles Boole, 1815-1864.)

**CDC:** acronym for the Centers for Disease Control, Atlanta, USA.

**Grey literature:** literature that is not formally published by a commercial publisher.

**HINARI:** Programme funded by the World Health Organization and a variety of publishers to provide free or low-cost access to medical information to not-for-profit institutions in low-income countries.


**ISSN:** acronym for International Standard Serial Number.

**MeSH:** acronym for Medical Subject Headings, the vocabulary that is used to index a number of databases.

**NLM:** acronym for National Library of Medicine.

**NGO:** acronym for non-governmental organisation.

**Proximity Searching** allows you to search for specific words in the title or abstract of items which appear close to each other, but not necessarily side by side.

**SCONUL:** acronym for Society of College, National and University Libraries, a consortium of libraries in the UK.

**Subject Headings:** A system that is used in a number of databases to index items by topic. Each database uses its own system. MeSH is the system used by the NLM databases.
**Truncation:** A search technique that allows you to retrieve items containing variations on a search term. To execute a truncation search, type the first few letters (stem) of the keyword followed by an asterisk (*).

**WHO:** acronym for the World Health Organisation.

**Wildcards:** a search technique that is often used by databases to allow you to search for variations in spelling of a search term. How this is executed depends on the database you are searching.

---

**What is a literature search?**

A literature search is a systematic, thorough, detailed and organised, step by step search for all the material available on a topic.

---

**When should you carry out a literature search?**

A literature search is not something that you carry out at one fixed point in a research study. Rather, you will need to carry out many literature searches during the design and conduct a study, and when writing the results of a study into a research paper. At each stage you are looking for slightly different information from the literature search.

---

**ACTIVITY 1**

Think about some of the reasons for searching the literature during the following four stages of a research study:

1. **Before starting**
2. **While writing the study protocol**
3. **During the study**
4. **While writing a research paper.**

**Feedback**

Here are some reasons for searching the literature at these four stages in a research study. You may have thought of some others.

1. **Before starting:**
   - To increase your breadth of knowledge of the subject area; to identify other researchers working in the subject area; to identify seminal works in the subject area; to identify questions, controversies or gaps in the existing literature.

2. **While writing the study protocol:**
   - To identify work that helps justify the study (importance of study question, originality of study, timeliness of study); to obtain background data relevant to selecting a suitable study population; to obtain background data for estimating the required sample size; to identify potential confounders and effect modifiers; to identify methods that may be useful for your study; to identify potential problems that may occur in your study and strategies for overcoming them.
3. During the study:
   To identify alternative methods useful for the study; to identify strategies for
   overcoming problems; to compare results with those of others; to identify works
   that help you interpret your results.

4. While writing a research paper:
   To identify new materials in the subject area; to compare your results with those of
   others; to identify work that helps you interpret your results.

The five-steps to an effective literature search

This session will take you through the following five steps to an effective literature
search. Following these five steps will ensure that your search is comprehensive, can
be reproduced, and is without bias.

1. Define your search topic
2. Choose the resources to search
3. Choose your search terms
4. Compile your search strategy and run your search
5. Find the full text materials generated from your search.

Step 1: Define your search topic

Before you start a literature search, you need to have a clear idea about what you are
searching for and what the extent of the search will be. The large amount of
scientific material available means that you should be very focused and selective
when reading or scanning scientific texts.

Asking questions

The first step in any literature search is to clarify what you are searching for. If you
do not do this, your search will be vague and unfocused. In order to focus, it helps
to turn your research topic into a series of questions that you are trying to find the
answers to. You will find that you will have a number of questions that you need to
answer and that each question will require a different search.

Sometimes you may be looking for a very specific piece of information, in which
case it is easy to construct your search question. At other times, particularly when
you are defining your study question for a new study, you may start off with a very
broad search question that you will refine as your search progresses. Remember that
no search aims to collect all the information required for a particular research study.
You will have to carry out a number of focused searches, each one aimed at
answering a different search question.
Example
When planning a study on the vertical transmission of HIV infection, you may ask the following search questions, amongst others:

- at the start: What is the current state of knowledge about the vertical transmission of HIV infection?
- when calculating required sample size: What is the prevalence of HIV infection in infants born to HIV positive mothers?
- when planning data collection methods: In previous studies of vertical transmission of HIV infection, what methods have been used to detect antibodies to HIV in infants?

To help you turn your topic into questions, you might find it useful to think about the following:

**Population**: what is it about the population you are interested in which makes them different from the general public?

**Intervention/Exposure**: What do you want to do with these people? Maybe you want to give them a drug, ask their opinion, or update policy?

**Outcome**: What is it you are trying to achieve in your study?

ACTIVITY 2

Define a research question on a subject of your choice.

Feedback

This first literature search will probably be aimed at helping you identify gaps in the literature or areas of controversy that will help you develop your study question (see EPM103/1.2). Don't forget that your search question should be short and focused. This first search will not be exhaustive. You will probably need to refine your search question and carry out other searches before you fully develop your study question.

Define the extent of your search.

Before every search, you should spend some time determining exactly what information you are looking for, in other words, defining the extent of your search. These are often called ‘search limiters’ or ‘inclusion and exclusion criteria’. Think about:

- **What is your topic?** How are you defining your parameters? Can you clearly define what each of the areas are?
  
  For example, if you are interested in respiratory disease, are you interested in all respiratory diseases or specific ones? Why?
• **What sort of information do you need** to answer your questions? An overview? Academic, peer-reviewed research? Statistics? Reports? Webpages? Current, ongoing research? Theses? To find these different types of information you will need to go to different places.

• **Which areas of the world are you interested in?** Is the location important? Are you interested in a particular country or region or environment type (e.g. urban vs. rural)?

• **Is there anything about the population that is important?** Would gender, ethnic background or age, etc. impact on the relevance of the information you find?

• **How recent do you need the information to be?** You should define the dates of the literature you will search. What is the earliest date of publication (or production) that you are interested in and what is the latest date? The time period that is relevant to your search will depend on what you are searching for. For example, if you are trying to identify the methods that have been used to detect antibodies to HIV in infants, there is no point searching the literature prior to the advent of tests for antibodies to HIV. If you are looking for review articles, you may want to restrict your search to the last few years, so that you can identify the most up-to-date reviews. However, it is generally best to start with a broad time period and then restrict it only if you find you are identifying too many articles.

• **Which languages may be important?** You should carefully consider which language(s) you can deal with in your search. You will probably want to include all the languages that you can read competently. However, you should also consider the implications of omitting other languages from your search. If important articles or reports relating to your search question are likely to be written in a language that you cannot read, you may want to include that language, and pay someone to translate the abstracts of the documents that you find. For example, if you are carrying out research on a health problem in Latin America, you are likely to miss important information if you do not search in Spanish and/or Portuguese in addition to English.

Some articles that are not written in English have an English abstract. To avoid missing such articles, you may want to search in all languages at the beginning of your search and only limit languages at a later stage.

Note: How and where you search will be determined by the nature of the information you are looking for. Very few people spend enough time thinking about this.
ACTIVITY 3

Define the search limiters for the question posed in Activity 2. Remember to include the following limits:

- Geographical area.
- Time period
- Language

Feedback

Do not worry if you are not sure about some of the limiters just now, once you learn more about your subject you will be able to apply these with more confidence.

Choosing search concepts

Once you have a question, you can split each question into subject areas, or concepts covered by that question. Your search concepts are the topics included within the question. If you are asking a clinical question, concepts can be determined using the PICO model (see below):

- **Population**: what is it about the population you are interested in which makes them different from the general public?
- **Intervention/Exposure**: What is it you want to do with these people? Maybe you want to give them a drug, ask their opinion, or update policy…?
- **Comparison**: Do you want to compare one intervention/exposure with another or with placebo? This is optional but often useful.
- **Outcome**: What is it you are trying to do? What change are you trying to achieve?

**Example**

My question is: “What is the current state of knowledge about the vertical transmission of HIV infection?”

In order to find information to answer this question, I need to find items covering two subjects simultaneously. These are the search concepts:

HIV infection
Vertical transmission

If an item does not cover both of these subjects, it is not going to answer my initial question.

ACTIVITY 4

Choose the search concepts for the question you set in Activity 2.
Feedback

You should have at least two concepts. If you have more than four, your question is too complex. In this case, try splitting your question into two separate questions, or making your topic less complicated.

Step 2: Choose the resources to search

Once you have defined your search question and the extent of your search, you need to decide which tools you are going to use to find the relevant information.

Searching for peer-reviewed academic literature

Databases are electronic indexing tools that store and provide access to large amounts of bibliographic data. They are the best tools to use to find peer-reviewed academic literature. There are hundreds of databases available, some are free for anyone to use and some require a subscription and access via a username and password. Some contain information on all academic subjects, others have a very specific subject focus. Some contain information on one type of information only (e.g., peer-reviewed journal articles or PhD theses), while others provide references to a number of different types of information.

Details of all of the bibliographic databases available from LSHTM Library are available on the Library databases webpages (www.lshtm.ac.uk/library/databases/databasesall.html).

Which databases you choose to search will depend on the topic of your search and the type of information you are looking for. The ‘About This Database’ link underneath the name of each database gives further information on the subject coverage and types of information included in each source.

The table overleaf gives some information on the databases, which you may find useful. This is not an exhaustive list, it is recommended that you spend time reading the ‘About This Database’ links on the Library website to familiarise yourself with the most useful databases for you. In particular, some of the subject- or geographically-specific resources may be of use to you.

In order to obtain a comprehensive set of search results, you should search as many resources as are applicable to your search topic. There will inevitably be some overlap between results obtained from each source, however much of the information contained in a source will be unique.

It is recommended that you start searching on a source you are familiar with or feel most comfortable with. Refine your search until you are confident you have found all of the relevant results from that source. Then you can use this successful search strategy as the basis of your search on the next database.
Searching for grey literature

Grey literature is information which is not formally published by a recognised publisher. It includes items such as NGO reports, official government publications, PhD theses, conference proceedings, and patient information, etc. The grey literature tends to be less well indexed and more difficult to search than the published literature. A large number of databases, including many of the NLM databases, contain some ‘grey’ materials such as reports and conference proceedings. However, the coverage in these databases is often patchy. You should consult the selection criteria and sources for each database to establish whether any of these types of documents are included and how extensive the coverage is likely to be.

A list of the databases which include grey literature is given on the Library website at www.lshtm.ac.uk/library/databases/database_grey.html. The New York Academy of Medicine Grey Literature Report and ELDIS are particularly useful. (ELDIS is an information service provided by the Institute of Development Studies at Sussex University, England. Its aim is to support evidence-based development knowledge). If you know which agencies are active in your subject area, search their website to see if they have published any literature online.

ACTIVITY 5

Use the table below and the list of databases on the LSHTM Library website to decide which databases cover the topic you defined in Activity 2.

Feedback

If you are unsure which databases to use, it is good to start with MEDLINE and Embase. Regardless of your topic, you will find useful information in these databases, as they cover all general health and medical subject areas.

Unpublished literature

The only way to get access to unpublished data is to contact the researchers or organisations directly. To increase your chances of getting a reply, you should be very clear about what you are asking for. For example, you may want to ask published authors if they have updated the results of ongoing studies or if they know anyone else who is doing work in the area. You could ask conference participants for further details of the work they have presented. In either case, try to ask specific questions about their work e.g. for an abstract of a particular study or an explanation or reference to a specific method used by the researcher, rather than generic queries such as “any information on a wide topic”. If you are trying to collect unpublished data in a systematic way, you could draw up a list of standard questions or even a short questionnaire to send to a number of researchers.
Table 1 Comparison of databases covering epidemiology

<table>
<thead>
<tr>
<th>Name</th>
<th>Subject coverage</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Health/Global Health Archive</td>
<td>International public health</td>
<td>The most comprehensive public health database.</td>
<td>Subject headings are rather general so can return lots of irrelevant results.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Very good international coverage.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Information from 1910 to present.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Available via the OvidSP interface.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Available from any PC, just enter your portal username and password.</td>
<td></td>
</tr>
<tr>
<td>Medline</td>
<td>Medicine and biomedicine, including veterinary</td>
<td>Wide coverage of most topics within the areas of clinical and laboratory</td>
<td>Biased towards information published in North American journal titles.</td>
</tr>
<tr>
<td></td>
<td>medicine</td>
<td>medicine, including other related topics and professions.</td>
<td>Only includes details of journal articles.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Updated every day.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Uses the MeSH subject headings.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Available via the OvidSP interface.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Available from any PC, just enter your portal username and password.</td>
<td></td>
</tr>
<tr>
<td>Embase¹</td>
<td>Medicine and biomedicine, including some</td>
<td>Wide coverage of most topics within the areas of clinical and laboratory</td>
<td>Biased towards information published in European journal titles.</td>
</tr>
<tr>
<td></td>
<td>veterinary medicine</td>
<td>medicine, including other related topics and professions.</td>
<td>Only includes details of journal articles.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Particularly strong in pharmaceutical information.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Updated every day.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Uses the Emtree subject headings.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Available via the OvidSP interface.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Available from any PC, just enter your portal username and password.</td>
<td></td>
</tr>
</tbody>
</table>

¹ Medline and Embase complement one another very well. If you think that Medline will be useful to you, search Embase too. See Woods, D., and Trewheellar, K. (1998). Medline and Embase complement each other in literature searches. *British Medical Journal* 316, 1166 for more details.
<table>
<thead>
<tr>
<th>Name</th>
<th>Subject coverage</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>CINAHL Plus</td>
<td>Nursing, midwifery and allied health</td>
<td>Very comprehensive, international coverage of topics relating to the subject. As well as journal articles, it also indexes books, accreditation requirements, websites, theses, legal cases, research instruments. Some of the content is in full text. Many journal articles have their reference lists included in the record. Available from any PC, just enter your portal username and password.</td>
<td>The search interface is not very user-friendly.</td>
</tr>
<tr>
<td>Web of Science</td>
<td>Science, social sciences, arts &amp; humanities</td>
<td>Broad subject coverage of almost every academic discipline. Available from any PC, just enter your portal username and password. Contains citation rates and other statistical data.</td>
<td>No subject headings. Only 50 search terms can be used in one search. Only 500 results can be downloaded at one time. Only indexes journal articles.</td>
</tr>
<tr>
<td>CAB Abstracts</td>
<td>Applied life sciences</td>
<td>Particularly strong in agriculture, food and nutrition, environment and sanitation. Updated every month. Available via the OvidSP interface. Available from any PC, just enter your portal username and password.</td>
<td>Subject headings rather general, so can return lots of irrelevant results.</td>
</tr>
</tbody>
</table>
Step 3: Choose your search terms

You must think quite carefully about which search terms you use. The terms you enter into the search resource will determine the results you retrieve from that resource. There are two distinct types of search terms you can use in the medical databases: 1) textwords and 2) subject headings.

1) Textwords

Textwords are often called keywords or free-text searching. This is probably the type of search term you are used to using in resources such as Google. Use textwords to search the text of the article, usually limited to the title and abstract rather than the full text. When you search in this way, you will only find a citation if the authors have used the exact word(s) that you use in your search in the Title or Abstract of the article. So, you have to try to think of all the possible ways that the concept you are interested in could be worded. You will have to allow for different ways of expressing a concept, synonyms and variations in spellings. This can be rather difficult.

Remember to include:

- UK and US spelling (e.g. organisation or organization)
- UK and US terminology (e.g., physiotherapist or physical therapist)
- abbreviations and non-abbreviated terms (HIV or human immunodeficiency virus)
- disease names and their vectors (if appropriate) (malaria or Anopheles or Plasmodium)
- generic and trade drug names (if appropriate).

Example

HIV could be worded in at least the following ways:

HIV or human immunodeficiency virus or human immuno-deficiency virus or HIV-1 or HIV-2

Likewise, vertical transmission could be worded in at least the following ways:

Vertical transmission or mother-child transmission or materno-fetal transmission or maternal-fetal transmission or materno-foetal transmission or transplacental transmission or transplacental transmission or perinatal transmission or peri-natal transmission.

To ensure that you capture all the articles containing the concepts ‘HIV’ and ‘vertical transmission’, your search should contain all of these options.

ACTIVITY 6

Brainstorm the different words and phrases which may be used by authors to describe each of the search concepts defined in Activity 4. Write them down in separate lists.
Feedback

Thinking of synonyms is not an easy task, particularly if you are searching for information on a subject that is unfamiliar to you or if English is not your first language. You are unlikely to think of all the different synonyms during your first literature search. As you read around your topic you will become familiar with the commonly used words and phrases. Keep adding to your list of synonyms as you conduct your background reading. By the time your study question is fully developed, you should have collected a comprehensive set of search terms.

2) Subject headings

Many databases have another way (in addition to textwords) to search for articles on a particular subject. This is using subject headings or “controlled vocabulary”. This is sometimes called “thesaurus searching”.

The database has a list of thousands of pre-defined subjects which it covers. These are arranged in a hierarchy of broad topics (e.g. sexually transmitted diseases) down to very specific ones (e.g. HIV seropositivity). Each database uses its own system, covering the subjects that database includes. The Medline system is called MeSH (Medical Subject Headings). Each subject heading has a distinct definition. Any article which is about that subject, as defined by Medline, will be indexed with that heading.

The MeSH tree structures are arranged from the most general term to the most specific term, for example:

Anatomy
   Body regions
      Extremities
         Arm
            Hand
               Fingers
                  Thumb

Example

For the search we have been discussing, HIV is best represented by the MeSH terms ‘HIV’ (which is used to index articles about the HIV virus) and ‘HIV Infections’ (which is used to index articles about the conditions resulting in infection with the HIV virus).

HIV is located within the following MeSH tree context:

Organisms (MeSH Category)
   Viruses
      RNA Viruses
         Retroviridae
            Lentivirus
               Lentiviruses, Primate
                  HIV
                     HIV-1
                        HIV-2

Two possible MeSH terms for 'vertical transmission' are ‘Infectious Disease Transmission, Vertical’ and ‘Maternal-Fetal Exchange’.
As noted above, the subject headings are arranged in a hierarchy. You can use this hierarchy to broaden or narrow your search. Below is the hierarchy for the substance-related disorders subject heading in MeSH. The numbers correspond to the number of articles indexed with that subject heading.

<table>
<thead>
<tr>
<th>Disorders of environmental origin</th>
<th>64872</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance-related disorders</td>
<td>1647</td>
</tr>
<tr>
<td>Alcohol-related disorders</td>
<td>124</td>
</tr>
<tr>
<td>Alcohol-Induced disorders</td>
<td>286</td>
</tr>
<tr>
<td>Cardiomyopathy, Alcoholic</td>
<td>670</td>
</tr>
<tr>
<td>Fetal alcohol syndrome</td>
<td>2785</td>
</tr>
<tr>
<td>Alcohol-Induced disorders, nervous system</td>
<td>3732</td>
</tr>
<tr>
<td>Liver diseases, alcoholic</td>
<td>663</td>
</tr>
<tr>
<td>Pancreatitis, alcoholic</td>
<td>2287</td>
</tr>
<tr>
<td>Psychoses, alcoholic</td>
<td>9545</td>
</tr>
<tr>
<td>Alcoholic intoxication</td>
<td>60406</td>
</tr>
<tr>
<td>Alcoholism</td>
<td>1185</td>
</tr>
<tr>
<td>Wernicke Encephalopathy</td>
<td>1181</td>
</tr>
<tr>
<td>Amphetamine-related disorders</td>
<td>4181</td>
</tr>
<tr>
<td>Marijuana Abuse</td>
<td>2897</td>
</tr>
<tr>
<td>Neonatal abstinence syndrome</td>
<td>609</td>
</tr>
<tr>
<td>Opioid-Related disorders</td>
<td>5873</td>
</tr>
<tr>
<td>Heroin dependence</td>
<td>6999</td>
</tr>
<tr>
<td>Morphine dependence</td>
<td>2808</td>
</tr>
<tr>
<td>Phencyclidine Abuse</td>
<td>210</td>
</tr>
<tr>
<td>Psychoses, Substance-Induced</td>
<td>4058</td>
</tr>
<tr>
<td>Substance Abuse, Intravenous</td>
<td>9859</td>
</tr>
<tr>
<td>Substance Withdrawal Syndrome</td>
<td>16684</td>
</tr>
<tr>
<td>Alcohol Withdrawal Delirium</td>
<td>1511</td>
</tr>
<tr>
<td>Alcohol Withdrawal Seizures</td>
<td>151</td>
</tr>
<tr>
<td>Tobacco Use Disorder</td>
<td>5164</td>
</tr>
</tbody>
</table>

If you were interested in articles about alcoholism, you could choose it and you would find 60,406 articles. If you wanted to move up the hierarchy and find all the articles about alcohol-related disorders, note that would only find 1,647. This is because articles are indexed using the most specific subject heading available. So the 1,647 articles indexed using alcohol-related disorders do not specify which disorder they are interested in. Articles which do specify are indexed under the specific disorder (alcoholism, alcoholic liver diseases etc). So if we want to find articles about alcohol-related disorders in general, plus items about the specific disorders, we would need to search on all of the subject headings. There is a quick way to do this, just explode the more general term.

Exploding your term automatically searches for articles indexed with any of the narrower terms appearing underneath it in the hierarchy. So exploding the term alcohol-related disorders will find the 1,647 articles indexed with the term alcohol-related disorders, plus the 124 articles indexed with the term Alcohol-Induced disorders and the 286 articles indexed with Alcohol-Induced disorders, nervous system etc. This will retrieve 19,271 articles in total.
Example

Here is the citation for an article which looks like it may help to answer my question:


It has been indexed in Medline with the following MeSH terms:

- Adult
- Developing countries
- Female
- *HIV Infections / prevention & control
- *HIV Infections / transmission
- Humans
- *Infectious Disease Transmission, Vertical
- Male
- Pregnancy
- Pregnancy Complications, Infectious / prevention & control
- *Preventive Health Services / organization & administration
- *World Health

The MeSH terms with an asterisk next to them are the major subject headings or the focused subject headings. These denote the main subjects covered by the article.

Some of the subject headings have a slash followed by another term. These are called subheadings and denote that the article covers a particular aspect of this subject. Sometimes more than one subheading is listed (there are two for HIV Infections in the example above).

Using subject headings vs. Textwords

There are clear advantages associated with subject heading searching. When you search using subject headings you are not dependent on the exact words that the authors have used. If a MEDLINE record does not contain an Abstract, you may only be able to find it using MeSH terms. However, you will sometimes have to use textwords if there is no subject heading term to represent a concept. You should also bear in mind that some articles may be indexed inconsistently, using a variety of MeSH terms.

MeSH terms also evolve over time. For example, ‘non-A non-B hepatitis’ became ‘Hepatitis C’ after HCV was identified. The terms are not retrospectively amended. Because of this, it is best practice to carry out your search using both textwords and subject heading terms to get the best retrieval.

This would be a good point to take a break if you wish.
Step 4: Compile your search strategy and run the search

Now you have a list of search terms and a list of resources to search, you can start searching.

Compiling your search strategy

Each database has a number of tools to help you put your search together. Most of these help with the textword search. The most popular tools are explained below.

Truncation

Truncation is used with textwords and allows you to specify different endings to words. Just enter the root of the word and the database truncation symbol (usually an asterisk). The database will then search for any word which starts with that root.

Example
Organisa* will find organisation, organisational, organisations. It will not find organised.

Warning: Do not make your word root too short or you run the risk of finding irrelevant words.

Wildcards

Wildcards are used with textwords and allow you to make allowances for differences in spelling, plural forms, etc. The punctuation used to denote wildcards varies between databases - check in the database’s help to find the correct format.

A number of the databases have two forms of wildcards: mandated wildcards and optional wildcards. A mandated wildcard allows for differences in spelling, where a character must be present. You can add more than one mandated wildcard to each word, but you must have at least two characters before it.

Example
In the OvidSP databases, the mandated wildcard symbol is a hash or pound sign (#). Organi#ation will find organisation and organization, wom#n will find woman or women.

An optional wildcard allows for a character to be present or absent. This is particularly useful for differentiating between UK and US spelling.

Example
In the OvidSP databases, the optional wildcard symbol is a question mark (?). Tumo?r will find both tumour and tumor.
Proximity searching

Proximity searching is also used with textwords and allows you to specify how close together different words should be to each other. Not every database allows you to do this, so check the help pages. This is particularly useful where you are looking for information on a subject where the vocabulary used can be very variable. The punctuation used to denote proximity searching varies between databases - check the database help to find the correct format.

Example

In the OvidSP databases, use ADJ\(n\) between words, where \(n\) is the maximum number of words permitted between your terms.

If you add ADJ4 between the words it will find them in any order within 4 words of each other. 

\text{lung ADJ4 cancer} will find cancer of the lung, lung cancer etc.

Combining terms together using Boolean operators

As you can see, we can very quickly build up a long list of search terms. We need to tell the search system how we want these terms combined together. To do this we use special words called Boolean operators, 1) OR and 2) AND.

1) OR

Use OR when you are entering your synonyms. OR will find articles with one or more of your terms. In the example shown in the Venn diagram above, both the lighter grey areas and the dark grey areas will be found.

Example

Entering \text{vertical transmission or mother-child transmission} will find articles containing the phrase \text{vertical transmission}, it will also find articles containing the phrase \text{mother-child transmission} and it will also find articles containing both terms.

You should also use OR when you combine your textword and subject heading searches together for the same concept.
2) AND

Use AND when you are combining different concepts together. AND will find articles with all of your terms. In the example shown in the Venn diagram above, only the middle dark grey area will be retrieved.

Example
Enter "HIV and vertical transmission" will find articles with both phrases. Any items only containing one of the terms will not be found.

ACTIVITY 7

Go back to the list of databases you identified in Activity 5. Read the ‘About this database’ links on the Library website at www.lshtm.ac.uk/library/databases/database_alphabetical.html, for each of the databases. Note which of the search options described under Step 4 above are available for each database and the symbols used for each.

Feedback
You will note that each database allows different options and uses different symbols for each option. For example:

- PubMed does not allow wildcards or proximity searching.
- CINAHL Plus and Africa-Wide Information use W and N to conduct a proximity search.
- Web of Science requires you to enter phrases in quotation marks.

It is important that you enter your search in the format required by the database you are searching. You will retrieve incomplete results if you do not.

Putting it all together

Using truncation, wildcards and proximity searching, you can quickly put together a very comprehensive textword search for each of your concepts.
Example

Here are some searches in Ovid Medline for articles on the search concept: lung cancer. Each search is increasingly more advanced, taking advantage of all of the search options available. The number next to each search is the number of items retrieved. As you can see, the search becomes gradually more comprehensive, making it less and less likely that an important article has been missed.

- lung cancer 64059
- lung cancer or pulmonary cancer or lung neoplasm or pulmonary neoplasm or lung tumor or pulmonary tumor or lung tumour or pulmonary tumour 68334
- lung cancer* or pulmonary cancer* or lung neoplasm* or pulmonary neoplasm* or lung tumo?r* or pulmonary tumo?r* 147341
- (lung or pulmonary) adj2 (cancer* or neoplasm* or tumo?r*) 148871

Note that including a comprehensive list of synonyms and truncation, wildcards and proximity searching, the number of items retrieved has more than doubled.

Remember, these search results are only for one search concept. When you add in another search concept, the number of results retrieved will fall dramatically. The above search is looking for everything that has been written about lung cancer, regardless of the context. Given the quantity of cancer research, one would expect to find nearly 150,000 articles.

Example

Using the punctuation and symbols available in the OvidSP databases, I can put together a textword search for vertical transmission which looks like this:

(vertical or mother-child or materno-fetal or maternal-fetal or materno-foetal or transplacental or perinatal or peri-natal) adj2 transmission

Notes: If you have a phrase that sometimes has a hyphen and sometimes does not, enter it with a hyphen, the database will then search for the phrase both with or without one.

Most databases do not distinguish between upper and lower case letters, so there is no need to allow for this in your search.

ACTIVITY 8

Using your list of synonyms from Activity 6 and your notes of the options available in your chosen databases from Activity 7, put together a textword search for each of your search concepts as in the example above.
Feedback

Some lists of synonyms lend themselves to using a variety of the options available, others very few. At the least, you use truncation where appropriate. Using these options makes a significant difference to the comprehensiveness of your results.

Using options such as truncation, wildcards and proximity searching allows you to search for a wide variety of alternative words and phrases. They make a huge difference to the comprehensiveness of your search.

Most databases allow you to build up a search in stages, remembering each search step as you go in the search history. They give each step of your search a number which you can use to combine searches together.

Thus, you can build up a search for a three-concept topic as shown below.

1. Concept 1 title and abstract search
2. Concept 1 subject heading search
3. 1 or 2
4. Concept 2 title and abstract search
5. Concept 2 subject heading search
6. 4 or 5
7. Concept 3 title and abstract search
8. Concept 3 subject heading search
9. 7 or 8
10. 3 and 6 and 9.

Example

A search to answer the question: What is the current state of knowledge about the vertical transmission of HIV infection? would look like this in Ovid Medline:

1. (vertical or mother-child or materno-fetal or maternal-fetal or materno-foetal or transplacental or perinatal or peri-natal) adj2 transmission
2. Infectious Disease Transmission, Vertical/ or Maternal-Fetal Exchange/
3. 1 or 2
4. (hiv or human immunodeficiency or (hiv adj1 "1") or (hiv adj1 "2")(or acquired immunodeficiency syndrome or acquired immune deficiency syndrome or aids
5. exp HIV/ or exp HIV Infections/
6. 4 or 5
7. 3 and 6.

ACTIVITY 9

Go to the Online Help sheets and Tutorials page of the Library website (http://www.lshtm.ac.uk/library/help/help.html). Download and view the videos and guides for one of the databases you chose in Activity 5. These will show you how to run a search in the database of your choice.
Feedback
These tutorials are available to anyone with Internet access, even once you have completed your studies. You can view them as often as you wish.

ACTIVITY 10

Run a search on the database of your choice using the textword searches you put together in Activity 8.

If your chosen database allows, also run a subject heading search for each of your search concepts.

Feedback
Remember to include all of your synonyms, together with the search options allowed by the database you are searching (truncation, Boolean operators, wildcards etc).

ACTIVITY 11

Do you wish to add limiters to your search? Go back to your notes from Activity 3 and apply the limits you specified. The guides and videos on the Library webpages will help you.

If you have a geographical limit, you will have to add this as a separate search concept.

Feedback
Limiters can be useful to restrict the number of items you retrieve. Remember, not all limiters are available in all databases.

Step 5: Find full text materials

There are two main ways to find links to electronic resources at LSHTM.

1. Via the SFX@LSHTM button

   The SFX button is available on most of the School’s database subscriptions and links you directly from your results to the full text of the article (if available).

   When you click the SFX button, the SFX window will appear.

   The citation of the item will appear at the top of the menu.
### ACTIVITY 12

Use the SFX links to find the full text for the articles you have found which answer your initial question set in Activity 2.

When you click the Go button, another window or tab will open, taking you to the electronic journal or the library catalogue.

### 2. Via the Library Catalogue

Links to all of our electronic books and electronic journals are available from the Library Catalogue. Details on how to use the Library Catalogue and find information in the library are given on the web-pages [www.lshtm.ac.uk/library/collections/using_catalogue.html](http://www.lshtm.ac.uk/library/collections/using_catalogue.html).
Feedback

You have access to all of the electronic journals LSHTM has subscribed to. If you have problems accessing the full text of a journal the Library has a subscription to, post a message on the Library web conference or email interloans@lshtm.ac.uk for help.

Usernames and passwords

The cost of an electronic resource depends on how many people will be accessing it. Therefore, most institutions only pay for their own staff and students to access electronic resources. This is why LSHTM staff and students cannot use electronic resources at other libraries.

In order to make sure that only those who are eligible can access the resource, a variety of different authentication systems are available. LSHTM uses two: IP address and username and password authentication.

When the Library subscribes to an electronic resource, the supplier is told the IP addresses of the School’s computers. IP addresses are unique to each computer and are the main way that computers recognise each other over the Internet. The Library suppliers know that only current LSHTM staff and students have a network username and password to log on to a School computer. Therefore, these computers are let into the resources the Library subscribes to.

If you are not using a School PC, you need to use another way to prove that you are a member of staff or a student. You do this using your username and password. When you click on a link, you will be asked to log on via an institutional login. You will then be asked where you are from. Choose London School of Hygiene & Tropical Medicine from the UK HE listing. Then you will be asked to login via this screen. Use your University of London Portal username and password.

If the system says your username and password are not recognised, even after checking the spelling is right, please contact IT Services.

If the system says you are not authorised to access the resource, please contact the Library.

Finding information not available at LSHTM

Sometimes you will want to read an item which is not available in electronic format from LSHTM. Depending on where you are located, you may be eligible to use another library’s resources. Some of the most commonly used schemes are listed below.

SCONUL Access

If you are resident in the UK, you may wish to apply for a SCONUL Access card. This allows reference access to a large number of other academic libraries throughout the UK. You will only get access to print resources, not electronic items.
To join another library using the scheme, you must first register for an LSHTM library card. Instructions are online at www.lshtm.ac.uk/library/libraryinfo/access.html. When you receive your LSHTM Library Access Card and SCONUL card, take them with you to the library you wish to use. They will give you one of their own cards to allow you access.

To see which libraries are part of the scheme and to see which ones you are eligible to use, go to the SCONUL Access website at www.access.sconul.ac.uk.

**HINARI**

If you are affiliated with an institution which has joined HINARI you will be eligible to access their resources. HINARI is a collaborative scheme between the WHO and various publishers which allows researchers for low-income countries access to content for free (or for a reduced fee). More information is available on their website (www.who.int/hinari).

Library staff are compiling details of other schemes available across the world. If you would like help in accessing other libraries, please email interloans@lshtm.ac.uk or ask on the web conferencing forum.

**Using the document delivery service**

The document delivery service will supply copies of items in the following instances:

- If the item is available in LSHTM but only in print, we can post or fax a photocopy to you (only available to overseas students – UK residents should use the SCONUL Access scheme to access another library).

- If the item is not available in either print or electronic format at LSHTM we can email, post or fax a photocopy to you (available to all distance learning students).

- If you have problems downloading files from the Internet due to your internet connection, we can print items for you and post or fax them.

To use this service you must register for an LSHTM library card. Instructions are online at www.lshtm.ac.uk/library/libraryinfo/access.html. You must also register for the document delivery service using the form at www.lshtm.ac.uk/library/iloans/.

Follow the instructions on the Inter-loans and document delivery page to submit a request for an item. You can order as many items as you need but a cost is payable on each item ordered.

**ACTIVITY 13 (Optional)**

If you think you will need to use the SCONUL Access scheme, or the Document Delivery service, register for a LSHTM Library card. Details on how to do this are on the Library website at: www.lshtm.ac.uk/library/libraryinfo/access.html.
Recording details of your searching

You should keep records of the searches you have done. As well as ensuring you do not repeat searches, this will also help when you come to write up your research.

You should aim to record the following:

- your search question
- databases searched, including the start date and date of last update if available, e.g. Global Health, 1910 to September 2008
- your final search strategy
- date search was run.

We recommend that you also keep a record of synonyms and subject headings for any topics you will have an ongoing interest in during your research. This will save you time in compiling lists of synonyms and searching for subject headings each time you wish to run a search.

Writing up your search in your assignments

You may be expected to include a brief summary of your literature search strategy in your assignments. You should include details of the databases and other resources searched, which topics were included in your search, and any limits you applied (e.g. English language, Randomised Control Trials, published in last ten years etc). You may wish to include details of your search strategy as an appendix.

There is a recognised convention to writing search strategies. If you only have to give one as an example, Ovid Medline is usually given (if used). You may need to include details of the search strategy used for each database.

Examples of search strategies can be found in the Cochrane Library or the SIGN search filters (www.sign.ac.uk/methodology/filters.html). Note how subject heading searches are differentiated from title/abstract searches. Also note how search steps are numbered and the numbers are used when combining searches together.

Summary

This session has covered the process of conducting a literature search. Literature searches are used for a variety of reasons, for example, to provide background context to research, to ensure that you are not duplicating work already completed, to compare your methodology to that of others or to provide a review of the knowledge to date on a particular topic.

Each literature search you conduct should follow the same five steps. This will ensure that your search is comprehensive, can be reproduced, and is without bias. The five steps are:
1. Define your search topic

This includes turning your topic into a searchable question and deriving search concepts from the question. At this stage you should also think about the types of information you are looking for and any limiters to the information (e.g. geographical location, language or date).

2. Choose the resources to search

There are hundreds of resources, both free and requiring a subscription, which you can use to find information. Which you decide to search will depend on the topic you are interested in. Bibliographic databases are the best resources to use to find peer-reviewed academic literature. Details of the databases available from LSHTM Library are on the website at www.lshtm.ac.uk/library/databases/databasesall.html.

3. Choose your search terms

A high quality, comprehensive search will include both textwords and subject headings. Textwords are words and phrases used to search the title and abstract of the items, subject headings look for items on a pre-defined subject. For each of the search concepts defined in step 1, you should build up a list of textwords and subject headings used to describe the concept.

4. Compile your search strategy and run your search

How you put your search strategy together is determined by your topic and the database you are searching. There are a number of options available to help with this including:

(a) Truncation
(b) Wildcards
(c) Proximity searching
(d) Boolean operators.

Some databases do not allow all of these options. Check the Library webpages or the database help pages for information on the options allowed and their syntax.

5. Find the full text

The SFX button is available on most of the LSHTM Library databases and allows you to quickly link to the electronic full-text (if available). If you would like to read an item which is not available in electronic format from LSHTM, you can either investigate whether it is accessible via another Library, or sign up for the document delivery service.

Remember to keep notes on your search activities. This will help you if you have to run a similar search in the future. You may also have to include details of your search in your assignments.

Now you can try the optional self-assessment exercise on literature searching which will be made available via the web conferences.
Getting more help

There are a range of help resources on the Library web pages (www.lshtm.ac.uk/library/help/help.html) that address each stage of the literature search process.

For example there is a document on searching the grey literature http://www.lshtm.ac.uk/library/help/wk6greylit.pdf

Library staff are available through the web conference forum to answer any queries you may have.

Additional references

The urls below take you to the SFX page of the LSHTM library, as in the example shown above. At the time of writing this study guide, access to full text of articles put online by Science Direct, is a little long-winded. You will find that you are taken straight to the abstract from the LSHTM library page but to get full text you need to login via institutional login (top right corner of the Science Direct webpage) then you have to search for the article afresh within the Science Direct website. It is often quicker to go to http://unicorn.lshtm.ac.uk, search on the journal and follow through from there.

- Shojania K G & Olmsted R N (2002) Searching the health care literature efficiently: from clinical decision-making to continuing education. American Journal of Infection Control; 30: 187-195. http://tinyurl.com/62vdu4k (this is an Elsevier publication via Science Direct). Another overview of the process using PubMed. (Note that PubMed has been re-designed since this paper was published and so the specific instructions on how to conduct the searches are no longer correct.)
http://tinyurl.com/63ghk48  (this is an Elsevier Publication via Science Direct). Introduction to the different versions of the MEDLINE database, together with some basic tips on effective searching.
Session 3

Evaluating the epidemiological literature

Overview

After you have carried out a literature search you then have to interpret and evaluate the materials you have located. In this session you will learn how to judge which documents are worth reading in detail and how to read them in a focused and critical manner.

Learning objectives

By the end of this session you should be able to:

- clarify your reasons for reading a particular document and judge whether the document is likely to be worth reading in detail
- state criteria for evaluating critically a research report, a research paper or a review paper,

Planning your study

In this session you will be reading through selected sections of Crombie’s book *The Pocket Guide to Critical Appraisal* and carrying out some activities related to the reading. You will also carry out a critical appraisal of a specific research article relevant to your study topic.

To complete this session you will need:

Provided textbook:


From websites:

  
  http://www.bmj.com/search?fulltext=Moher&submit=yes&xx=9&y=7


**Key terms**

**Effective reading:** getting out of a paper the information relevant to you; not spending time on details that are irrelevant nor reading uncritically nor reading so superficially that you do not absorb the information.

**Bias:** the systematic distortion of observations causing a difference between the estimated parameter and the true value of the parameter

**Data-dredging:** running analyses until an estimate comes up that has a low p-value or deciding to ‘test’ the comparison that looks most extreme although there was no prior hypothesis about it. The point being that, even chance findings will appear statistically significant if many tests are done (up to one in 20 results with p<0.05 can arise by chance, being in the tails of the normal distribution).

You should allow yourself approximately five hours for this session. A stopping point for a break is suggested.

**The need for effective reading**

We are constantly bombarded with new information from various sources, including scientific and non-scientific journals, magazines and books as well as information from the Internet. Keeping up with the information that interests us has become a difficult task. Reading skills are increasingly being challenged as we need to be more selective in what we read. When faced with any piece of written information it is important to be clear on why you are reading it and what you wish to get from it. Sometimes scanning (looking for particular information) or skimming (covering a pre-selected section to gain a general overview) is all you need to do before exploring relevant pieces of information in more detail, or even discarding the reading as not relevant for your purpose. Current evidence shows it is possible to read fast and effectively. Surprising as it may seem for some, one often picks up more information by reading quickly rather than slowly. Interest, objectiveness, concentration and reviewing are key factors that influence the retention of new materials we read. Keep these factors in mind generally, and particularly when you are reading the recommended texts in this module. Although fast reading techniques
are beyond the objectives of this course, good books on the subject are available if you wish to learn more about these techniques.

**Clarify your reasons for reading**

Even a focused literature search will often yield a large number of references that appear to be relevant to your needs. To deal with a large number of documents, your reading will also have to be focused. Before you start to read a document, you should have a clear idea of what information you are looking for. It is often useful to express this in terms of a question that you are hoping to find an answer to. The question may be quite broad (e.g. What does this article tell me about the current state of knowledge on the vertical transmission of HIV infection?) or very specific (e.g. What method(s) did the researchers use to detect antibodies to HIV in infants in this study?). Of course, you may read a specific document hoping to find the answer to more than one question. It is also important to be open to unexpected information that may be of use to you.

**Is this document worth reading?**

The first decision you need to make when approaching a specific document is whether or not to read it in detail. You should be able to make this decision after reading through the abstract or summary of the document. This will usually enable you to judge whether the full document is likely to contain the information you require. If the document does not contain an abstract or summary, the Introduction of a research paper, research report or review paper should clearly state the purpose of the document and the Methods section should explain how the authors went about trying to achieve it. The information provided in these sections should enable you to judge whether the document is likely to respond to your needs.

**Evaluating a document**

Whatever your reasons for reading a document, you will need to approach it in a critical manner. Several structured checklists have been developed to help readers critically evaluate epidemiological research papers. The textbook that you will use in this session, *The Pocket Guide to Critical Appraisal*, provides a number of such annotated checklists and the full STROBE, CONSORT and PRISMA lists are also invaluable (see below). You can use these checklists as a framework for assessing the quality and validity of a research document. You should always use your wider knowledge of conceptual, methodological and practical issues in epidemiological research to inform your evaluation.

If you want a reminder about the limits of what one can conclude from statistical significance tests or about some concepts like ‘confounding’, see Chapter 4, pages 12-19 of Crombie’s book and the boxes in the paper on STROBE by Vandenbroucke et al. This is an optional activity.
ACTIVITY 1

Read Crombie the first section of Chapter 5 ‘Introduction to the checklists’, beginning on page 20. Stop at the subheading ‘Evaluating the flaws’ on page 21. Note his warning about checklists.

Feedback
This reading provides an introduction to the checklists presented in the rest of Crombie’s book. You will probably have noticed that this book has been written for a clinical audience, so the importance of assessing the clinical relevance of a paper is discussed. As a researcher, you will be judging the relevance of a paper for your research purposes. You will probably also have noticed that the book only refers to 'published papers'. However, the framework for critical appraisal set out in the book can be usefully applied to any research documents, including unpublished research reports (the grey literature), PhD theses, and conference papers.

Note the warning that the quality of papers cannot be judged just by ticking the boxes on check lists. You need to evaluate the quality of the methods, the accuracy of the results, the plausibility and logic of the interpretation and the coherence of the whole. It would be rare for a study to be flawless so you have to assess how detrimental those flaws are.

Evaluating flaws

An important component of critical appraisal is the detection of flaws in the conduct and interpretation of the research. Critical appraisal goes beyond the detection of flaws to the evaluation of the impact of the flaws on the interpretation study findings.

ACTIVITY 2

Read Crombie the rest of Chapter 5 ‘Introduction to the checklists’, beginning at the subheading ‘Evaluating the flaws’ on page 21.

What do you learn from this?

Feedback
This reading stresses the importance of not simply discarding a study because it contains some flaws. This is especially important when you are reading a document for research purposes. You will often learn as much from the flaws in previous studies as you will from their successes. The deficiencies in previous studies may help you to identify research questions that have not yet been adequately answered. Similarly, the specific methodological problems encountered in previous research may help you to anticipate and minimise potential problems in your own study.

Critical appraisal of a research paper or research report

There are some standard questions that you should ask when appraising any research document, and other more specific questions that depend on the individual study design. In Activity 3 you will read Crombie’s checklist of standard appraisal questions applicable to any research document and the rationale behind their use.
In activities 4-7 you will look at Crombie’s checklists that are specific to individual study designs. In addition, we will refer to the STROBE and CONSORT statements.

STROBE is the product of an international collaborative initiative of epidemiologists, methodologists, statisticians, researchers and editors involved in the conduct and dissemination of observational studies, with the common aim of STrengthening the Reporting of OBservational studies in Epidemiology. It offers a helpful guide to the factors to look out for in appraising cohort, case-control and cross-sectional studies.

CONSORT comprises a checklist of items that need to be addressed in reporting randomised controlled trials and a flow diagram which provides readers with a clear picture of the progress of all participants in the trial. CONSORT aims to help improve the quality of reports of randomised controlled trials and reflects the expectations of key medical journals such as JAMA and The Lancet in reporting such trials.

The Vandenbroucke and Moher papers give explanations of the various features of papers on observational studies and randomised controlled trials, respectively. They will be used several times during this module.

ACTIVITY 3

First, make a note of some appraisal questions you think should be asked when evaluating an epidemiological research paper.

Then read the whole of Crombie Chapter 6 ‘The standard appraisal questions’ (pages 23-29). This chapter warns you about some of the pitfalls of papers that may not immediately be obvious. Compare the suggestions here with the ones in your own list.

Feedback

You may want to bookmark the summary list of standard appraisal questions on page 23.

Your epidemiological training should lead you to assess the reasons for a finding – whether there could be a causal element or whether associations are explained by chance (sample size important), confounding (issues of covariates and validity), bias, or reverse causation. You are a detective trying to work out what accounts for the findings. The authors should provide the information for you to judge this. Although the authors will interpret the results themselves, you should not rely on their discussion but think it through for yourself. Conclusions involve judgement. Note that p-values are not necessarily sufficient to judge clinical or public health importance of a finding. As an author with an idea of what you want out of the study, it is easy to ignore contradictory results, or to overplay a result that fits one’s preconceptions. Readers should be alert to this.

This would be a good point to take a break if you wish.
ACTIVITY 4

First make a list of information you would want to see in a paper reporting a cross-sectional survey. Use the IMRaD headings as a guide (described in Session 1). You may find it easiest to think of a survey or study you know. Some well-known international surveys are the Demographic Health Surveys, undertaken in many countries and designed to answer a range of health questions. For example, they contain questions intended to enable assessment of knowledge, attitudes and behaviour concerning HIV.

Second, read Crombie the whole of Chapter 7 ‘Appraising surveys’ (pages 30-35). Note that in the rest of this module we have used the term ‘cross-sectional study’ instead of ‘survey’ to refer to this study design.

Third, look at Table 1 in Vandenbroucke et al. where the STROBE checklist is given (no need to read the text at present unless you want to check what is meant by an item).

Compare the lists you drew up with the ones in Crombie and Vandenbroucke et al.; if there is anything in their checklists that puzzles you, check through the respective texts for an explanation.

Feedback– some points that can be made (note that this and subsequent feedbacks in this Session are not comprehensive lists)

Cross-sectional studies can be purely descriptive or include an analytic element (i.e. be looking at associations between factors).

Descriptive studies often aim to estimate prevalence of a particular condition (e.g. using condoms). In this case one wants to know:

- What is the target population of the study?
- Is the source population representative of this target population?
- Were people given equal chances of selection or did the analysis compensate for unequal chances?

For an analytical cross-sectional study, one wants to know whether anything could bias the observed association between factors:

- Could information bias have influenced the results?
- Were the data collectors blinded; if not, could knowledge of exposure have influenced the judgement of the outcome or knowledge of the outcome influenced the way they record the exposure?
- If data were collected on past exposures, could recall bias have occurred?

With all studies, you want to know whether the results could have arisen by chance (are there confidence intervals, p-values?) or whether the authors did “data-dredging” – (see Crombie’s note on serendipity, page 17).

You may want to bookmark the summary list of appraisal questions for cross-sectional studies on page 35 and add any additional questions to the list.
ACTIVITY 5

First, note down any items of information that are specific to cohort studies and which you think need to be reported for research that used a cohort study. Again, it may help to think of a cohort study you know. A famous example in the USA is the Nurses’ Study which was originally designed to look at contraceptive use and subsequent health – but the original sample was not selected according to contraceptive use (i.e. the sampling was not reliant on exposure) and it has been used to look at many exposures and health outcomes since.

Second, read Crombie the whole of Chapter 8 ‘Appraising cohort studies’ (pages 36-41). Also look again at Table 1 of Vandenbroucke et al. and note the items specific to a cohort study.

Third, again compare the lists you drew up with the ones in Crombie and Vandenbroucke et al.; if there is anything in their checklists that puzzles you, check through the respective texts for an explanation.

Feedback – some points that can be made

In a cohort study, where the selection of participants depends on the exposure, it is critical that the exposure is identified well – so you want to know how this was done and how the exposed and unexposed participants were selected. Also, if the exposed and unexposed were matched, how was this done?

Even if the sample was not initially selected on the basis of the exposure- one will be able to deduce more about exposures if there are comparison groups for any particular analysis in the paper; the writer should say how the comparison groups were selected for the analysis, e.g. how was contraceptive use defined and determined in the Nurses’ Study.

What were the recruitment levels in both the exposed and unexposed (or 'control') groups?

It is also important to know how the outcomes were identified – are you told how complete the follow-up was, both in terms of subjects lost from the study and the completeness and accuracy of the information on the outcome.

The power of the study depends on number of outcome ‘events’; events will happen quickly for some research (e.g. hospital discharges for a cohort of patients undergoing minor surgery), not for others (e.g. onset of lung cancer in a cohort recruited in adolescence) – so is the follow-up sufficiently long to detect the events?

In a cohort study collecting data on past exposures, could recall bias have occurred?

Note that there are many situations where different levels of exposure can be considered instead of one “unexposed (control) group”.

You may want to bookmark the summary list of appraisal questions for cohort studies on page 42 and add any additional questions to the list.

This would be a good point to take a break if you wish.
ACTIVITY 6

First, note down the characteristics of randomised trials that you think should be reported in a paper.

Second, read Crombie the whole of Chapter 9 ‘Appraising clinical trials’ (pages 43-49). Note that the points covered in this chapter can be applied to any intervention study.

Third, look at Box 1, Table 1 and Figure 1 in the CONSORT paper by Moher et al.

Finally, again compare the lists you drew up with the ones in Crombie and Moher et al.; if there is anything in their checklists that puzzles you, check through the respective texts for an explanation.

Feedback—some points that can be made

What were the criteria for inclusion? These may be sufficiently restrictive to limit the extent to which the results can be applied elsewhere.

A randomised controlled trial aims to minimise the possibility of a group difference in an outcome being due to something other than the intervention. Thus, comparability of groups in other respects is important—and the way in which randomisation is done and followed through is part of this. If randomisation is not done properly or at all there will be far more ‘noise’ in the comparison (i.e. possibility of confounding). There is also more scope for allocation to intervention or control being influenced by the vulnerability to the outcome, hence biasing the result.

Loss to follow-up should be fully described.

Were those managing the patients and measuring outcomes aware to which group the patient belonged (blinding)?

Ethical issues may be particularly sensitive in randomised controlled trial (RCTs) because one is asking participants to agree to an intervention and usually the participants do not have control over which group they are in.

The intervention should be described such that someone else could replicate it.

As with cohort studies, the length of follow-up should be long enough to detect enough important events (should be part of the sample size calculation).

Note that the CONSORT list has items in addition to those given by Crombie, e.g.: changes to methods after the trial began, subsidiary analyses, effect size and precision.

You may want to bookmark the summary list of appraisal questions for intervention studies on page 49 and add any additional questions to the list.

ACTIVITY 7

First, note down the characteristics of case-control studies that you think should be reported in a paper. Thinking of an example might help. A famous example of a case-control study is that by Doll et al. on lung cancer and tobacco consumption in which the smoking habits of lung-cancer patients in a hospital were compared with those of other patients. (Doll R, Hill AB. Smoking and carcinoma of the lung. *Brit Med J* 1950; 2:739-748.)
Second, read Crombie the whole of Chapter 10 ‘Appraising case-control studies’ (pages 50-55). Also look again at Table 1 of Vandenbroucke et al. and note the items specific to a case-control study.

Finally, again compare the lists you drew up with the ones in Crombie and Vandenbroucke; if there is anything in their checklists that puzzles you, check through the respective texts for an explanation.

**Feedback - some points that can be made**

Case-control studies are particularly prone to selection bias so the methods should show how this has been avoided. Selection bias can arise not only from the way the sample is initially chosen but from the way in which losses to the sample occur. If bias was unavoidable, the discussion should pick up on the implications of this.

If cases and controls are matched, the way in which they are matched could affect how much one can infer from the results – and the analysis must take account of the matching.

Was the exposure period sufficiently well defined to ensure that the exposure preceded the outcome?

Case-control studies allow examination of several exposures - but was there data-dredging?

Cases and controls may differ in many respects – has sufficient action been taken to minimise confounding?

You may want to bookmark the summary list of appraisal questions for case-control studies on page 55 and add any additional questions to the list.

**Critical appraisal of a review article**

Like primary research documents, review articles are of variable quality and are subject to bias and other problems of interpretation. As with primary research documents, you should critically appraise review articles to assess their validity and usefulness for your purposes.

The next reading provides a framework and checklist for the critical appraisal of review papers. We will cover systematic reviews separately in Session 5.

**ACTIVITY 8**

Read Crombie the whole of Chapter 11 ‘Appraising review papers’ (pages 56-62). Also look at Table 1 of Liberati et al. regarding the PRISMA statement.
Feedback
The clarity of the research question is essential. Also the meticulous and systematic way in which the literature was sought out and the actions the author took to check whether the studies were sufficiently comparable in order to justify the combining results is also of great importance. Note Crombie’s warning that review articles are not infallible despite thorough searches.

You may want to bookmark the summary list of questions for the appraisal of review papers on page 62.

Summary

Clarify your reasons for reading
Before you start to read a document, you should have a clear idea about what information you are looking for. It may be useful to express this in terms of a question that you are hoping to find an answer to.

Is this document worth reading?
The information contained in the abstract or summary should enable you to judge whether the document is likely to meet your needs.

Critical appraisal of a research document
You should critically appraise a document to assess its validity and usefulness for your purposes. There are a number of structured checklists that you can use to aid your appraisal. You should also use your wider knowledge of conceptual, methodological and practical issues in epidemiological research to inform your evaluation.

Critical appraisal of a review document
Review articles provide a critical overview of research from a number of primary sources. As with primary research documents, you should critically appraise review articles to assess their validity and usefulness for your purposes.

Additional references

- The website address for the STROBE statement is: http://www.strobe-statement.org/ if you would like to know more about how it is developed.
- More about the background to the CONSORT statement can be found on http://www.consort-statement.org/.
- Guidelines for reporting a variety of different types of paper can also be found via www.equator-network.org.
Session 4

Critical evaluation of original papers

Overview

In the previous session, you learned how to read epidemiological literature in a focused and critical manner. In this session you will practice and hone those skills by reading and critically assessing a variety of published scientific papers.

Learning objectives

By the end of this session you should be able to:

- critically evaluate research papers that use various epidemiological designs.

It is assumed in this session that the articles are of relevance to your research and that you are now wishing to look at the detail with the intention of seeing what there is to learn from a paper and what conclusions you can draw from it, given its strengths and weaknesses. These detailed evaluations could help inform your own research.

Planning your study

In this session you will now critically appraise four published research papers.

To complete this session you will need:

Provided textbook:


From websites:


You should allow yourself approximately five hours for this session. Effective reading will be key in order for you to manage this session (and indeed other sessions in this module) within the suggested time. You should try to spend no more than one hour appraising each of the papers. Remember that in “real life” you will need to be able to manage your reading time. A suitable stopping point is suggested, should you wish to take a break.

**ACTIVITY 1**

Without going back to Session 3, try to recall questions that you can ask when critically appraising cross-sectional studies. Write down on a piece of paper at least three such questions.

**Feedback**

Some of the questions you could have noted down for survey studies include:

- How was the sample obtained? Is it representative?
- Is there evidence of data-dredging?
- How could selection bias arise?
- Could information bias distort the results?

There are many others (see previous session and page 35 of Crombie).
ACTIVITY 2

Critically appraise the paper by Neal et al. ‘Prevalence of gastrointestinal symptoms six months after bacterial gastroenteritis and risk factors for development of the irritable bowel syndrome: Postal survey of patients’.

This study could be considered either a prevalence survey amongst exposed individuals (see the checklist on page 35 of Crombie) or as a cohort including only exposed individuals in which exposures are collected retrospectively (see the checklist on page 42 of Crombie). We suggest using the list from Crombie to identify major faults and then using the STROBE guidelines to see whether all the information needed has been given. Also use your epidemiological knowledge. The feedbacks are given using the IMRaD framework. You do not need to have a comment on every detail of the STROBE!

It is good practice to summarise the objectives and main message of a paper as part of your appraisal to demonstrate that you have understood the paper. In addition, when making notes on papers for your own use, perhaps as a precursor to your own research, we suggest that you include some summaries of key features alongside your comments on what you consider to be good or not so good about that paper. When doing your critique try to bear in mind whether the point you are making is a comment on the quality of research or the quality of the writing-up. Poor presentation does not necessarily invalidate the research.

Feedback

Some points that you may have included in your appraisal of this paper include those listed below. Do not worry if you do not pick up all the points listed. However, try to understand the ones that have been made and their implications for the strength of evidence.

Main message of paper: bacterial infection of the bowel causes disabling symptoms 6 months later, making this a major public health problem.

TITLE reflects subject matter and population but could indicate whether postal survey collected data retrospectively.

ABSTRACT

- The abstract is well structured.
- The objectives were twofold: to estimate prevalence of gastrointestinal symptoms 6 months after bacterial gastroenteritis; to determine risk factors for change in bowel habits. For the second objective it is not clear whether they intended to focus on Irritable Bowel Syndrome (IBS) or altered bowel habits.
- In the results paragraph, it is recommended that they use the term “associated with greater risk” rather than “increased risk”, which implies causation (a point of style).
- As noted below, the conclusions are not warranted (major point).

INTRODUCTION

- The introduction provides justification for looking at the long-term aftermath of food poisoning.
• The research question as specified in the introduction refers only to prevalence and severity - not to risk factors - and is inconsistent with the abstract (a criticism of the way it is written up rather than the research itself but can distract from a clear focus).

SUBJECTS & METHODS
• The design is longitudinal set in one health authority in England.
• The study sample comprised 544 people who had bacterial gastroenteritis that was notified between July and December 1994 and confirmed by a laboratory test.
• There was no comparison group – without this, one does not know whether the symptoms were more common than among a group who had not had bacterial gastroenteritis (this is a major weakness).
• The exposure is well-defined in terms of laboratory-confirmed characteristics but not whether it is meant to be confined to infection arising from food poisoning. Also severity of exposure is never given explicitly – although the authors appear to use duration of diarrhoea (table 2 and discussion) (important if others wish to replicate or to use the result in clinical practice).
• The IBS outcome is defined but not how the authors decided that a bowel habit was altered (this is important for other researchers who want to look at this further).
• There is brief mention of questions about general health, diet etc but these do not appear to be used (so may be residual confounding).
• Information on symptoms was collected by postal questionnaire; the questionnaire was sent to the address used for notification of the original infection. Type of infection was obtained from the laboratory.
• Diagnosis of IBS was thorough, with two experienced clinicians. Otherwise, there was no information about attempts to reduce bias. The use of information collected retrospectively could lead to recall bias, e.g. those with problems now may exaggerate the likelihood that they started with the infection because they want an explanation (measurements may not be valid and reliable).
• Sample size was not justified.
• Statistical methods are partially described; the use of Wilcoxon matched pairs should have been justified even though it is appropriate. However, it would also have been helpful to know the criteria for retaining variables in a model – can we be sure that omitted ones were not statistically significantly associated?
• Ethics approval was not mentioned.

RESULTS
• Numbers of individuals were reported, and comparisons were made between respondents and total notified cases. Response rate was reasonable but implications of differential response by age need to be taken into account. It is mentioned for the first time in the discussion that young men had a particularly low response rate – it should have been explicit in the results. Having similar characteristics does not rule out bias – whatever a person’s sex or age, those with recent problems may be more likely to respond, leading to an overestimate of prevalence. This point should be raised in the discussion (it would have been better to have had two response chasers and made more effort to find new location for movers – after the event, the authors cannot change this but something to note for future research).
• No information on item missingness; whether all 386 had answered all the questions. It appears there was “missingness” because e.g. in Table 3 the numbers for duration of diarrhoea add to 220 and for vomiting to 265 (numbers do not add up).
• Summary measures given in Table 2.
• Unadjusted and adjusted estimates are given in Tables 3 & 4. This is potentially good so that we can see what difference is made by confounders but it is not clear what the adjustments were. In the text the authors mention that age was adjusted for duration of diarrhoea and sex – why not for vomiting? A footnote to the table would clarify this.

• It seems that no use is made of information in the questionnaire about treatment received, medical history etc (as mentioned under methods). Treatment may be on a pathway between severity of exposure and symptoms at follow up and have modified the outcome. It might have been possible to stratify analyses by treatment. Some aspects of medical history might be confounders. The authors should tell us if they did try out some analyses with these variables.

DISCUSSION

• The authors conclude that bacterial food poisoning causes disability through altered bowel habit. The survey does not show this as there is no control group and there are potential biases.

• Some weaknesses are discussed, e.g. response bias that may distort gender differences in symptoms at follow-up and they admit that results may not be generalisable to those who did not report their infection. There could also be residual confounding (see comment on absence of some other health variables above).

• There is no discussion of recall bias by those who did take part (this could affect the conclusions that can be drawn).

• It is questionable whether the bias towards ‘illness behaviour’ is removed by the fact that treatment tended to take place in the community rather than in a hospital – the sample still comes from those who made the effort to report their diarrhoea. (Possibility of selection bias?)

• The statement “association of persistent bowel dysfunction with markers of initial severity is not surprising” is too strong since only duration of diarrhoea and vomiting seem to have been analysed.

• Overall, the paper allows very limited conclusions because of the lack of a comparison group and scope for residual confounding, although it is of interest to practitioners to be alert to the long-term aftermath of bacterial infections (implications for practice).

ACTIVITY 3

Without going back to Session 3, try to recall questions which you can ask when critically appraising cohort studies. Write down on a piece of paper at least three such questions.

Feedback

Some of the questions you could have noted down for cohort studies include:

• What are the comparison groups – is there a control group?
• Was the exposure accurately measured?
• How were outcomes identified?
• Was the follow-up of sufficiently long duration?
• Did the analysis allow for the passage of time?

See the checklist on page 42 of Crombie for other examples.
ACTIVITY 4

Critically appraise the paper by Vella et al. ‘Determinants of stunting and recovery from stunting in northwest Uganda’.

This is a cohort study, so the appropriate appraisal checklist can be found on page 42 of Crombie. Use your epidemiological knowledge, the Crombie checklist and the STROBE checklist to carry out a critical appraisal of this paper.

Feedback
Main message: recovery from stunting is possible after the first 2-3 years of life and is equally likely as for those who are stunted during the first year of life.

TITLE – the title could indicate the study design, case-control or cohort.

ABSTRACT
- Requirements of this journal were less stringent at the time the paper was published than they would be now. Now, one would expect the outcome to be defined and some numeric results given. It is consistent with the text but thereby carries through an error (see under Results and Discussion).

INTRODUCTION
- The case for using international anthropometric measures is made, as is the likelihood of environmental determinants of stunting. No reference is made to previous studies of recovery from stunting (those with knowledge of the area would be in a better position to judge the originality).
- Three objectives are given.

SUBJECTS and METHODS
- It is a cohort study set in 30 villages in the Arua district in Uganda. Children were initially measured in February-March 1987 and then again two years later in March 1989.
- Eligibility is clear and the way in which the sample was taken. However, if villages were selected with probability proportional to size \( \left( \frac{c_n}{N^1} \right) \) and then 100% of children in the age range selected, the overall probabilities of selection differ from village to village (i.e. \( \frac{c_n}{N} \) where \( n_v \) varies from village to village) and the analysis ought to include some re-weighting (more important for the prevalence information than the associations).
- Anthropometric measurements were taken by field staff and information about the child and family obtained from questionnaires. It does not say who within the household answered the questions (e.g. mother) this may affect the accuracy of the information. (Is the information valid and reliable?)
- Age was estimated from birth/baptismal certificates or events round the time of birth. There could be some discussion of the validity of these estimates. There could be bias from estimating age once the child’s length or height was known – was anything done to minimise bias? (Age is the main exposure so if it is not valid then this could distort the main finding).
- Stunting is defined but not all the exposures, e.g. socioeconomic status, which in the results we learn was measured by extra income besides farming – presumably this provides both status and resources.

---

\(^1\) c is number of villages to be selected \( n_v \), the population in village v and N the total population of all villages.
• There is no attempt to justify sample size.
• Statistical methods are incomplete. The criteria should be given for choice of covariates to enter in the models. The reader could also be more confident in interpretation if the models were specified and how it was decided which ones to show in the tables, e.g. is the logistic regression in Tables 2 and 3 multivariable or univariable - probably the latter but we might be wrong.
• The above comments give cause for concern regarding possible biases.

RESULTS
• Basic numbers and distributions not adequately described. There is limited information on loss to follow-up.
• Person-years are not used because the follow-up was 2 years for all.
• Numbers of outcome events are not given, only % of an unknown base number (see next comment).
• Would have liked to see more descriptive information about the sample; a simple table would show this. The reader could then see whether any groups are very small (e.g. those with extra income) making the power to detect it as a risk factor low.
• The main results of change in prevalence of stunting and % recovering from stunting are clearly given in Figure 1.
• Tables 2 & 3 would be more useful if:
  o Reference groups were given explicitly
  o Confidence intervals were given (could replace the coefficient and SD)
  o The models were specified and separate parameters given for univariable and multivariable analysis.
• Would be improved if had justification for using the same covariates for recovery as for onset of stunting – the mechanisms could be very different. Had other variables been tried? (leaves some doubt as to whether the best estimates were obtained).
• The text and tables are well linked except that in the text the father’s lack of income other than farming is said to be a statistically significant factor for onset of stunting. In Table 2 the p-value is 0.075, so it is of borderline significance.

DISCUSSION
• It is helpful to start with a simple summary of the results and only discuss implications after exploring strengths and weaknesses; they should also be presented in the light of comparisons with other literature (this is not very important as long as the conclusions are justified).
• The first paragraph of the discussion repeats the error that the socioeconomic status is associated with the onset of stunting.
• Strengths and weaknesses were not discussed – they could include accuracy of information, bias from loss to follow-up, potential confounders that were not measured (e.g. diet), generalisability (major concern; overlooks some potentially important limitations).
• The authors note that incidence of stunting may be offset by recovery or death ending up with similar % stunted at different ages and masking the actual changes taking place. This is a good point and it is a strength of the study that they measured the same children over time and could see the incidence and recovery separately.
• Interpretations are discussed but could be strengthened e.g. is onset of stunting less common after two years because the biologically susceptible are already stunted at an earlier age.
Otherwise, the conclusions are reasonable in terms of age but the policy implications could be different if socioeconomic status is not a substantial factor (contrary to expectations). The results could be used to give ideas for further research, e.g. collecting information on diet and illness as part of a longitudinal study, more research on cohort effects and their relation to external events. Overall, the paper seems useful in countering a common perception that recovery from stunting is very unlikely after the second or third year of life (implication for practice) but further studies are needed in case this one is biased.

- Interestingly a null finding is highlighted as the most important finding.
- The funding, conflict of interest and ethics would be included in a modern paper.

This would be a suitable stopping point if you wish to take a break.
ACTIVITY 5

Without going back to Session 3, try to recall questions which you can ask when critically appraising clinical trials. Write down on a piece of paper at least three such questions.

Feedback

Some of the questions you could have noted down for clinical trials include:

- Were treatments randomly allocated?
- Could lack of blinding introduce bias?
- Were the treatment groups comparable at baseline?
- Were results analysed by intention to treat?

See the checklist on page 49 of Crombie for other examples.

ACTIVITY 6

Critically appraise the paper by Grosskurth et al. “Impact of improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania: A randomised controlled trial”

This is a clinical trial, so the appropriate appraisal checklist can be found on page 49 of Crombie. Use your epidemiological knowledge, the Crombie checklist and the CONSORT checklist and flow diagram to carry out a critical appraisal of this paper.

Feedback

Main message: Treatment of sexually transmitted diseases (STDs) in a community reduces the incidence of HIV – in this study by 40% compared to the control communities.

TITLE: The title is good. The authors could have specified whether they were interested in incidence or prevalence of HIV infection. The summary makes this clear.

INTRODUCTION

- The introduction is clear as to the reason for the trial and its objectives – these included the pragmatic objective of establishing a workable treatment program as well assessment of the impact of this program on incidence of HIV and of sexually transmitted diseases (STD). The authors also make it clear that this paper deals with one aspect of the trial only.

SUBJECTS and METHODS

- Many of the details are in another reference. This is acceptable but there must be sufficient information in this paper for the reader to understand how the study worked.
- The trial randomly assigned whole communities to provision of a treatment facility for bacterial STDs or not. The intervention and control communities were matched in pairs according to whether they were roadside, lakeshore, island or rural (as the opportunities for infection vary across these types of area), district (a pair in the same district) and previous STD attendance rates.
- Setting: rural Tanzania.
- Participants: community residents aged 15-54 who lived within 90 minutes walking distance of one of the trial health centres.
Sample selection: 12 communities were randomised but not themselves randomly chosen. Within the communities clusters of households selected such that 1000 in total. Details are available in another paper. The lack of a random selection at the first stage could limit generalisability of the results – e.g. if the chosen villages were ones where residents were more health conscious.

Interventions: this could be more fully described. It appears to be setting up a facility within local clinic such that staff were trained in treatment of STDs, and were kept supplied with appropriate drugs. Health educators periodically visited the villages to provide information on STDs and to encourage prompt attendance at the clinics if symptoms occurred. It is not specified how the health educators interacted with the community members. Presumably the control clinics had no special training and neither benefitted from the visits nor from the new drug delivery system. (*Knowing what happened to the controls is as important as the intervention because we need to know what was making a difference to the outcome.*)

Outcomes were incidence of HIV and of STDs, identified by specified laboratory methods.

Supplementary outcomes were symptomatic urethritis and *N. gonorrhoea/C. trachomatis*.

Surveys were conducted at baseline and two years later. Demographic, behavioural and socioeconomic information, plus history of STD was collected by survey; sexually transmitted infections were measured by laboratory tests on serum or urine samples, as appropriate. There is little information about other variables such as self-reported STD history and behaviour questionnaires. There is no mention of whether validation of the survey data was attempted. (*Some measures may not be valid and reliable?*)

There is a sample size power calculation correctly accounting for the randomisation being at community level.

They did not specify how the randomisation was done, but being at the community level there is less risk of misallocation than at the individual level.

There could not be blinding to the intervention except for laboratory tests but it is only specified in the discussion that the latter was done- it should have been specified in the Methods (*minor point*).

Statistical methods correctly test differences at community-level and include variables that differed between the intervention and control arms. Adjustment could have been made for sexual behaviour. Given that we later learn that baseline HIV prevalences differed within pairs, it is not clear that the authors took full account of this.

Ethical issues seem satisfactory:

- the control communities received the intervention after two years.
- there was Informed oral consent.
- treatment given for symptomatic STDs and other illnesses that became apparent.

**RESULTS**

Initial response and loss to follow-up are described and some information tabulated; a flow chart would have made this more transparent. Success of randomisation was described and adjustment made in analysis for the factors that differed between intervention and control communities. This was appropriate.

The response rate was not bad but perhaps more effort could have been made to trace movers and return to those temporarily absent or affected by the rains. (*However, major bias seems unlikely, since the reasons for moving or being away should be the same in intervention and control villages.*)
There could be a table showing the demographic characteristics of each group; the clinical characteristics are given.

There were some differences at baseline –mostly taken account of in analysis but remains some concern regarding HIV prevalence (see later comment).

The number of events are given and numbers generally appear to add up; Table 3 and Figure 1 neatly summarise these for HIV. Prevalence of STDs at follow up is given – this was not part of the objectives of this paper but presumably they were given to help understand why HIV incidence differs between intervention arms. Infections may have come and gone during the two-year interim period. Was there an assumption that prevalence at the end of the period would strongly correlate with overall experience of STDs during the period?

Estimates were given before and after adjustment for potential confounders, which is good.

The supplementary analyses are shown in Table 4.

DISCUSSION

The results are summarised.

Strengths of the study are well covered (RCT, correct analysis).

Limitations are considered. Differential patterns of reason for loss to follow-up are mentioned; the explanation does not suggest any particular bias likely to arise but more precise information could have been provided. Perhaps the main danger was contamination across pairs but the authors checked whether individuals had visited clinics in the paired community rather than their own and found that this was rare. However, a major weakness was the inadequate power to detect differences in symptomatic infections, which were a smaller percentage of total infection than expected (null findings were not overlooked).

Potential biases from incomplete blindness to the intervention could have been discussed – e.g.: participants in intervention villages over-stating 'good' sexual behaviour because of the health educator visits; field researchers interpreting vague answers to fit their beliefs about the intervention; laboratory staff were meant to be blinded but could discover from the delivery people and in cases of uncertainty fit the assessment to the hypothesis.

Sensitivity and specificity of the HIV identification could have been given – the small number of cases means that a few false positives or negatives could have made a difference to the results.

As the incidence rate is likely to be influenced by baseline prevalence rate of HIV, fuller discussion of the baseline differences could have been given.

Mechanisms were sought to explain the results and changes in behaviour considered but the survey results did not show sufficient differences in behaviour across time or between intervention and control to explain the differences in HIV incidence. An attempt is made to justify a role for reduced STDs but the information is insufficiently strong to be sure of this. Generalisability to rural Africa is argued.

It is an important study as it suggests a method by which HIV transmission may be reduced in some parts of the developing world. However, the study should be repeated elsewhere with power to detect differences in symptomatic behaviour and to develop theory on mechanisms for reduction in HIV incidence.

ACTIVITY 7

Without going back to Session 3, try to recall questions which you can ask when critically appraising case-control studies. Write down on a piece of paper at least three such questions.
Feedback
Some of the questions you could have noted down for case-control studies include:

- Is the control group appropriate? Could there be selection bias?
- Was there data-dredging?
- Could there be confounding?

See the checklist on page 55 of Crombie for other examples.

ACTIVITY 8
Critically appraise the paper by Comba et al, ‘Cancer of the nose and paranasal sinuses in the metal industry: a case-control study’.

This is a case-control study, so the appropriate appraisal checklist can be found on page 55 of Crombie. Use your epidemiological knowledge and the Crombie checklist and the STROBE checklist to carry out a critical appraisal of this paper.

Feedback
Some points that you may have included in your appraisal of this paper are:

Main message: Working in foundries or the textile industry increases the risk of malignant tumours of the nasal cavity or paranasal sinuses.

TITLE: the title gives the main information – although it could have specified the country.

ABSTRACT: The abstract is not structured as the journal did not require it. It describes the main features of the study and gives some results but asserts that risks were higher in certain industries although their results could have arisen by chance.

INTRODUCTION
- Although it is not a major public health problem in terms of numbers, the possibility of intervention to reduce nasal cancer in specific occupations makes this potentially a worthwhile study. The objectives are not clear as to whether the authors were looking for specific jobs or other exposures and whether they were only interested in the metal industry.

SUBJECTS and METHODS
The study is case-control based in the Brescia region of Italy, which has a concentration of metal industry workers and a high rate of nasal cancer relative to Italy as a whole.

- Cases were people diagnosed with malignant epithelial neoplasms of the nasal cavity and paranasal sinuses at the ENT and radiotherapy departments of one hospital during the period 1980-1989. It would be useful to know what % of the Brescia population would go to this hospital if they were suspected of having this condition. Exclusions were people living outside Brescia.

- Controls were also from the ENT department, and included patients with neoplastic diseases of the head and neck. Exclusions were those with tumours at sites that are associated with alcohol use and also non-residents of the province (may not be appropriate – see below).

- For every case they sought four controls matched on sex and age (five-year bands) but settled for fewer controls when the number of potential control people available was insufficient. It is not stated whether date of diagnosis was taken into account in matching - as the recruitment period was long this could be relevant if working conditions have changed over time.
The response rate is given in the methods section – four controls who refused were substituted. (This is a small number but if it happened for many controls the latter sample could be distorted. There may be a characteristic that is common to those who did not take part and is associated with the relevant exposure).

Outcomes were defined by case-ness and exposures referred to occupational history, especially the industry in which the participant worked. The precise definitions of the exposures are not given.

Information was collected by telephone questionnaire from the patients or, for dead patients, from near kin. The reliability of information from near kin is questionable.

There is no information on whether the diagnoses were checked for accuracy or the questionnaire was piloted or any attempts made to validate it (validity of data).

Although the interviewers were meant to be blind to case-control status, it is hard to see how this would be maintained since the interviewee might make a comment that gives the game away (validity of data).

There is no power calculation.

Collection of smoking data is not mentioned under methods; there is no mention of whether other potential confounders were considered.

There is no information on how variables were categorised.

The analysis strategy is insufficiently brief and does not explain the conceptual thinking behind the modelling – e.g. how covariates were chosen. There is no explanation for analysing men and women separately.

RESULTS

A brief description of cases and controls is given. The odds ratios are not particularly useful – for something to be a confounder the ‘substantiveness’ rather than the statistical significance of differences between cases and controls is more important.

There is no information on missingness and how it was handled.

The text suggests that analyses were done post-hoc, e.g. looking at textile and garment workers separately. There were 35 cases but the numbers of cases in Table 2 do not add to 35, suggesting some overlap and perhaps some who had no occupation. The cell numbers in Table 2 are very small and the confidence interval very wide, making the results too imprecise to be useful. (If subgroup analysis was planned in advance then it should be specified in the Methods section; if it was decided after some analyses were done then it should be treated as hypothesis generating rather than hypothesis testing and this should be explicit.)

Odds ratios before and after adjustment are given and footnotes explain the adjustments.

Numbers were too small to subdivide into different kinds of job, whereas the introduction implied that this was an interest of the authors.

The lack of power is a major weakness. Results are highlighted which involve only a handful of cases. It is not surprising that there were no statistical differences for women garment workers if there were only four cases overall. There is a sense of data-dredging. (Numbers do not add up; serendipity?)

Table 2 is odd because different adjustments were made for different groups, without explanation. Were any adjustments made for foundry workers?

Multiple comparisons are made – hence some apparently statistically significant results could arise by chance.
DISCUSSION

- The authors recognise that power was low but claim that information bias was not present as the interviewers were blinded to caseness. However, to avoid all bias, the interviewers would also have to be ignorant of the hypotheses being tested.

- There could have been more discussion about the choice of controls. They would come from the same population as we know that they were treated in the same hospital (controls should be as likely as cases to attend the treatment centre if they developed the same condition). However, they may have been more likely to work in one of the assumed ‘at risk’ industries compared to a community sample of controls – there is no discussion of whether the aetiology of these other malignancies could be similar to those for nasal cancer.

- Biases are dismissed rather too lightly, perhaps – e.g. is the smoking information good, the potentially major bias from choice of controls, whether information really was blinded. Alcohol consumption is mentioned as a factor in some tumours of the head but not included in models (could be confounding).

- Although only one result was statistically significant at the 5% level and the odds ratio for textile workers for women was below 1.0, the authors claim causation for foundry workers and textile workers.

- Comparisons are made with other studies; these other studies had different categorisations of occupation but some consistency with raised risks among foundry and textile workers (or at least subgroups of them) can be seen.

- The conclusion is too strong for the evidence. At best they should claim compatibility with, rather than confirmation of, previous findings.

- Overall the paper is poor, lacking in clarity and appearing to involve data-dredging.

Summary

Critical appraisal of a research paper

There are a number of structured checklists that you can use to aid your appraisal. You should also use your wider knowledge of conceptual, methodological and practical issues in epidemiological research to inform your evaluation.
Session 5

Systematic reviews and evidence-based medicine

Overview

In the previous session, you critically assessed a variety of published scientific papers. In this session, you will learn to distinguish between a general review, a systematic review, and a meta-analysis, and you will be introduced to the concept of evidence-based medicine. You will also learn more about the Cochrane Library, which comprises databases of review studies, and you will be given optional activities related to its use.

Learning objectives

By the end of this session you should be able to:

- critically evaluate review papers
- distinguish between general review papers, systematic reviews, and meta-analyses
- access and carry out a search of the Cochrane Library online (optional)
- explain the concept of evidence-based medicine.

Planning your study

In this session you will read selected materials on general reviews, systematic reviews, meta-analyses, evidence-based medicine and the Cochrane Library. If you have access to Cochrane Library online you will be encouraged to familiarise yourself with it.

To complete this session you will need:

Textbook provided:

Via websites:
- access to the Cochrane Library online (if available)
  http://www.thecochranelibrary.com/view/0/index.html
- Cochrane centre user guide and quick reference guide available in various languages via http://www.thecochranelibrary.com/view/0/HowtoUse.html

You should allow yourself approximately four-five hours to complete this session.

**Key terms**

**Review**: A review is any attempt to synthesise the results and conclusions of two or more publications on a given topic.

**Systematic review**: A systematic review is a review that strives comprehensively to identify and synthesise all the literature on a given topic (sometimes called an overview). Each specific study forms a unit of analysis and the same scientific principles and rigour apply as for any study. If a review does not state clearly whether and how all relevant studies were identified and synthesised, it is not a systematic review.

**Meta-analysis**: Meta-analysis is a statistical technique for assembling the results of several studies in a review into a single numerical estimate.

**Evidence-based medicine**: Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values.
ACTIVITY 1

Without going back to Session 3, try to recall questions which you can ask when critically appraising review studies. Write down on a piece of paper at least three such questions.

Feedback

Some of the questions you could have noted down for review studies include:

- how were the papers identified?
- is the topic well defined?
- were the detailed, individual study designs reviewed?

See the checklist on page 62 of Crombie for other examples.

ACTIVITY 2

Critically appraise the paper by Lamptey ‘Reducing heterosexual transmission of HIV in poor countries’.

This is a review paper, so the appropriate appraisal checklist can be found on page 62 of Crombie. Use your epidemiological knowledge and the Crombie checklist to carry out a critical appraisal of this paper.

Feedback

Some points that you may have included in your appraisal of this paper include:

- How were the papers identified? The author identifies specific databases which he searched, but he does not give information about key terms which he used to narrow his search. The search was not comprehensive, e.g. it did not include manual searches of peer-reviewed journals or efforts to identify important unpublished studies.

- Is the topic well defined? The topic is extremely broad, addressing a range of ways in which heterosexual transmission of HIV may be reduced, in many dozens of countries. The topic is so broad that a vast number of papers would have been relevant to it. It is highly unlikely that the author was able to examine all of the relevant, important papers.

- It is also unclear what criteria the author used to decide which papers to include in the review, and which to exclude. It is likely that the selected papers and their conclusions represent the personal views of the author.

- Was missing information sought? It seems not.

- How was quality of individual papers assessed? No assessments of paper quality and strength of evidence were made prior to summarising the results.

- Were the detailed study designs reviewed? Detailed study designs were rarely described or reviewed, and when they were the description was very superficial. For example, the Mwanza and Rakai interventions were described as ‘the same’, when in fact their different findings could be attributed in part to very different designs. Specifically, the Mwanza intervention consisted of continuous availability of syndromic STD treatment, while the Rakai intervention consisted of mass treatment every 10 months.
• Are the statistical methods described? No statistical methods were used in appraising the papers reviewed. Statistical analysis thus was not used to determine whether any variation between studies could be expected by chance. Instead, results were simply described in general statements, which are often then illustrated with an example of a specific study or country. Tables summarising data from key studies would have been more informative.

• Was publication bias taken into account? Was heterogeneity of effect investigated? The author refers to several successful interventions to reduce the heterosexual spread of HIV, and other studies with positive findings, but studies which have found no intervention impact or negative intervention impact are hardly mentioned. Publication bias was also not taken into account.

• Are the conclusions justified? The conclusions do not follow from the information presented in the body of the paper.

• This is not a full systematic review. Overviews such as this one can have a valuable place in introducing important, broad issues to a non-specialised audience and giving some idea of the range of options available (in this case for HIV prevention and treatment). However, the breadth of such an overview means that any background literature review is rarely comprehensive, and it is important for the author to acknowledge such limitations.

ACTIVITY 3

Note down why you think it is important to undertake systematic reviews.

Feedback

Systematic reviews are useful in summarising the current state of knowledge and in showing where there are still uncertainties. When reviewing previous research, as when conducting new research, steps must be taken to minimise bias (systematic error) and imprecision (random error). Thus the reviews should be systematic in the sense of being meticulous about following transparent criteria of selection, assessment, and synthesis that minimise the scope for either bias or random error leading to misleading conclusions. New research should be dealing with uncertainties left by previous research. A systematic review of existing research is thus a prerequisite for the design of new research studies, and an increasing number of funding bodies request one before funding new studies.

Systematic review vs metanalysis

A systematic review involves a well-formulated question, a comprehensive data search, unbiased selection and abstraction, critical appraisal of data, and valid synthesis of data. A meta-analysis involves systematic analysis of the results, often with the aim to produce a single estimate of an intervention effect. Systematic reviews of observational studies may be more complex, as there is more scope for problems of selection bias, information bias, and confounding. A meta-analysis can only be done when more than one study has estimated an effect, when there are no differences in the study characteristics that are likely to substantially affect outcome, when the outcome has been measured in similar ways, and when the data are available. A systematic review may or may not include a meta-analysis, but a meta-analysis must be a systematic review.

In a meta-analysis, a single summary statistic is calculated to represent the overall effect (combining the effects found in each study). If done properly, it improves the
precision of an estimate by using all of the available data. A meta-analysis does not simply add together the data from the control groups for all trials to compare them with the data from the treatment groups for all trials, because imbalances within trials introduce bias, and break the power of randomisation. Similarly, a meta-analysis does not simply average the summary statistics from each study, because this would give each study equal weight, and some studies are more likely to give an answer closer to the ‘true’ effect than others. More weight is given to studies which give more information, such as those with more participants, more events and, especially, lower variance. Weight is generally proportional to the inverse of the variance.

ACTIVITY 4

Read the following sections of the paper by Liberati et al. on the PRISMA statement: abstract, Table 1, the text in boxes, the explanation for item 26. You may also wish to read other sections.

The meticulous detail needed for a good review will be apparent. You will see that the PICO system is used – this was introduced in Session 2.

Now, make a note of what you consider:
(a) could be the challenges in doing a systematic review
(b) could make a paper unethical (this is not explicit in the paper)
(c) are some similarities with research papers you have been dealing with in Sessions 3 and 4.

Feedback

Some of the considerations are given below:

(a) Specifying the question, the key search terms, seeking out as many sources of information as possible, avoiding publication bias, assessing potential bias, synthesizing verbally and numerically

(b) The main sources of ethical concern are failure to be fully systematic and failure to declare details of methods or results such that the results could mislead. Some examples are: biased selection of publications but failing to specify some of the criteria for inclusion or rejection; being more lenient about biases in the source papers that fit the reviewer’s preconceptions than in those that do not fit the reviewers’ preconceptions; failing to give information on heterogeneity especially where there is considerable heterogeneity so that a meta-analysis may not be appropriate

(c) Like research papers, specification of the research question and justifying it is critical; also the methods should enable replications, the results should be accurate, and the discussion should consider potential for biases as well as draw conclusions in answer to the research question.

Note that the PRISM guidelines focuses on randomised trials. Systematic reviews can also be undertaken on other forms of intervention or on observational studies. The PRISMA guidelines are still useful for these reviews but there may be some differences.

Module EPM304 Advanced Statistical Methods in Epidemiology covers meta-analysis in more detail.
This would be a suitable stopping point if you wish to take a break.

**Publication bias**

There are two kinds of publication bias: reporting a biased selection of studies; reporting a biased selection of outcomes from within studies. Studies that show a significant effect of treatment are more likely to be published than studies with less favourable results. These studies are also more likely to be published in English and to produce multiple publications.

**ACTIVITY 5**

Obtain the paper by Dwan et al. ‘Systematic review of the empirical evidence of study publication bias and outcome reporting bias’. Read the Abstract, Introduction, and Discussion (the latter spreads across pp22-30 but you can skip the diagrams and tables). Also look at Figure 1 to see the possible sequences that can occur between approved application for a study and publication or non-publication of results.

What types of selection of results to report occur that could lead to bias?

Should we blame the editors?

Why does publication bias matter?

**Feedback**

The main selections were:

- Reporting positive results, i.e. ones favourable to the intervention that an industry or author wants to promote.
- Ignoring findings where there is no statistically significant difference between intervention and control.
- Reporting findings for subgroups or a particular period of follow-up where a favourable result is found.
- Choosing the way that an outcome is calculated to give the most favourable light (e.g. endpoint score or change from baseline).

The editors are not all to blame. Often it is the researchers who do not write up the results or submit them for publication. If they present results at a conference they may go no further than the abstract for that conference. Peer reviewers may give less favourable opinions of non-positive results. Some studies suggest that source of funding is a factor in publication – commercially funded studies may be less likely to be published (perhaps for competitive reasons or perhaps because they do not want to admit a ‘failure’).

Publication bias matters because it can lead to overestimation of intervention or treatment effects and hence, at its most extreme, to resources being invested in treatments that are not as effective as claimed.
Systematic reviews can add to bias by being limited in the range of languages they cover, by the omission of grey literature (see Session 2), and by failing to contact authors to obtain information about outcomes that were planned but not reported.

A number of measures are now used to reduce publication bias, some of which are described in the Liberati paper.

1. Firstly, registers of controlled trials have been established. Researchers must register controlled clinical trials before data collection starts. They receive a number which must be quoted if the results of the study are to be published.
   Two registers for this can be found at the following websites: http://www.controlled-trials.com/ or http://prsinfo.clinicaltrials.gov/

2. Steps are taken within systematic reviews to identify unpublished results. The trial registers should be checked for studies which are completed but not published. Authors in the field may be contacted and conference abstracts may be searched.

3. Statistical methods are used to investigate publication bias in meta-analysis.

4. Some journals actively encourage publication of ‘low-impact’ non-definitive studies so that a more complete picture can be drawn up. The BMJ Open journal, started in 2011, is a case in point.

ACTIVITY 6

Read the paper by Sterne et al. ‘Investigating and dealing with publication and other biases in meta-analysis’.

After reading it and without looking back at the article write down the two main causes of funnel plot asymmetry.

How can you, with caution, examine the relative importance of different types of bias?

Feedback

There are several sources of funnel plot asymmetry but the two main ones are publication bias and a larger observed treatment effect in small studies. In the first of these, the studies with null effect, especially small ones, may not have been published. In the second of these, larger effects are sometimes observed in smaller studies because either the target group is more specialised (e.g. high-risk patients) or the smaller number of clinicians involved means that there can be tighter control over the protocol or that an experienced practitioner can do all the work.

Apart from the funnel plot, one can model the trial results against their respective standard errors or against features of the trial such as an indicator of type of blinding. However, the number of points in the regression is the number of trials and may be small – also there may be confounding. If a trial characteristic like mean age is used this can lead to a kind of ‘ecological fallacy’. This is quite a complex topic and it is advisable to seek help of a statistician until you are well versed in these techniques.
The Cochrane Collaboration and the Cochrane Library

The Cochrane Collaboration is an international organisation that aims to help people make well informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic, up-to-date reviews of the effects of healthcare interventions. The Cochrane Library comprises several individual databases, including those for:

- systematic reviews
- abstracts of reviews of effectiveness
- register for controlled trials
- methodology reviews
- review methodology
- health technology assessment
- economic evaluation.

The Cochrane Library is available online. Access is free in many countries See http://www.thecochranelibrary.com/view/0/FreeAccess.html

It can also be purchased as a CDROM http://www.thecochranelibrary.com/view/0/HowtoOrder.html

To find reviews on Cochrane you use the same strategy as described in Session 2:

1. Define your search topic
2. Choose the resources to search
3. Choose your search terms
4. Compile your search strategy and running your search
5. Find the full text.

ACTIVITY 7 (Optional)

Watch the first two podcasts in the list of online self-paced training tutorials on http://www.thecochranelibrary.com/view/0/HowtoUse.html

Find a review in your own field.

Evidence-based medicine

Now that you have developed an understanding of systematic reviews and meta-analyses, and how to access them quickly online, it is a good time to consider their value in clinical practice. The next section on evidence-based medicine addresses this question.
ACTIVITY 8

Read Sackett et al. ‘Evidence-based medicine: What it is and it isn’t.’ Then answer the following question:

What two factors must come together in evidence-based medicine?

Feedback

Evidence-based medicine necessarily involves clinically relevant research. This research may be drawn from the basic sciences of medicine or from clinical research on patients. This clinical research may be into the accuracy and precision of diagnostic tests, the power of prognostic markers, or the efficacy and safety of therapeutic, rehabilitative and preventative regimes. External research does not provide a fullproof recipe for action. Evidence-based medicine also involves use of clinical skills and experience to rapidly identify each patient’s unique health state and diagnosis, their individual risks and benefits of potential interventions, and their personal values and expectations.

ACTIVITY 9

Jot down some justifications for evidence-based medicine.

Feedback

Clinicians have a daily need for valid information about diagnosis, prognosis, therapy and prevention. However, traditional sources for this information such as textbooks are frequently wrong, out-of-date, ineffective or too overwhelming in their volume and too variable in their validity for practical clinical use. In addition, there is a disparity between diagnostic skills and clinical judgement (which usually increase with experience) and up-to-date knowledge and clinical performance (which usually decline with experience). Finally, clinicians are generally unable to afford more than a few seconds per patient for finding and assimilating evidence, or less than an hour each week for general reading and study.

Fortunately, evidence-based medicine incorporates the following developments that can assist clinicians in surmounting these problems:

- strategies for efficiently tracking down and appraising evidence for its validity and relevance
- systematic reviews and concise summaries of the effects of health care
- evidence-based journals of secondary publications (e.g. reviews, summaries of evidence)
- information systems that make the above accessible within seconds
- effective strategies for lifelong learning and for improving clinical performance.

Progress in evidence-based medicine and implementation

The philosophy of evidence-based medicine has extended from looking at evidence of trials of efficacy to the more real-world of clinical practice. It has now recognised that values and preference judgment are implicit in clinical decision-making. Decision trees are created that bring in other information. However, it is not an
easy task to reconcile all the pressures on clinicians with beneficence, sensitivity to patients’ values and wishes, and firm evidence.

Evidence-based medicine is controversial. Even if accepted universally, the evidence has not been collected for all topics or conditions. However, it is widely accepted. Two examples are:

- The American Psychological Association has a policy to encourage evidence-based policy, defined as “the integration of the best available research with clinical expertise in the context of patient characteristics, culture, and preferences.” APA (2005)
  http://www.apapracticecentral.org/ce/courses/ebpstatement.pdf
- the Nursing Services of the University of Iowa have a number of evidence-based practice projects

In addition to the Cochrane centre, the UK has a number of other centres that collate and disseminate information, e.g. the Oxford Institute for Evidence Based Medicine and the York Centre for Reviews and Dissemination. In Glasgow the Medical Research Council’s Social and Public Health Sciences Unit evaluates the health effects of social interventions. You may know of institutions in your own country. One of the Cochrane Databases (DARE), which is provided by the York Centre, provides summaries of quality-assessed reviews of effectiveness from other sources:

The Database of Abstracts of Reviews of Effects (DARE) is the only database to contain abstracts of systematic reviews that have been quality-assessed. Each abstract includes a summary of the review together with a critical commentary about the overall quality. DARE is a key resource for busy decision-makers and can be used for answering questions about the effects of specific interventions, whether such questions arise from practice or when making policy. DARE covers a broad range of health related interventions and thousands of abstracts of reviews in fields as diverse as diagnostic tests, public health, health promotion, pharmacology, surgery, psychology, and the organization and delivery of health care.

http://www.thecochranelibrary.com/view/0/AboutTheCochraneLibrary.html#DARE

The National Institute for Health and Clinical Evidence provides guidance on treatments to the National Health Service and makes available evidence on which their guidance is based. For example, one of the early set of standards that they set up concerned treatment of stroke. A useful summary of evidence on many aspects of health care is provided by a small group in the UK

http://www.medicine.ox.ac.uk/bandolier. There are also several journals that provide digests of the current evidence for health care, e.g. bmj.com publishes at least three search journals and the Journal of Evidence-based Medicine is produced by the Chinese Cochrane Centre.

1 Principle of aiming to do good to others.
Summary

Critical appraisal of a review paper

As with primary research papers, you should critically appraise review articles to assess their validity and usefulness. Systematic reviews generally have a higher scientific rigour and value than non-systematic reviews. Meta-analyses, when available, may be particularly useful as they can provide a single estimate of intervention effect. The Cochrane Library is an excellent resource enabling quick access to high quality reviews on specific topics.

Evidence-based medicine

Evidence-based medicine is an important way to integrate the best research evidence with clinical expertise and patient values. There are many sources of information summarising the best evidence available at present.

Additional references

- The York Centre for Reviews and Dissemination produced a guide which includes reviews of public health interventions, often much more complex to assess than clinical trials.
  This is a textbook written from the point of view of a practitioner who has to take decisions about treating patients.
  This report concerns publication bias. Executive summary available via http://www.hta.ac.uk/pdfexecs/summ1408.pdf
- At the time of writing this guide, there were plans for a register of systematic reviews. To learn more about its progress go to http://www.york.ac.uk/inst/crd/projects/register.htm
  There are various articles about the application – or lack of – evidence based medicine. These are just a few:
http://www.bmj.com/content/329/7473/990.full.pdf (accessible if you have registered with the BMJ).

http://www.neurology-asia.org/articles/20082_087.pdf

Session 6

Peer review of epidemiological research papers

Overview

In the previous sessions, you learned how to find, interpret and criticise the information available in the epidemiological literature. The idea of peer review was introduced in Session 1. In this session, we will introduce the requirements of peer review as this is something that most of you will be expected to do but generally without any preliminary training. You will first be invited to reconsider in more detail what is meant by peer reviewing of scientific papers and then learn more about how to become a good reviewer. This session builds on what you have learned in Sessions 4 and 5 as similar tools are used to assess published and draft manuscripts. For this reason, this session will focus primarily on the purpose, process and value of peer review rather than on the assessment itself.

Learning objectives

After working through this session you will be able to:

- describe the role of peer reviewers and how they are chosen
- outline the potential value and limitations of the peer review process
- describe what is generally expected from a review
- outline the qualities of good peer review reports.

Planning your study

To complete this session you will need:

Book available online:


and the following articles:

information for reviewers from the BMJ, http://resources.bmj.com/bmj/reviewers and the checklist for statisticians http://resources.bmj.com/bmj/authors/checklists-forms/statisticians-checklist


Review of paper 1508: ‘Risk of testicular cancer in men with abnormal semen characteristics’ by Professor David Forman (in the module reader)


Rapid responses to: Fatigue and psychological distress (electronic responses).

The last three references are together on:

http://www.bmj.com/content/320/7233/515.2.full?sid=7757fdfa-f728-4923-90e5-c6c5ab1b028

You should allow yourself approximately five hours to finish the work in this session (excluding the optional activities) and about one hour to do the optional activities. A suitable place for taking a break is suggested should you need it.

What is peer review?

Peer review is an inescapable process that epidemiologists face in different parts of their work: when they want to apply for a grant, submit an abstract to a conference, get a paper published, assess someone else’s work, and when they are assessed for employment or promotion by their publication record. In Section 10, you will again meet the role of peer review in the context of the submission of manuscript for publication in a scientific journal.
**ACTIVITY 1**

Write down what you anticipate, or know, to be the role of peer reviewers of epidemiological papers.

**Feedback**

The role of peer reviewers is to act as advisors to the editor of a journal by giving expert opinions on different aspects of the papers they are invited to review. To do this, editors often supply peer reviewers with detailed forms that indicate the kinds of judgments sought (this will be covered in Activity 7).

**ACTIVITY 2**

Read Wager, Godlee and Jefferson from the top of page 3 to just before the section entitled ‘How are reviewers chosen?’ on page 8.

What is the difference between ‘top-down’ and ‘bottom-up’ reviewing? What are the different ways in which responsibility is divided between internal and external reviewers?

**Feedback**

‘Top-down’ creams off the ‘best’ manuscripts for publication whereas ‘bottom-up’ rejects the worst and keeps the rest, making for a higher acceptance rate but likely to lower the overall quality of the journal.

Some journals send the majority of papers out to external reviewers, while others undertake an internal review and only send out those which are considered by the internal board to be appropriate in topic for the journal and to have some merit – more likely to be a ‘top-down’ system. At the end of the day either the editorial board or a specific editor take the final decision on publication. Using external reviewers takes time as they are fitting reviews into their schedules (often already full-time). Tables 2.2-2.4 in the textbook provide useful summaries of the different systems.

The authors mention some of the consequences of advances in technology to electronic publication – they were writing in 2002 and further changes have taken place. Switch from paper publication to electronic publication has changed the emphases with more ‘space’ for publishing and the possibility of quicker turn-round. For example, the BMJ introduced BMJ Open in 2011, which will publish articles previously rejected because too narrow in focus (e.g. geographically) or not sufficiently novel or definitive. The research still has to be scientifically and ethically sound. Electronic publishing has also encouraged more open peer reviewing (see Activity 4).

**ACTIVITY 3**

The use of peers to assess the work of fellow scientists is designed to act as a filter to raise the quality of the papers published and to provide a mechanism for rational, fair and objective decision making. Yet some people are very critical of the usual peer review process.
Without looking at any text, suggest potential shortcomings of peer review in biomedical journals. Then read Wager and Jefferson ‘Shortcomings of peer review in biomedical journals’ and expand or edit your list.

Feedback

Some possibilities in your list are:

- failure to recognise important papers
- failure to identify errors in papers
- failure from the part of the reviewers to comment on all defects/weaknesses of a manuscript (e.g. discrepancies between abstract and main body of text, errors in bibliography etc.)
- lack of consistency and objectivity
- inability to spot papers that had previously been published
- inability to spot lack of originality
- potential bias in relation to authors’ identities, institutions, and publication language
- inability to spot research misconduct (e.g. fraudulent results)
- abuse of the peer review system
- expensive
- labour intensive
- takes time (with potential effects for example on the authors, patients, and commercial companies).

While scientific publishing without peer review is hard to imagine, Wager and Jefferson conclude their paper by stating that more research is needed into the outcomes of peer review into the establishment of sound methods for measuring the quality of the process and its outcomes. Comparisons with alternative methods are also needed. There is now some literature on this although the validity and usefulness of peer review is still controversial (see additional references at the end of this session). For example, the BMJ has conducted research into open peer review and peer review training.

**ACTIVITY 4** (Optional)

An increasing number of journals, such as the BMJ, now have a system of open peer review. This means that the reviewer’s identity is revealed to the author (they sometimes have to briefly say who they are and where they work, and declare any competing interests).

Read the two brief Head to Head papers from the BMJ on open peer review by Groves and Khan. Which would you opt for: open or anonymous?

**Who are the peer reviewers?**

Obtaining useful peer review reports for an editor depends on various factors including, among others, the expertise of the chosen reviewer, the reviewer’s availability and willingness to review the manuscript, and his/her ability to prepare a valuable report. The following activity discusses how peer reviewers are selected.

**ACTIVITY 5**

Take a few minutes to think of ways for an editor to identify volunteers who could help with the peer review process.
Feedback

There are many ways for editors to identify volunteers to help with the peer review process. An important method is through personal contacts. A list of potential reviewers might also be developed based on the following:

- existing database of the journal
- well-known authors/researchers in the field
- researchers who previously published on a similar topic in the journal or other journals (e.g. from the citation list of the submitted paper, from Medline etc)
- reviewers suggested by authors of manuscripts (a common occurrence these days)
- reviewers suggested by other reviewers
- authors who volunteer to become reviewers (if you would like to become a reviewer for a given journal, you could for example send your name and list of publications to the editor of the journal).

ACTIVITY 6

Read Wager, Godlee and Jefferson pp13-15 stopping just before the section entitled ‘Assessing the manuscript’. Describe the points you should consider before accepting an invitation to review a manuscript.

Feedback

Before accepting to review a paper, make sure that the following points are met:

- the manuscript is in your field of expertise
- you feel comfortable with the review process (e.g. masked vs. open review)
- you are clear about what is expected from you
- you have enough time to meet the deadlines expected by the editor of the journal
- you have no conflict of interest.

You could contact the editor if one of these is not met or to discuss any problem. If you decide not to review the paper, simply tell the editor quickly and if possible suggest the name of other potential reviewers. If you do agree to review the manuscript, then let the journal know, confirm (and respect) the deadline, keep the review confidential, do not contact the authors unless this is accepted by the journal, and aim to be as objective, constructive, conscientious and systematic as possible.

What kind of information is expected from a peer reviewer?

In the following activities, you will look at the detailed guidelines to peer reviewers provided by the BMJ and read about what constitutes a good review report.

ACTIVITY 7

Read the BMJ webpage entitled ‘Guidance for peer reviewers’ http://resources.bmj.com/bmj/reviewers/peer-reviewers-guidance to identify the specific points that peer reviewers are asked to comment on when reviewing research papers for this journal.

Then, without looking at the webpage, jot down some of the characteristics they ask peer reviewers to look for. These will be similar for many other journals.
Feedback

Peer reviewers for the BMJ are asked to comment on the following aspects of a paper:

- originality
- importance of the work to general readers
- writing style and clarity (paper reads well and makes sense)

Scientific reliability:
- research question — clearly defined and appropriately answered?
- overall design of study — adequate?
- participants studied — adequately described and their conditions defined?
- methods — adequately described? Are the relevant guidelines followed (e.g. CONSORT for randomised control trials).
- ethical?
- results — answer the research question? Credible? Well presented?
- interpretation and conclusions — warranted by and sufficiently derived from/focused on, the data? Message clear?
- references — up to date and relevant? Any glaring omissions?
- abstract/summary/what the paper adds’ box — reflect accurately what the paper says?

Some types of papers need more specific appraisal, and the BMJ may ask reviewers to use one or more of these special checklists:

- general statistical checklist http://resources.bmj.com/bmj/authors/checklists-forms/statisticians-checklist
- checklist for statistical assessment of randomised controlled trials
- checklists for health economics papers
- checklist for appraising clinical management guidelines
- checklist for lessons of the week
- checklist for drug points.

Look at the general statistical checklist and if interested you can look at the others as well on http://resources.bmj.com/bmj/authors/checklists-forms.

Warning: Remember that a journal’s guidelines may change from time to time. It is therefore always a good idea to visit the journal website for the most up-to-date version of the peer reviewers’ guidelines.

A note on originality

In terms of whether a paper is worth publishing, the question here is not so much whether anyone has researched on the topic before but whether this paper adds something new, even if it is results that are more reliable than previous studies by being a more rigorous study. It may be looking at a different population, use a different method of data collection or analysis, or follow up the participants for a longer period. The previous literature needs to leave some doubt about the answer to the research question that the paper is trying to address. Also, note that meta-analyses rely on there being multiple studies with the same exposure and outcome.

**ACTIVITY 8 (Optional)**

Read how Wager, Godlee and Jefferson describe what is expected from reviewers by reading the section entitled ‘Assessing the manuscript’ on pages 15-17 in their book.

**Feedback**

You will see that the advice provided by the BMJ agrees with the points made by the authors. They also make the point that

> “the text should tell the story, the tables should provide the detailed data, and the figures should illustrate the story” (p16)

This is a useful point to bear in mind for your own writing too.

In addition to the points made in the previous readings, it is helpful to the writers and editors if you make it clear which points you consider to be major and which minor.

---

**Flaws in the design or execution - what should a peer reviewer do?**

As noted in Session 1, it is rare for a study to be devoid of flaws. When reading papers in order to decide how to carry out your own study, you may learn from the flaws of others and plan to avoid them. When you are doing a peer review, take into account that flaws in the study design and data collection already exist and cannot usually be undone. Methods of analysis can usually be changed, however. You have to decide whether the flaws are so fundamental that the paper should not be published. If the paper is to be published you want to be sure that the flaws are addressed and the author has discussed their implications. Do you agree with their conclusions about any implications for bias?

It is also helpful if they explain why a flaw exists, e.g. why there was no blinding or why there was a non-random sample. It may be that this was the best they could do given constraints of money, staff available, and the information available to them, etc. Sometimes compromises have to be made when undertaking studies. On the other hand, a series of flaws that are ignored by the authors may be the result of lack of due diligence in their research and might make you feel dubious about the whole study.

---

This would be a suitable stopping point if you wish to take a break.

**ACTIVITY 9**

Read the section entitled ‘Writing your report’ in Wager, Godlee and Jefferson, pages 17-18. Note their advice.
Feedback

The points listed by Wager, Godlee and Jefferson stress the importance for the reviewer’s report to be useful for both the editors and the authors, while being courteous and clearly organised. A few of their points refer to paper-based reviews but most of them are still relevant. Note they also advise that the presence of flaws is not in itself a reason for rejection – the authors explicitly acknowledge weaknesses but what matters is the usefulness of the paper despite these.

ACTIVITY 10

Imagine that you just submitted to the BMJ a paper on childhood consultation rates in general practice and that you received the following reviewer’s report.

Comment on the usefulness and tone of the report.

Report on the manuscript entitled ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales’.

This paper gives results of a study of socioeconomic differences in childhood consultation rates in General Practice in England and Wales.

Background

1 The author missed some well-known references in the area.

Materials and methods

2 The writing is sometimes unclear and the section needs to be reorganised and shortened.

3 The authors mention that data were transferred to OPCS by computer link where ICD9 code was assigned to practitioner-independent degree of severity. The validity and reliability of the instrument used need to be discussed. During the interviews for the collection of socioeconomic data, were the interviewers blind to the GP’s assignment of outcome? What was the validity and reliability of the instruments used? Describe how age- and sex-adjusted rates were calculated.

4 More data from ethnic minorities should have been collected.

Results

5 Table 1 is clearly not useful as it repeats results presented in Table 1!!

6 There are way too many tables! Cut cut cut!

Discussion

7 I object to the author describing feelings (‘I feel this unique study contributes…’) as it shows a complete lack of objectivity.

8 The discussion contains a list of possible explanations. Surely the list is an interesting exercise but it is only a list of possibilities!! It would be much more helpful with added documentation that showed that one or more of these possibilities actually happened.

9 A major weakness of the paper is the lack of discussion of the limitations of current knowledge.

10 Another methodological weakness is the failure to come to grips with the potential effect of non-random sampling of practices.

11 In the conclusion, it is unreasonable to assume that GPs and health planners are unaware of social class differentials in minor childhood illnesses!!

Conclusion

I think that after a good re-write, and hopefully with more data from ethnic minorities, the paper might be of interest to the readers of the journal.
Feedback

What did you think? How did you feel as the presumed author of the paper? You will be right if you say that the reviewer is clearly not very courteous and definitely not constructive! Not the type of reviewer who will help an editor reach a decision and help an author improve the manuscript. But believe it or not, many of the points included in the example are adapted citations of true reviewer reports! Other points that you may have included in your list of comments on the review’s report include:

General points:
- There is no comment on important points such as the originality of the paper, the importance for general readers, or novelty.
- The design, methods and interpretation of the study are not discussed explicitly and in detail (ideally with references from within and outside the manuscript) – scientific reliability.
- The reviewer makes several judgmental comments, some even being sarcastic.
- Several points are ambiguous and unclear.

Structure:
- It is a good idea to start with a brief outline of the paper. However, in this example, the reviewer just restated the title so we do not know if he/she understood the study.
- It is a good idea to divide-up the comments according to the papers’ sections and to number the comments. This helps the authors when responding and editors when judging the author’s response. However, the reviewer could have used page/paragraph/line numbering to direct the editor and author to the specific problems.

Comments on specific points:
- Point 1: The reviewer could have helped the authors by suggesting some of these references (which he/she seems to know of).
- Point 2: There is no information as to what is meant by ‘unclear writing’ and no help as to how the section could be reorganised to be improved, or shortened.
- Point 3: Several points are made in one big block. It would be better to divide them up.
- Point 4: As the study is finished and the sort of data the reviewer is looking for have not been collected, the reviewer could suggest instead how this limitation could be discussed in the paper and if necessary what analyses could be done to assess the impact of this limitation.
- Point 5: This sentence is confusing as ‘Table 1’ is repeated twice. The comment could be clearer and more constructive.
- Point 6: Although the reviewer might be right, a more useful comment would have suggested ways of reducing the number of tables or organising data presentation. The way he/she phrased this comment was not very courteous.
- Point 7: The reviewer could have suggested more politely how to re-write the sentence.
- Point 8: This is a disparaging comment of no help to the authors.
- Point 9: This is both unclear and not constructive. The reviewer could suggest ways of improving the discussion of the limitations of current knowledge or important references that appear to have been missed.
- Point 10: The reviewer could have suggested ways of dealing with this problem.
• Point 11: This is a critical (possibly personal) remark with its basis unexplained.

• Conclusion: It is not clear what ‘a good re-write’ means, and the expectation that more data should be collected is probably unrealistic at this stage. Writing style should not be treated as a marker of the potential interest of the readers in the topic presented.

**ACTIVITY 11**

Read the paper by Jacobsen et al. entitled ‘Risk of testicular cancer in men with abnormal semen characteristics: cohort study’. This is a real draft manuscript that was submitted to the BMJ a few years ago. Although the topic covered may not be in your area of expertise, use the BMJ guidance notes for peer reviewers to draft a list of points you would make in a reviewer’s report.

When you are finished, read and comment on the review prepared by Professor David Forman.

**Feedback**

You may find some similarities between the points made by Professor Forman and the ones you listed, but maybe also some discrepancies. You may also have included more points in your review. If you were not an expert in the field, it may have been harder for you than for Professor Forman to review more technical parts of the paper as well as the overall originality and importance of the work. This is normal.

Based on the BMJ reviewer guidelines we can make several comments on Professor Forman’s review. The list you prepared may look like this one:

- He clearly discussed the originality, novelty and importance of the work.
- He made several points regarding the scientific reliability of the paper with regards to the research question, overall design of the study, methods, results, interpretation and conclusions, but he did not comment on selection of study participants or on the fact that the authors did not include a statement on ethical issues.
- By using specific headings for the references and abstract, he showed the editor that he had checked these sections of the paper.
- He did not comment on the writing style and clarity of the paper.
- Regarding the presentation of his report: he organised the report in a way that is close to the ordering of the sections included in the BMJ reviewers’ guidelines. However, he could also have numbered each comment.
- He was courteous and constructive in the way he wrote his remarks.
- He made not only criticisms but also several positive remarks.
- He justified the points he made and provided several concrete suggestions for improving the paper.

You may read, if you wish, the published version of the paper
doi:10.1136/bmj.321.7264.789
**When the process fails: post-publication peer review**

One of the shortcomings of peer review is that it does not guarantee that all errors present in a manuscript will be identified through the reviewing process (see Activity 2 above). Post-publication peer review thus takes place when mistakes come to light after publication. A famous case of hidden unethical behaviour was the Wakefield paper about autism and MMR (measles, mumps, rubella) vaccine, initially published in *The Lancet* in 1998. After a journalist catalogued conflicts of interest that the first author had not declared, the editors retracted the paper but there was a sharp drop in vaccination rates for a while. The controversy led to further studies and a Cochrane review.


**ACTIVITY 12**

Turn to the JAMA paper from Altman entitled ‘Poor-quality medical research – What can journals do?’ Read the section discussing post-publication peer review (starting on page 2766, at the bottom of the second column).

**Feedback**

In this paper discussing the problem of errors in published research papers, Altman stresses the importance of post-publication peer review. His main point is that in order to advance scientific knowledge, editors should promote and facilitate the correction of errors in published material (either those found by the authors or those reported by readers). Ways to facilitate this include giving special attention to letters making criticisms of methodology (the use of rapid publication of correspondence on web pages could facilitate this) and eliminating the time limit on submitting letters commenting on published articles.

**ACTIVITY 13 (Optional)**

Now it is your turn to do some post-publication peer review (in fact you have already had plenty of practice in Sessions 4 and 5). Turn to the paper from Pawlikowska (‘Population based study of fatigue and psychological distress.’). Read the Introduction and Methods sections. Then concentrate on the Results and comment on that section.

**Feedback**

You can now compare your answers with those of another post-publication peer reviewer by reading the letter by Martin Bland (‘Rapid responses to: fatigue and psychological distress.’). Six years after the publication of the original paper this researcher reported several statistical problems in the results section, suggesting either that the peer review process failed (errors went unnoticed by the reviewers) or that errors occurred at the editing or printing stages (when the paper was processed after having been accepted). What is more certain, however, is that once the paper was published, readers have accepted its results uncritically with potentially adverse effects on patients’ care. This example shows the importance of learning how to become experts in reading the scientific literature critically and of reporting potential flaws to the journals.
You can also read the authors’ reply to the letter sent to the *BMJ* by Bland, as well as the correspondence that followed. This correspondence reveals, sometimes in humorous ways, further details of where errors might have happened in the publication process of this paper.

While some letters imply that errors might have happened at the editing stage (the original manuscript being fine), the editor suggests that errors might also have been introduced by a reviewer asking for a change and the authors not making it correctly. So we are unfortunately left without a true answer. But one thing is certain: all the parties involved had a nice dinner in the end!

**Summary**

The peer review process has the potential for acting as a filter to raise the quality of the papers published and provide a mechanism for rational, fair, and objective decision making. It is also used to identify manuscripts with the greatest relevance, importance and interest to the readers of a journal.

Potential limitations of the peer review process include the failure to: recognise important papers; spot lack of originality, consistency or objectivity; identify papers that have previously been published; notice all errors; or recognise misconduct. The process is also labour intensive, time consuming and subject to potential bias.

Peer reviewers act as advisors to the editor of a journal by giving expert opinions on different aspects of the papers they are invited to review.

In general, peer reviewers are asked to comment on various characteristics of a manuscript, such as the originality, importance, novelty, scientific reliability (e.g., research question, design, choice of study population, methods, results, interpretation and conclusions), chosen references, abstract, writing style and clarity.

A good quality report will help the editors decide what to do with the paper (thus it should follow the instructions for reviewers provided by the journal) and help the authors improve it before publication. It should be written in a courteous, constructive, clear, and well organised manner, and be sent on time.

Post-publication peer review takes place when mistakes come to light after publication.

Now you should be ready to do the FA1 on critiquing a paper.
**Additional references**


- The *BMJ* has a section on training for peer reviewers, which include three sample feedbacks and their comments on them. [http://resources.bmj.com/bmj/reviewers/training-materials](http://resources.bmj.com/bmj/reviewers/training-materials).

- When doing a peer review, look at the specific instructions and guidelines from that journal but as an example of a journal that takes a different approach to the *BMJ* – e.g. does not do any copyediting for good English – see the guidelines from *PLoS One*. Note that they specifically ask reviewers to state the main claims of the article. [http://www.plosone.org/static/reviewerGuidelines.action](http://www.plosone.org/static/reviewerGuidelines.action).

- The Biomed central publishers make pre-publication history available on the internet. One can see the original submission, reviewers’ comments, authors’ responses, and revised manuscripts. The web links for two examples are given below. You will find that there may be 8 or 9 versions of the manuscript but several of these will be the results of minor editorial changes. Focus on the original, the peer reviews, authors’ response and their resubmissions in the light of the peer reviews. Be warned that much of the reviewing does not follow best practice. The examples given below are considered to be relatively good in the information that the peer reviewers gave. Note that in the first example none of the reviewers follow Wager et al.’s recommendation to give an outline of the paper to show that it has been understood. In the second example, the authors changed the nature of their paper as a result of one reviewer’s comments. [http://www.biomedcentral.com/1471-2458/10/775/prepub](http://www.biomedcentral.com/1471-2458/10/775/prepub) [http://www.biomedcentral.com/1472-6874/8/19/prepub](http://www.biomedcentral.com/1472-6874/8/19/prepub).

Session 6: Peer review of epidemiological research papers
Session 7

Writing an outline of an epidemiological research paper

Overview

In this session you start to write your own paper using the data provided in the module reader to which you were introduced in Session 1. Many of the questions you have been asking about published papers in the last few sessions also apply to your own work. Once you have clarified the main focus of your paper and selected the journal that you plan to submit it to, you are ready to write an outline of the paper, which includes an outline of the Introduction, Methods, Results and Discussion sections.

Learning objectives

After working through this session, you will be able to:

- describe the key content of each section of an epidemiological research paper
- write an outline for a specific research paper.

Planning your study

For this session you will read from one of your textbooks, a paper in your reader and the documents available from the internet, and you will carry out a number of activities related to your reading. It is recommended that you use your computer and word-processing software for the activities in this session and the rest of this block, but it is not essential. The notes you make will form the basis of future written work and may be more useful on your computer than made on paper. In this session you are not trying to write a fluent script but simply to make notes of the information and comments to include in your paper.

To complete the work in this session, you need:

The ebook available via the LSHTM library:

  Library reference:
In the module reader:

- Saxena S. Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.

From the internet:

- The BMJ information for authors: http://resources.bmj.com/bmj/authors

Two online papers from the BMJ:

  http://www.bmj.com/content/342/bmj.d715.full

  http://www.bmj.com/content/342/bmj.d1016.full

The explanatory paper concerning the STROBE Statement:

  http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040297

The explanatory paper concerning the CONSORT Statement:

  http://www.bmj.com/search?fulltext=Moher&submit=yes&x=9&y=7

You should allow yourself approximately eight hours to complete this session. You will probably want to do the session in more than one sitting. Three suitable points to take a break are shown. Although a long session, you will achieve much during it.

**Key terms**

**IMRaD:** the acronym for Introduction, Methods, Results and Discussion – giving the main sections of a research paper.

**RCT:** randomised controlled trial.
Why write an outline?

Starting to write is often very difficult. Even after you have clarified the main study question and identified the relevant data, it can be hard to imagine writing a full research paper. You may be nervous about your writing style, or unsure about what to put in and what to leave out. A good way to start is by writing an outline of each section of your paper. This enables you to clarify the order and content of the paper without worrying about how it is written. As an outline gives an overview of the whole paper, it also helps you to develop and organize a clear argument. A good outline provides the key statements that form the backbone of the full draft at the next stage.

To write an outline, you start with the headings of the main sections of your paper:

- Introduction
- Methods
- Results and
- Discussion.

Next, you list the key points that you want to include under each heading. However, before you can do this, you need to know what types of information to include in (and exclude from) each section of a paper. In this session, you will learn in more detail the content of each of these sections of a research paper. You will also learn how to build up an outline for a specific research paper.

Introduction

In this section a research paper you state what your main study question is and why it is important. You need to convince your readers that your study question is relevant to public health, clinical medicine and/or furthering scientific knowledge. To do this, you need to mention previous relevant research, and demonstrate what your particular study adds to the literature. However, you should only include background information that is directly relevant to the main study question.

ACTIVITY 1

Read chapter 5 in Albert’s ‘Winning the Publications Game’ entitled ‘Making a plan or four’ pages 41-49. This gives a feel for the purpose and relative length of each of the IMRaD sections. The numbers of paragraphs he recommends are not prescriptions but guides. Further, as he recommends, you should research your target journal to learn their rules or usual format.

Go through a piece of writing you have to hand – a newspaper article, some pages from a book. Can you pick out the key sentences? If you cannot, was the piece of writing easy to follow?
The suggestions made by Albert are all with the intention of getting across your story clearly and ending with a ‘take-home’ message for the reader. The purpose of his book and of this module is to help you communicate effectively.

ACTIVITY 2

Before looking at any other documents, write down the types of information you would expect to see in the Introduction. Also note some of the information that you would NOT put in the Introduction.

Turn now to the paper by Vandenbroucke et al. on STROBE and look at the items listed under ‘Introduction’ in Table 1 then read the Section labelled ‘Introduction’. Also look at Moher et al. on CONSORT and their section on the Introduction.

Feedback

Your notes should look something like this.

Include in the Introduction:

- Why the research was started – what is known, where are the gaps
- What you believe your paper will add to current knowledge
- The main study question and objectives (primary and secondary) which include:
  - brief specification of the study population
  - the exposures and outcomes (but these are fully defined in the Methods Section).

The study design is useful to note because it already gives some indication of the type of question you can answer – for example, a cross-sectional study is appropriate for prevalence studies, a case-control study can look at predictors of rare outcomes.

DO NOT include in the Introduction

- Detailed explanation of basic terms
- Exhaustive review of the subject area
- Exhaustive review of current literature
- Results
- Conclusions.

There are differing views about the best place for specifying subsidiary questions—some like to specify all objectives and hypotheses in the Introduction, others put subsidiary questions in the Methods. Most importantly, make sure that it is clear which objectives are primary and which are secondary, and look at your target journal to see if they specify where the objectives should be listed.

Many papers involve secondary analysis of data, i.e. are using a study to answer a question for which it was not originally designed. The research study’s original aims can be stated in the Methods.

Also, sometimes additional unplanned analyses are done – these are not usually included in the Introduction but must be clearly set out in the Methods.
As said in Session 1, getting the research question right is critical to the analyses and the paper as a whole.

**Writing an outline Introduction**

In Session 1, you did the initial planning for a research paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales’. In the following activity, you will write an outline Introduction for this paper.

**ACTIVITY 3**

Read the Introduction to the two BMJ papers by Smith *et al.* and Luo *et al.* Do they fulfil the criteria for a good Introduction?

**Feedback**

Both concern topics that have been researched by several others but the authors tell us why they believe there is not yet a definitive answer. The second paper makes the case for their particular contribution a little better than the first paper, perhaps. Both give the purpose of the paper in terms of an objective rather than hypotheses.

**ACTIVITY 4**

Read Chapter 1 of Saxena’s research report in the module reader.

Make a list of the key points to include in the Introduction for your paper (use only information contained in Saxena’s report; you are not expected to find any additional information). Use the points that you identified for inclusion in the Introduction in Activity 2 as a starting point.

Remember:

- The main study question for your paper is simply ‘Does the rate of consultations with a General Practitioner differ for children of different social classes?’ (So do not include unnecessary information.)
- You are preparing the paper for submission to the BMJ.

**Feedback**

Chapter 1 of the research report contains much more information than you would include in the Introduction section of a research paper. You should have carefully selected the information that is appropriate to the main study question.

Here is a possible outline Introduction for this research paper. Your outline may be slightly different; each author will emphasize different points. However, it is important that you have covered the key content of an Introduction.

- Why the research was started:
  - one-quarter of GP workload is children under 15 years (references 7–18)
• large differences in morbidity and mortality between social classes (OPCS 1988)
• child health inequalities seem to be worsening (reference 24) – but some studies inconsistent (references 22 and 23)
• little known about how socioeconomic differences affect childhood consultations with GPs
• previous studies rely on area indices and parental recall (not good-quality individual level data).

- Main study question and associated objectives or hypotheses:
  - ‘Does the rate of consultations with a general practitioner differ for children of different social classes?’

Objectives:
- to assess whether rate of consultations with a General Practitioner differs by social class for the following types of consultation:
  - common childhood illnesses;
  - mild, moderate, severe illness;
  - preventive care;
  - home visits.

- Study population:
  - data from Fourth National Morbidity Survey, person-based socioeconomic information on 106,102 children aged 0–15 years from GPs around UK.

- Study design:
  - cohort study tracking consultations taking place during a one-year period.
  - study design chosen because national, large, and collecting data prospectively.

This would be a suitable stopping point if you wish to take a break.
Methods

The Methods section of a research paper explains how you went about answering your main study question. In this section, you describe the methods that you used. The scientific process is based on methods that are explicit, open to criticism, and reproducible by other investigators. Consistent with this, you should describe the methods you used in enough detail to enable your readers to:

- judge whether the methods were appropriate for answering the study question
- judge any weaknesses in methodology that could influence the interpretation of the results
- repeat the study if they wish to do so.

General content of a Methods section

The study design, subjects, observations and statistical analysis are all part of the general content of this section. You should include a description of any laboratory methods and the statistical methods used, giving enough detail to enable someone with access to the original data to verify your results. You should also specify which computer program you used to carry out your analysis. Although your description of the methods used should enable readers to judge the validity of your results and interpretations, you should not mention your results, conclusions, or any assessment of their validity in this section. You will provide your own assessment of the strengths and weaknesses of your methods in the Discussion section later in the paper. In the Methods section, you are providing the reader with the details to enable them to carry out their own appraisal.

ACTIVITY 5

Jot down some headings that you think may be appropriate for the Methods Section.

Then look at Table 1 in Vandenbroucke et al. on the STROBE statement and read the section on Methods and amend your list in the light of this.

Feedback

Some journals (e.g. BMJ) like you to put subheadings, others not – you need to check – but, either way, at this stage they help (you can always delete them afterwards). One possible set of subheadings is as follows:

- Study design
- Setting and Subjects/participants
- Measurement: outcome, exposures, covariates
- Study size
- Action taken to address potential sources of bias
- Statistical methods.

Although it is not explicitly stated in Vandenbroucke et al., ethical considerations should also be addressed.
Specific content of a Methods section

The specific content of a Methods section depends on the type of epidemiological study that you carried out.

The content of a Methods section from an observational study (cross-sectional, case-control or cohort study) should include the following additional details:

- whether cohort, case-control, or cross-sectional
- the intended population for the study and the setting (e.g. geographical location, clinical or community setting, period of data collection)
- how the different study groups were defined (include the specific criteria used)
- by what procedures were the study subjects recruited. Appropriate procedures differ according to type of study how the outcome and exposure variables were defined and measured (What is already known about validity and reliability of the instruments used? For cohorts, how was follow-up information ascertained? For case-control, how was exposure measured – was the information recorded at the time of the exposure (e.g. a medical record) or after the outcome was known? Were the measurements made in the same way for all comparison groups)
- what other variables were measured, how and why (potential confounders, effect modifiers)
- measures to minimise bias (e.g. tests of reproducibility of information, laboratory diagnostics, sub-studies to compare measures with a gold standard, action to contact those who are hard to reach, blinding of study participants and observers)
- analysis plan
- ethical issues (e.g. informed consent, compliance with regulatory agencies, confidentiality).

The content of a Methods section from an intervention study are the subject of Activity 6.

**ACTIVITY 6**

Even if you have little experience of randomised controlled trials (RCTs), note any features that you know or believe to be specific to one.

In Moher et al. on the CONSORT statement read Box 1 page 2 and the text on Methods pp. 5-14. Note from this the special characteristics of an RCT and compare with your list.
Session 7: Writing an outline of an epidemiological research paper

Feedback

Some features specific to an RCT are:

- Trial design (parallel, crossover?)
- Trial organization and procedure, including randomisation and concealment procedures
- Interventions and what the control group received
- Monitoring, including interim analysis and stopping guidelines
- Changes to methods after trial commencement, and reasons for these changes.

Note that this paper addresses parallel group RCTs, i.e. one where there are different groups of people for each treatment being tested (as opposed to crossover where the same group are given different treatments in a given sequence over time). Most of the CONSORT statement applies equally to all randomised trial designs, but there are a few additional issues to address for each design. Separate papers have been produced to cover some other forms of trial that are not covered here (see references in the Moher paper).

Remember also that RCTs are used for many types of healthcare intervention to see how that intervention changes the prognosis of a disease or the chance of developing a disease – the intervention may be a drug, a surgical intervention, use of a device (e.g. an implant or prosthetic), an action designed to alter behaviour or a preventive vaccine.

Writing an outline Methods section

You are now about to write the outline Methods section for your research paper ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’

ACTIVITY 7

Read chapter 2 of Saxena’s research report in the Reader.

While you are reading, make a list of the key points that you would like to include in the Methods section of your paper. Use the notes that you made on what to include in the Methods section in Activity 5, and add in the additional details necessary when describing an observational study.

You may find that some important information is not contained in this section of the research report. Make a note of any missing information in your outline. If you were writing a real paper, this would remind you of extra information that you need to look up before writing your first draft.

Feedback

Again, this chapter contains much more information than you would include in the Methods section of a research paper. You should select the points that are relevant to describing the methods used for answering the main study question.

Your outline Methods section should look something like this (text in italics indicates information one would like to have but is not available).
Session 7: Writing an outline of an epidemiological research paper

- **Study design:**

- **Setting and subjects/participants:**
  - General Practices in England and Wales
  - Data source: Fourth National Morbidity Survey intended to cover 1% of population of England and Wales, 502,493 patients
  - Participants were 106,102 persons aged 0-15 years registered with 60 volunteer General Practices from all health regions
  - Practices volunteered to take part
  - Within practices, all eligible patients on the register were included for as long as they remained on the register; patients joining the register during the data collection period were included from the date the practice was approached for a new registration.

- **Measurement and observations:**
  - Outcomes: Morbidity data
    - GPs and nurses recorded information at all face-to-face contacts
    - every problem was given a diagnostic Read code
    - data were transferred to OPCS (Office of Population Censuses and Surveys) by computer link; coders at OPCS assigned each ICD9 code to a degree of severity. Thus, this assessment was independent of any that the GP might make.
  - Exposure: Socioeconomic data
    - socioeconomic data for all registered persons collected by interviewers
    - occupation of child’s parent or guardian recorded and converted to social class
    - classification given
  - Covariates: sex, age (source?).

- **Study size** – no power calculation; sample was determined by availability of patients.

- **Action** taken to minimise bias -blinding, validity and reliability of instruments use, accuracy of recording.

- **Statistical methods:**
  - Stata version 5 software used
  - outcomes: mean consultation rates by sub-group of social class for any reason, for specific diagnostic categories, for severity of illness episode, for home visits and for preventive care
  - age- and sex-adjusted rates calculated
  - mean difference in rates compared to baseline rates in social classes I and II
  - linear trends across categories of social class compared by constructing linear regression model.

- **Ethical issues** – not mentioned.

Note: you should not have included any reference to the results (Tables 1–11) in this section.
This would be a suitable stopping point if you wish to take a break.

**Results**

In the Results section of a research paper you present the data that support the answer to your main study question.

**General content of a Results section**

The data that support your answer should be of two main types:

- data that enable the reader to judge the validity of your conclusions (e.g. data comparing the characteristics of the study groups, data on participant dropout etc)
- the data that directly support the answer to your main study question.

If you can break your main study question down into a number of more specific questions, you will need to present the data necessary to support the answer to each of them.

In this section, you may also want to present some subsidiary study questions and the data to answer them. You would do this only if these subsidiary questions were likely to be of interest to the same audience as your main study question and if they did not merit a paper of their own (see Session 1). You should not present any data that do not support the answers to either your main study question or the subsidiary study questions.

In this section, you should only present the data. You should not interpret them. The Results section does not provide the answer to your study question; it only provides the data that support your answer. You will provide your answer to the study question after giving your assessment of all the evidence in the Discussion section of the paper.

**ACTIVITY 8**

In Vandenbroucke et al. on the STROBE statement read the text on Results, pp. 1641-7.

Make brief notes on what to include in the Results section, using the subheadings:

- Participants
- Descriptive data
- Outcome data
- Main results.
Feedback

This reading gives you guidance on the content and order of the data that you should include in your Results section. Note how the detail of the requirements varies according to the design of the observational study; make sure that you understand why this is so.

Results section for an RCT

Again, clinical trials are a special case that require additional specific information.

ACTIVITY 9

In Moher et al. on the CONSORT statement read the text on Results, pp. 14-top of page 20.

Make brief notes on what to include in the Results section, using the subheadings:

- How did the trial proceed? e.g. participant flow, success in assignment.
- Trial findings.

Feedback

It should be clear from the Results section whether the protocol was followed and the trial completed or stopped early. All losses to the study should be catalogued. As with other studies you are advised to set the scene by giving descriptive information before the analytic results.

You will have seen that the guidelines are exacting in the detail they propose for the Results section. Also, note the section on harms. This will not apply to every intervention but measuring these is both a requisite of drug trials and an ethical obligation in its own right.

Writing an outline Results section

In the following activity, you will write an outline of the Results section for your research paper ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales’.

ACTIVITY 10

Read chapters 3 and 4 of Saxena’s research report in the module reader. You have seen some of this before in Session 1 Activity 4.

While you are reading, make a list of the tables of data you need to present in your Results section in order to support all aspects of the answer to your main study question. Do not forget that your main study question can be broken into a number of more specific sub-questions.
Your list will include the tables identified and condensed in Session 1 Activity 4. However, you will also need to include references to additional data or tables. Use the notes that you made on what to include in the Results section (Activity 6 above). It is recognised that you may not have all the information you would want if you were doing the research yourself.

**Feedback**

Your outline of the Results section should look something like this:

- Baseline characteristics of children and mean consulting rates with GPs; construct a table combining the following two tables from the research report:
  - Table 1 Baseline characteristics of children aged 0–15 years in survey
  - Table 2 Consulting rates by age group, sex, tenure, living with sole adult and ethnicity.
- The tables identified in Session 1 Activity 4.

This would be a suitable stopping point if you wish to take a break.

**Discussion and Conclusions**

In the Discussion you interpret your findings and critically evaluate your work. You should take into account any limitations in your methodology and include an assessment of evidence from other sources. Once you have considered all these issues, you will be able to provide the final answer to the question that you posed in your Introduction.

**Content of a Discussion section**

Some journals expect you to separate your discussion and conclusions into distinct sections; others expect to find the conclusion at the end of the discussion. You should consult the information-for-authors pages for your target journal to check which style to follow. In any event, for the purposes of the outline and first draft of your paper, it is often most useful to treat the two separately. In the next activity you will consider the content of a Discussion section.

**ACTIVITY 11**

Without looking at any papers or documents, write down the kinds of information you think should be included in the Discussion

In Vandenbroucke *et al.* on the STROBE statement read the text on Discussion, pp. 1647-9

Adjust your list in the light of this.
Feedback

Your list should look something like the one given below (this list contains some extra points that are not mentioned in detail in the reading):

- the provisional answer given by your data to the main research question – the results are summarised
- an evaluation of your methods, including any possible sources of bias or confounding. Vandenbroucke focuses on limitations but strengths should be highlighted too
- cautious interpretation, involving:
  - presentation and evaluation of evidence from other papers that support or contradict your findings
  - an attempt to explain any differences between your findings and previous research
  - discussion of mechanisms by which A could lead to B but avoid over-interpreting and reading causality into results where other explanations are likely.

The Discussion should not contain any new data that has not already been presented in the Results section.

Content of a Conclusions section

Once you have critically evaluated your findings, you will be ready to give your final answer to the main study question and to discuss the implications of this answer. Remember, even when the conclusions and recommendations are included in the discussion of the final paper, it is often useful to separate them out when you are writing the outline and the first draft.

Vandenbroucke et al. do not have a separate section for conclusions but at the end of your paper you should clearly give your verdict as to the answer to your main study question and the main message that you want to get across. You should also discuss the implications of your answer, including an assessment of:

- the generalizability of your findings
- the theoretical implications (including suggestions for future research in the field)
- the practical implications (for public policy or clinical practice).

The conclusions should be firmly grounded in the evidence. You should avoid wild speculations about the economic or political implications of your findings unless these have been directly addressed in your paper. Do not force the conclusion into the answer you hoped to get if the data and other evidence do not justify it.

Writing an outline Discussion and Conclusions section(s)

In the following activity, you will write an outline of the Discussion and Conclusions section(s) for your research paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood
illness vary with social class? A descriptive study of General Practice in England and Wales.

Emphasising the point that you should always check specific instructions for your chosen journal, the BMJ make the following request for the Discussion section:

“Please ensure that the discussion section of your article comprises no more than five paragraphs and follows this overall structure, although you do not need to signpost these elements with subheadings:

- statement of principal findings
- strengths and weaknesses of the study
- strengths and weaknesses in relation to other studies, discussing important differences in results
- meaning of the study: possible explanations and implications for clinicians and policymakers
- unanswered questions and future research.”

(From: http://resources.bmj.com/bmj/authors/types-of-article/research.)

**ACTIVITY 12**

This is your chance to give your own interpretation of this research study. Based on what you have already read of this report, make brief notes on what you would like to include in the Discussion and Conclusions sections. Remember, you will probably find it easier to write the outline Discussion and Conclusions under separate headings. Use the notes that you made in Activity 11.

You may also want to read Chapter 5 of Saxena’s research report, to get some more ideas. Use only the information contained in the report. If you cannot find some important information, make a note of this. If you were writing a real paper, this would remind you of extra information that you would need to look up before writing your first draft.

**Feedback**

Here is a possible outline Discussion and Conclusions section for this paper. Your outline will probably be slightly different.

**Discussion**

- Provisional answer to main study question (summary of results):
  - overall consultation rates in children increased from social classes I–II to classes IV–V
  - children from social classes IV and V consult more with minor, moderate and severe illnesses
  - children from social classes IV and V consult less frequently for preventive activities.

- Evaluation of method:
  - sampling non-random; self-selected general practices not representative of whole population
  - high levels of data quality and validity
  - comparison with other studies—*need to look this up*. 
Conclusions

- Final answer:
  - strong trend for higher consulting rates in children from social classes IV and V for both minor and severe illnesses
  - children from social classes IV and V use the service more and are sicker.
- Generalisability of findings:
  - ethnic minorities under-represented; unlikely to influence class-specific morbidity differentials.
- Practical implications:
  - GPs and health planners need to be aware of social class differentials in minor and serious childhood illnesses
  - children from social classes IV and V should be targeted for preventive care.

Summary

- In the Introduction you state what your main study question is and why it is important. In this section:
  - you need to convince your readers that your study question is relevant to public health, clinical medicine and/or furthering scientific knowledge
  - you should mention previous relevant research, and demonstrate what your particular study adds to the literature.

- In the Methods section you explain how you went about answering your study question; you should describe the methods that you used in enough detail to enable your readers to:
  - judge whether the methods were appropriate for answering the study question
  - judge any weaknesses in methodology that could influence the interpretation of the results
  - repeat the study if they wish to do so.

- In the Results section you present the data that support the answer to your main study question; the data that support your answer should be of two main types:
  - data that enable the reader to judge the validity of your conclusions, e.g. data comparing the characteristics of the study groups, data on participant drop-out etc.
  - data that directly support the answer to your main study question.

- In the Discussion section you interpret your findings. In this section:
  - you should take into account any limitations in your methodology and include an assessment of evidence from other sources.

- Once you have considered all these issues, you will be able to draw conclusions and provide your final answer to the question you posed in your Introduction.
Further material

Video from BMJ on writing a paper – lasts over 50 minutes - http://www.bmj.com/site/video/how-to-write.xhtml.
Session 8

Writing the first draft

Overview

Once you have developed a clear outline of all the sections of your paper, you should make a first attempt at writing the full paper, including the title and the Abstract. In this session, you will learn how to write this first draft, starting with the Title, followed by each of the IMRaD (Introduction Methods Results and Discussion) sections, and ending with the Abstract.

Learning objectives

After working through this session, you will be able to:

- write the Title for the first draft of a research paper
- write the Abstract for the first draft of a research paper
- write the text for the first draft of a research paper
- construct the tables for the first draft of a research paper.

Planning your study

For this session you will be reading from one of your textbooks, using the Saxena paper in the module Reader, and referring to guidance found on the internet. You will start writing a paper, building on the outline developed in Session 7.

Your computer and word-processing software would be useful (but are not essential) for the activities in this session and the rest of this block. The draft paper you write will form the basis of future written work and may be more useful on your computer than made on paper.

To complete the work in this session, you need:

- Saxena S. Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales (in the module reader)
- the outline of your research paper (produced in Session 7) ‘Childhood consultation rates in General Practice’ based on the research report by Saxena
- the tables you identified and condensed in Session 1, Activity 4
Session 8: Writing the first draft

The ebook:

  
  Library reference
  

From the internet:

- BMJ information for authors: [http://resources.bmj.com/bmj/authors](http://resources.bmj.com/bmj/authors)

We advise using reference management software from the first draft onwards if possible. See part C of pages 13-14 in the *Academic Writing Handbook* available on the DL website. If you need help with it make use of the web-based conference forum specifically set up for library queries. [http://dl.lshtm.ac.uk/programme/epp/docs/Misc%20Docs/Academic%20Writing%20handbook%202010-11.pdf](http://dl.lshtm.ac.uk/programme/epp/docs/Misc%20Docs/Academic%20Writing%20handbook%202010-11.pdf)

You should allow yourself approximately six and a half hours to complete this session. Albert recommends writing your first draft in concentrated but fairly short sessions (Activities 5-9, 11). We have indicated suitable points at which to take a break but you may find you want to spread it over more, shorter, blocks of time.

The guidance here is modelled on the systems used by many journals but we cannot emphasise enough that every time you are writing a paper you should check instructions for authors on the journal’s own website. If they give few guidelines, then using the Uniform Requirements for Manuscripts (URM) is a good starting point.

**Key terms**

**Reference management software:** software packages that capture references from databases of publications and enable you to insert references into your own writing, choosing from a range of layouts. Those recommended by the School are EndNote, Mendeley or Zotero. See the *Academic Writing Handbook*.

**The Title**

The Title is the first part of a paper that potential readers see. Whether they are scanning through the table of contents of a journal, or actively searching an electronic database, they see the Title and then decide if they want to read any further. A good title will enable readers to judge quickly if the paper is likely to be of interest to them. It should do no more than that. Interested readers can then go on to read the Abstract from which they will be able to judge, in more detail, whether or not to they want to read the rest of the paper.
A good title should:

- provide readers with enough information to enable them to judge whether or not the paper is likely to answer questions that they are interested in
- present this essential information in a clear, easily accessible format
- not be cluttered up with unnecessary detail.

ACTIVITY 1

What do you think are the three most important pieces of information that potential readers use to judge whether or not a paper is likely to be of interest to them?

Feedback

Your answer will probably look something like this.

Potential readers tend to look for information on:

- the subject matter addressed by the paper (e.g. malaria incidence; risk factors for diabetes)
- the study design (e.g. prospective cohort study; community-based prevalence survey)
- the study population (e.g. children under five years; post-menopausal women; villages in the Amazon region of Colombia).

A good title will contain these three important pieces of information, and little or nothing else, for example:

- ‘Incidence of malaria among children under five in the Amazon region of Colombia: a community-based incidence survey’

Having said that, journals vary considerably in the format of titles that they use and approve so you may need to adjust your title to fit the style of the journal.

Indicative or informative titles?

An indicative title specifies the purpose of the study and the design; an informative title gives the conclusion. An example of each is given below:

Indicative title


Informative title

The title of the above article could have been:

‘Mental health declines with longer duration of residence in a deprived or fragmented neighbourhood: a multilevel prospective analysis’.
Partly informative title
The third form is a half-way house, implying that there are neighbourhood differences, but not indicating what they were.
‘Mental health trajectory associated with neighbourhood environment: a multilevel prospective study.’

Informative titles usually contain an active verb like “prevents” “reduces” “increases” but can be misleading – there is a temptation to make the findings appear stronger than they are. Some journals accept informative titles, others not, so look through the titles in recent editions if there are no explicit instructions on this.

An indicative title should tell the reader what the paper is reporting but should not state the main study question nor the results and conclusion. The most important term or terms (the ones that you want to catch your readers’ attention) should come first. This means that it is usually better to put the subject matter (e.g. incidence of malaria) before the study population or study design.

An informative title has some dangers in that they purport to give the conclusion but may be conveying only a part of the story or may be ambiguous. In the example above we do not learn that the association between neighbourhood characteristics and physical functioning was less clear than that for mental health. While one could try to fit this into the title there is the danger of it becoming cumbersome. Also, we do not know from the title what happens to mental health over time in other neighbourhoods (it tended to improve).

As said above, journals vary in preferred formats – so you should always look through recent issues of your target journal to get an idea of the style used, and structure your title accordingly.

ACTIVITY 2
The title given below contains too much information: a reader who glance at it is likely to miss the essential terms. Write an improved version of the indicative title.

‘Does exposure to tobacco smoke in pregnancy influence the outcome of that pregnancy? An epidemiological study to investigate the relations of smoking, both by the mother and by her partner and close work colleagues, on placental and birth weights at term using a prospective cohort study design in a population of women receiving ante-natal care from a teaching hospital in Moscow.’

Feedback
Here is an improved version of this title (your title may be slightly different, but should contain the key terms in a short, clear format).

‘Influence of active and passive smoking on outcome of pregnancy in Moscow: a cohort study.’
Writing a first draft title

In Session 7, you wrote an outline for a research paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’ Now is the time to consider a working title. You may decide to revise this when the whole paper is drafted.

ACTIVITY 3

Use the outline you wrote in Session 7 to identify the subject matter, the study design and the study population of the research paper and use this information to write a first draft title.

Feedback

Your title will probably look something like this (again, do not worry if your title is slightly different). ‘Socioeconomic differences in childhood consultation rates in General Practice in England and Wales: a cohort survey.’

After you have written the paper you should revisit the Title to see that it is correct and appropriate (see Session 9) – some writers leave the title until the end anyway but it can help you focus on the paper’s content.

NOTE: The Abstract is often the last section that authors write. Therefore, we will cover this later on in the session.

The main text

In your first draft of the main text of your paper, you will expand your outline to produce a full text version of the IMRaD sections. You will probably find it easiest to write one full section at a time, starting with the Introduction, then the Methods, Results and Discussion. However, you may prefer to write in a different order. You should refer back to your lists of what to include for each section, compiled in Session 7. You may find it useful to use the bullet points in these lists as subheadings. If your target journal does not use subheadings, you can always remove them at a later stage.

While you are writing the first draft, you should take into account the ideal length of each section (recall Session 7 Activity 1). This will help you to concentrate on the essential information, and to exclude unnecessary detail. Remember to check the information-for-authors pages of your target journal to find out any limitations on overall length and to look at some recent issues to obtain an idea of number of paragraphs in each section. However, do not worry too much if each section is longer than required at this stage.

Do remember that this first draft is only your first attempt at writing the paper. It is not meant to be perfect. You will have to revise it many times before you come to write your final manuscript. So, do not worry too much about your writing style at
Session 8: Writing the first draft

this stage. The most important thing is to get this first draft written. Then you will have material for further work.

**ACTIVITY 4**

Read Albert, Chapter 6, “Writing the first draft” pp. 50-56. What are his main messages?

**Feedback**

He recommends having only your plan and writing your first draft from that without any other information to hand. For this first draft, move forward; do not keep going back to what you have written to see whether it reads OK. Work in short bursts and tackle a section at a time. Write in a style that is natural to you – we will deal with polishing it for the journal in Session 9. He also has some tips for overcoming writer’s block.

When you have done your first draft this way you can go back to the Saxena information to fill in the gaps or correct the information.

**Introduction: first draft**

Remember that the Introduction is the section of a research paper where you state what your main study question is and why it is important. You need to convince your readers that your study question is relevant to public health, clinical medicine and/or furthering scientific knowledge. You should mention previous relevant research (having done a literature review as described in Session 2), and demonstrate what your particular study adds to the literature.

**Writing the first draft of the Introduction**

You might want to look back at the section on the Introduction in Session 7 to remind yourself of the purpose and content of an Introduction.

**ACTIVITY 5**

Write the first draft of the Introduction for your research paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’

Start with the outline Introduction that you produced in Session 7, and develop each point into a few sentences. Albert suggests two paragraphs for the Introduction but between one and three paragraphs long is fine.

Then use Chapter 1 of Saxena’s research report to fill in any necessary details (but in this case you are not doing your own literature review but only using the information contained in Saxena’s report).
The BMJ use the Vancouver System for references (numeric sequence). However, if at this point you are just making a text note for yourself without using reference manager software, you will make life easier for yourself later if you put author and year rather than a reference number.

**Feedback**

Well done! You have now written the first draft of your Introduction. In Session 9, you will learn how to revise it.

**Methods section: first draft**

Remember that the Methods section of a research paper explains how you went about answering your study question.

You should describe the methods that you used in enough detail to enable your readers to:

- judge whether or not the methods are appropriate for answering the study question
- judge any weaknesses in methodology that could influence the interpretation of the results
- repeat the study if they wish to do so.

Methods sections are usually written in the past tense as you are reporting on what has happened in the past. Most journals allow the use of the active tense, like “we measured blood pressure…”, but some do not. If not, you may be able to use a phrase like “nurses measured blood pressure…”. However, unless a journal expresses a preference for the passive tense, such as “blood pressure was measured…”, use it as little as possible. Check the journal’s style by looking at recent editions of your chosen journal and/or the information-for-authors.

**Writing the first draft of the Methods section**

You might want to look back at the information on the Methods section in Session 7 to remind yourself of the purpose and content of the Methods section.

**ACTIVITY 6**

Write the first draft of the Methods Section for your research paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’

Start with the outline of the Methods section that you produced in Session 7, and develop each point into a few sentences. Use Chapter 2 of Saxena’s research report to fill in any necessary details. A Methods section is usually between four and six paragraphs long.
Feedback

Well done! You have now written the first draft of your Methods section. In Session 9, you will learn how to revise it.

This would be a suitable stopping point if you wish to take a break.

Results section: first draft

Remember that the Results section of a research paper is where you present the data that support the answer to your main study question.

The data that support your answer should be of two main types:

- data that enable the reader to judge the validity of your conclusions (e.g. data comparing the characteristics of the study groups, data on participant dropout etc)
- data that directly support the answer to your study questions.

The text should emphasize or summarize the important results; it should not describe every detail of every number or statistic you produced while doing the analysis.

What to put in the tables

You might want to look back at the information on the Results section in Session 7 to remind yourself of the purpose and content of the Results section.

When you wrote your outline of the Results section, you decided which data to present in your paper. You now have to decide how to present these data using a mixture of text and tables.


Tables are best used for:

- Presenting precise numeric values rather than proportions or trends.
- Presenting many numbers that show how two or more variables relate to each other, e.g. a description of several characteristics of cases and controls in a cross-tabulation or showing the risk ratios or odds ratios in a model containing several covariates.
- Presenting complex information more clearly than in the text or in a figure.
Do not use tables where a few of sentences of text can summarise the data clearly.

Use figures instead of tables to show a trend of one variable over time or the relation of two variables (e.g. height against weight). Figures have the disadvantage that exact numerical values are not usually available to the reader so the writer should consider how important this is when deciding whether to use a figure or not. If in doubt, it is better to use a Table. Please note that, although you should never duplicate information from the Tables in the text, it is acceptable (and sometimes necessary) to provide the exact numerical values of a figure in the text. As a test as to whether you have given enough information, ask yourself whether someone doing a meta-analysis could obtain the information they need from your results.

Check whether the journal specifies any limits on numbers of tables and also look at recent articles to see how many tables are the norm. With internet publishing the constraints have become more generous than they used to be with paper journals, e.g. the BMJ web articles may have 6 tables and some figures while the one-page printed versions (known as PICO – see Session 1) only have one table or one figure. The greater freedom of online publishing does not mean that you should put in every number you have in your analyses – information that is irrelevant to your research question and objectives is distracting.

Constructing the tables

You will probably find it easiest to construct your tables for the first draft of the Results section before you write the text even if, as Albert suggests, you go on to write a first draft without looking at them. Preparing the draft tables should help you to organise your thoughts.

Tables should be understandable on their own without reference to the text. The BMJ advise that “Tables should be simple and should fit on one page, and they should not duplicate information in the text of the paper” (http://resources.bmj.com/bmj/authors).

Parts of the table:

Title and number: the placing of this depends on the journal, sometimes above and sometimes below. For the BMJ it is placed above the table. It should be apparent from the title whether you are providing descriptive or analytic information.

Rows and columns, each of which must have a heading. Column headings are sometimes known as “box headings”. Row headings are sometimes called “stubs”.

There may be levels of heading e.g. the overall variable “age group” and under that the specific age groups, or in another example there may be some columns referring to physical functioning and some to cognitive functioning, with subheadings specifying the specific functions measured.

Specify the units of measurement used, e.g. years for age groups, metres/second for walking speed, mmol/l for serum glucose.
For analytic tables specify the statistic, e.g. mean, median, rate ratio, odds ratio, 95% confidence interval. Where p-values are given, a footnote can specify exactly what kind of test the p-value refers to, e.g. a test for heterogeneity or a test for trend.

Where statistics in columns are column percentages, give the total n at the head of the column (in the example below “Intervention birth attendants (n=60)” is given in the column head to show that the numbers in brackets refer to the column percentages). If row percentages are used you should specify the total in a final column. For descriptive tables, journals often expect the number and the percentage to be given for each cell as in the example below.

Baseline characteristics of traditional birth attendants.
Values are numbers (percentages) unless stated otherwise.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention birth attendants (n=60)</th>
<th>Control birth attendants (n=58)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SE) age (years)</td>
<td>49.2 (0.79)</td>
<td>49.6 (1.32)</td>
</tr>
<tr>
<td>Education:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-Never attended school</td>
<td>3 (5)</td>
<td>17 (29)</td>
</tr>
<tr>
<td>-Some primary education</td>
<td>47 (78)</td>
<td>36 (62)</td>
</tr>
<tr>
<td>-Some secondary education</td>
<td>10 (17)</td>
<td>5 (9)</td>
</tr>
<tr>
<td>Mean (SE) years of education</td>
<td>6.3 (0.48)</td>
<td>4.3 (0.55)</td>
</tr>
<tr>
<td>Mean (SE) No of deliveries during study</td>
<td>33.6 (3.12)</td>
<td>24.6 (1.90)</td>
</tr>
<tr>
<td>Marital status:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>42 (70)</td>
<td>47 (81)</td>
</tr>
<tr>
<td>-Single</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>-Divorced</td>
<td>8 (13)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>-Widowed</td>
<td>9 (15)</td>
<td>9 (16)</td>
</tr>
<tr>
<td>Main occupation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-Traditional birth attendant</td>
<td>1 (2)</td>
<td>5 (9)</td>
</tr>
<tr>
<td>-Farmer</td>
<td>59 (98)</td>
<td>53 (90)</td>
</tr>
<tr>
<td>Sources of training as birth attendant before LUNESP†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-Family</td>
<td>7 (12)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>-Community not family</td>
<td>26 (43)</td>
<td>31 (43)</td>
</tr>
<tr>
<td>-Lufwanyama District Health Management Team</td>
<td>36 (60)</td>
<td>38 (65)</td>
</tr>
<tr>
<td>-Other government organisation</td>
<td>20 (33)</td>
<td>11 (20)</td>
</tr>
<tr>
<td>-Trained by non-governmental organisation programme</td>
<td>20 (33)</td>
<td>14 (24)</td>
</tr>
<tr>
<td>Mean (SE) No of years as traditional birth attendant</td>
<td>6.3 (0.81)</td>
<td>7.0 (0.95)</td>
</tr>
</tbody>
</table>

LUNESP=Lufwanyama Neonatal Survival Project.
*Baseline demographic data only collected among initial group of 120 randomised birth attendants; two control birth attendants did not complete a baseline assessment questionnaire.
†Birthing attendants may have received basic training from more than one source.
Footnotes provide details that help explain the table, e.g. definition of a term or fuller specification of who/what is included in the group being analysed, variables included in a model. If you are reproducing a table from another publication you use a footnote to give the reference for the source. The symbols used to link table item to footnote vary across journals, sometimes being letters a, b, etc, sometimes symbols such as * † ‡.

Cells or fields carrying numerical data

- It is easier to make comparisons running your eye down a column rather than across a row so, if the main purpose of the table is to see associations across categories of variable (e.g. education) within a group, have rows for the categories. Looking at the table above, it is also easier to see whether patterns across education are similar for two groups if the groups are determined by column and education by row.

- Be consistent in number of decimal places within a column. Keep the number of digits to the minimum required to show the patterns so that the table can be more easily assimilated by the reader. One suggestion is to provide maximum of two digits that change:
  - For example if you have ten values 1.34, 1.54, 2.54, 2.68, 2.97, 3.65, 3.12, 3.22, 3.46, 3.78 it is probably sufficient to show them in the table as 1.3, 1.5, 2.5, 2.7, 3.0, 3.6, 3.1, 3.2, 3.5, and 3.8
  - However if you have ten values 1.334, 1.354, 1.387, 1.391, 1.395, 1.465, 1.412, 1.433, 1.476, 1.499 then you need to show as 1.33, 1.35, 1.39, 1.39, ..., 1.50 to show up variation across the numbers.

- To avoid having many digits the numbers can sometimes be rescaled e.g. 1400 grains per kilogram becomes 14 per gram or 0.0045 deaths per person year becomes 0.45 deaths per 1000 person years.

- If a cell is empty use a symbol to indicate this, e.g. ‘-‘ to indicate not applicable and explain this symbol in a footnote.

- Order the rows and columns logically, e.g. a table giving information by educational level would have the lowest level first and successively higher levels down the rows as in the table above (or vice versa). If there is no natural order, a table can be easier to read if the rows are in descending order of magnitude of the statistic, e.g. if you are showing mortality rates for a series of towns, show the highest mean on the first row and work down.

- White space helps to demarcate variables or groups but, if too large, makes it difficult to compare across the variables or groups (however, the journal layout policy may not allow you much flexibility in this).

Most journals do not use vertical lines on Tables. Some use a horizontal line at either the top or base of the Table. The rules for this vary between journals, so it is essential that you read the information-for-authors when preparing your manuscript for a specific journal.

The guidelines on tables from the Uniform Requirements for Manuscripts (URM) are reproduced below. Note that the BMJ style used in the example above differs in
some respects from the format guidelines below but the URM guidelines are a good starting point in the absence of specific instructions in your chosen journal. One point that is essential is to cite every table in your text – if you do not need to cite it the table is probably redundant.

**Uniform Requirements for Manuscripts Submitted to Biomedical Journals:**

**Writing and Editing for Biomedical Publication**

*Updated April 2010*

**Publication Ethics: Sponsorship, Authorship, and Accountability**

**International Committee of Medical Journal Editors**

**IV. A. 10. Tables**

Tables capture information concisely and display it efficiently; they also provide information at any desired level of detail and precision. Including data in tables rather than text frequently makes it possible to reduce the length of the text. Type or print each table with double-spacing on a separate sheet of paper. Number tables consecutively in the order of their first citation in the text and supply a brief title for each. Do not use internal horizontal or vertical lines. Give each column a short or an abbreviated heading.

Authors should place explanatory matter in footnotes, not in the heading. Explain all nonstandard abbreviations in footnotes, and use the following symbols, in sequence:

*, †, §, _, ¶, **, ††, §§, ‡‡, ¶¶, etc.

Identify statistical measures of variations, such as standard deviation and standard error of the mean.

Be sure that each table is cited in the text.

If you use data from another published or unpublished source, obtain permission and acknowledge that source fully.

Additional tables containing backup data too extensive to publish in print may be appropriate for publication in the electronic version of the journal, deposited with an archival service, or made available to readers directly by the authors. An appropriate statement should be added to the text to inform readers that this additional information is available and where it is located. Submit such tables for consideration with the paper so that they will be available to the peer reviewers.

Many journals require that lines are kept to a minimum – usually above and below the whole table, below the column headings and above the total row. However the BMJ, for example, has changed its style and its online tables often now include horizontal lines.

**ACTIVITY 7**

Construct the tables for your research paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’

You should have to hand the tables that provide evidence to support the answer to your main study question (i.e. the ones you identified and condensed in Session 1, Activity 4 and in Session 7, Activity 10). You may now want to modify these tables slightly, and construct them in the appropriate form for a research paper. You should also now construct tables to display any additional data that you identified in your outline.
Feedback

In addition to your existing tables, you have probably constructed an additional table that looks something like Table 1.

Table 1 Baseline characteristics of children and mean consulting rates with general practitioners

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No.</th>
<th>%</th>
<th>Mean consulting rate</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-4</td>
<td>37,904</td>
<td>35.7</td>
<td>6.11</td>
<td>6.01-6.21</td>
</tr>
<tr>
<td>5-9</td>
<td>31,963</td>
<td>30.1</td>
<td>2.52</td>
<td>2.42-2.61</td>
</tr>
<tr>
<td>10-15</td>
<td>36,235</td>
<td>34.1</td>
<td>2.21</td>
<td>2.16-2.26</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>boys</td>
<td>54,312</td>
<td>51.2</td>
<td>3.67</td>
<td>3.58-3.75</td>
</tr>
<tr>
<td>girls</td>
<td>51,790</td>
<td>48.8</td>
<td>3.73</td>
<td>3.67-3.78</td>
</tr>
<tr>
<td><strong>Tenure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>owner-occupier</td>
<td>63,832</td>
<td>60.2</td>
<td>3.63</td>
<td>3.59-3.66</td>
</tr>
<tr>
<td>council</td>
<td>21,155</td>
<td>19.9</td>
<td>4.43</td>
<td>4.28-4.59</td>
</tr>
<tr>
<td>other rented</td>
<td>8,306</td>
<td>7.8</td>
<td>4.29</td>
<td>3.12-4.45</td>
</tr>
<tr>
<td>communal</td>
<td>641</td>
<td>0.6</td>
<td>2.79</td>
<td>2.44-3.14</td>
</tr>
<tr>
<td>not known</td>
<td>12,168</td>
<td>11.5</td>
<td>2.40</td>
<td>2.13-2.68</td>
</tr>
<tr>
<td><strong>Single-parent family</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no</td>
<td>82,373</td>
<td>77.6</td>
<td>3.81</td>
<td>3.71-3.90</td>
</tr>
<tr>
<td>yes</td>
<td>10,938</td>
<td>10.4</td>
<td>3.88</td>
<td>3.83-3.93</td>
</tr>
<tr>
<td>not known</td>
<td>12,746</td>
<td>12.0</td>
<td>2.42</td>
<td>2.16-2.69</td>
</tr>
<tr>
<td><strong>Ethnic group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>white</td>
<td>89,713</td>
<td>84.6</td>
<td>3.86</td>
<td>3.81-3.90</td>
</tr>
<tr>
<td>Afro-Caribbean</td>
<td>735</td>
<td>0.7</td>
<td>3.79</td>
<td>3.44-4.14</td>
</tr>
<tr>
<td>South Asian</td>
<td>1,415</td>
<td>1.3</td>
<td>4.23</td>
<td>3.86-4.74</td>
</tr>
<tr>
<td>other</td>
<td>1,158</td>
<td>1.1</td>
<td>3.95</td>
<td>3.65-4.25</td>
</tr>
<tr>
<td>not known</td>
<td>13,081</td>
<td>12.3</td>
<td>2.50</td>
<td>2.24-2.76</td>
</tr>
<tr>
<td><strong>Social class of parent or guardian</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I-II</td>
<td>31,306</td>
<td>29.5</td>
<td>3.54</td>
<td>3.49-3.60</td>
</tr>
<tr>
<td>III non-manual</td>
<td>10,825</td>
<td>10.2</td>
<td>3.95</td>
<td>3.95-4.01</td>
</tr>
<tr>
<td>III manual</td>
<td>28,499</td>
<td>26.7</td>
<td>3.95</td>
<td>3.89-4.01</td>
</tr>
<tr>
<td>IV-V</td>
<td>18,499</td>
<td>17.4</td>
<td>4.18</td>
<td>4.01-4.36</td>
</tr>
<tr>
<td>other</td>
<td>4,199</td>
<td>4.0</td>
<td>4.15</td>
<td>3.98-4.32</td>
</tr>
<tr>
<td>not known</td>
<td>12,774</td>
<td>12.0</td>
<td>2.43</td>
<td>2.17-2.69</td>
</tr>
</tbody>
</table>
Writing the first draft of the Results text

Once you have constructed your tables, you can write the first draft of the text of the Results section. Use the text to summarize or emphasize the important features of your data. The features that you should cover include:

- the basic characteristics of the study groups, to establish how comparable they were
- the data that directly support the answer to your main study question
- the data that answer any subsidiary questions.

Do not use the text merely to repeat all the data in your tables or to repeat methods already well described in the previous section. You should refer to every table and figure. Also, remember you should not comment on the implications of any of your results in this section.

Results sections are generally written in the past tense as you are reporting what was found in your particular study.

Use the active voice rather than the passive e.g. use “Mean walking speed was slower among older than younger people” rather than either “Mean walking speed was shown to be slower among older than younger people” or “Among older people it was found that mean walking speed was slower than among younger people”. To make the text more interesting, the occasional sentence in the passive voice is acceptable but, for most journals, the active voice should dominate.

Remember always to specify the direction of a difference e.g. “Mean walking speed was slower among older than younger people” rather than “There was a difference in walking speed between older and younger people”.

When comparing groups, you should always remember to specify who you are comparing e.g. “Mean walking speed was slower among older than younger people” rather than “Mean walking speed was slower among older people.”

ACTIVITY 8

Write the first draft of the Results Section of your paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’

In your text, you should refer to the tables that you are presenting and briefly summarize or emphasize:

- the basic characteristics of the study population
- overall consultation rates
- the differences in specific consultation rates across social class.
Feedback

Well done! You have now written the first draft of your Results section. In Session 9, you will learn how to revise it.

This would be a suitable stopping point if you wish to take a break.

Discussion and Conclusions section(s): first draft

Remember that in the Discussion and Conclusions section you interpret your findings. You should take into account any limitations in your methodology, and include an assessment of evidence from other sources. Once you have considered all these issues, you will be able to provide the final answer to the question that you posed in your Introduction. When you have digested the results and taken into account the strengths and weaknesses, what is the main message that you want your readers to ‘take home’ after reading the paper?

Writing the first draft of the Discussion and Conclusions section(s)

You might want to look back at the information on the Discussion and Conclusions section(s) in Session 7 to remind yourself of the purpose and content of this section.

ACTIVITY 9

Write the first draft of the Discussion and Conclusions Section of your paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’

Start with the outlines of the Discussion and Conclusions sections that you produced in Session 7, and develop each point into a few sentences. Use the research report to fill in any necessary details. Again, use only the information contained in this report.

Feedback

Well done! You have now written the first draft of your Discussion and Conclusions section(s). In Session 9, you will learn how to revise it.

The Abstract

The Abstract provides a brief summary of the main contents of a research paper. After the title, it is the part of your paper that will be read by the largest number of people. Potential readers will scan your Abstract in order to decide whether or not to read the rest of your paper. Some will realize that the paper is not of sufficient
Session 8: Writing the first draft

relevance to them, and read no further. Others will go on to read the rest of the paper in detail. However, a significant proportion of readers who are interested in the content of your paper will read no further than the Abstract. This may be because they lack either the time or the critical skills to read in more detail. The result is that many people will judge your paper on the Abstract alone. You should therefore write an Abstract that provides a clear, concise summary of all the important features of your paper.

ACTIVITY 10

Read Albert “Winning the Publications Game” on abstracts pp. 81-83 (note this includes the instructions for an abstract given in the URM).

After you have finished reading, answer the following questions:

1. What is the essential content that you should include in an Abstract?
2. In what circumstances should you write a structured Abstract?

Feedback

1. An Abstract contains key summary information from each of the IMRaD sections of your paper.

   Context (but background detail is the first thing to be sacrificed if the word count is tight)
   Purpose
   Basic procedures
   Main findings with numerical results
   Conclusion

Although the above are not the headings used in the BMJ and many other journals, they are the points you should convey in the abstract.

Many journals have specific requirements for Abstracts. You should always consult the information-for-authors pages of your target journal to check whether or not there are any specific guidelines on the style and content of the Abstract. Although the URM states that the funding source is given in the abstract most journals have this as a separate item in the paper.

2. You should always write a structured Abstract if the information-for-authors pages request you to do so. Even when a structured Abstract is not requested, you may find it useful to write the first draft of your Abstract in a structured form. This helps to ensure that you have included all the necessary information. You can then remove the subheadings before you submit the final version of your paper.

Writing a first draft of the Abstract

One of the advantages of writing your paper in the order demonstrated in these sessions is that you will already have produced a complete outline of the paper before sitting down to write the first draft of the Abstract. This outline is divided into the same sections as a structured Abstract (IMRaD). To write the first draft of your Abstract, you should select the most important information from each section, and expand the key points into short paragraphs. You will need to summarise the key data from your tables briefly for the results section of your Abstract.
The BMJ give detailed instructions for an abstract, as listed in the box below.

**BMJ Structured abstract.**

Source: [http://resources.bmj.com/bmj/authors/types-of-article/research](http://resources.bmj.com/bmj/authors/types-of-article/research) (accessed Jan 2011)

Please ensure that the structured abstract is as complete, accurate, and clear as possible—but not unnecessarily long—and has been approved by all authors. We may screen original research articles by reading only the abstract. For randomised controlled trials please provide all the information required for a CONSORT style abstract.

Please note the general rules for abstracts in the BMJ:

- should be 250-300 words long; you may need up to 400 words, however, for a CONSORT or PRISMA style abstract. Medline can now handle up to 600 words
- use active voice but avoid “we did” or “we found”
- numbers over 10 do not need spelling out at the start of sentences
- sentences starting with a number do not require a capital letter
- p values should always be accompanied by supporting data and denominators should be given for percentages
- abstracts do not need references.

The first few items (objective, design, setting) may be note-like and need not form full sentences. The results and conclusions sections should be written properly. Do not mix notes and full sentences in one section.

If the standard headings do not suit the type of study, substitute something sensible such as “population” as a heading instead of “participants” in an economics article. Please do not simply delete the heading.

For standard original research articles please provide the following headings and information (for RCTs please add the trial registration details - but there is no need to provide the additional subheadings which are used in the CONSORT statement on abstracts, as long as you include all the required information, and the same applies to the PRISMA statement):

- **objectives** - a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- **design** - including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests etc
- **setting** - include the level of care eg primary, secondary; number of participating centres. Be general rather than give the name of the specific centre, but give the geographical location if this is important
- **participants** (instead of patients or subjects) - numbers entering and completing the study, sex, and ethnic group if appropriate. Give clear definitions of how selected, entry and exclusion criteria
- **interventions** - what, how, when and for how long. This heading can be deleted if there were no interventions but should normally be included for randomised controlled trials, cross over trials, and before and after studies.
- **main outcome measures** - those planned in protocol, those finally measured (if different, explain why)
- **results** - main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm.
- **conclusions** – primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article. Conclusions are important because this is often the only part that readers look at.
- **trial registration** - registry and number (only for clinical trials)

Please note that confidence intervals should be written in the format (15 to 27) within parentheses, using the word "to" rather than a hyphen.
ACTIVITY 11

Write the first draft of the Abstract of your paper on ‘Childhood consultation rates in General Practice’ based on the research report ‘Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales.’ Remember that you are preparing this paper for publication in the BMJ.

Write your draft Abstract, consulting the outline that you produced in Session 7 and the BMJ instructions for abstracts given in the box.

Feedback

Here is a possible draft Abstract for this paper. Your Abstract will probably be slightly different, but should contain the same headings and be no more than 250 words (as required by the BMJ).

Objective To establish how consultation rates in children for episodes of illness, preventive activities, and home visits vary by social class.


Setting 60 General Practices in England and Wales.

Participants 106 102 children aged 0–15 registered with the participating Practices.

Main outcome measures Mean overall consultation rates for any reason, for illness by severity of underlying disease, for preventive episodes, for home visits and for specific diagnostic category (infections, asthma, and injuries).

Results Overall consultation rates increased from social classes I and II to classes IV and V (mean rate difference 0.57 consultations per person per year; 95% confidence interval 0.42 to 0.72). Children from social classes IV and V consulted more frequently than children from classes I and II for illnesses (mean rate difference 0.60 consultations per person per year; p<0.001). They also had significantly higher consultation rates for minor, moderate and severe illnesses and higher home visiting rates (mean rate difference 0.2 consultations per person per year; p<0.001). Consultations for preventive activities were lower in social classes IV and V than in children from social classes I and II (mean rate difference −0.04 consultations per person per year) although this difference was not statistically significant.

Conclusions Childhood consultation rates for episodes of illness increase from social classes I and II through to classes IV and V for all levels of severity of illness. These findings suggest that the health of children from lower social classes is worse than that of children from higher classes. These results have important implications for health planners.
Summary

- The Title is the first part of a paper that potential readers see. A good title should:
  - provide readers with enough information to enable them to judge whether or not the paper is likely to answer questions that they are interested in
  - present this essential information in a clear and easily accessible format
  - not be cluttered up with unnecessary detail.

- The Abstract should provide a clear and concise summary of all the important features of your paper.

- It is usually easiest to write the first draft of your Abstract in structured form, even if you remove the subheadings for the final version.

- To write the first draft of the main text, expand your outline notes into sentences thus producing a full text version of the IMRaD sections of your paper.

- Remember that the first draft is your first attempt at writing the paper. It is not meant to be perfect. It will be revised many times before you submit it.

Further reading

For advice on data reduction and appearance of tables and figures, see Ehrenberg A (1975) ‘Data Handling’, available as a pdf through http://www.members.byronsharp.com/empgens/P1DataReduction.pdf

This was written in the days before electronic communication but has many interesting suggestions for making tables and figures easier for the reader to digest.

One source of information on writing is a website called Biotech. They recommend a different order of writing but have some useful tips about tenses to use and avoiding duplication of information.
Session 9

Revising drafts and preparing the final manuscript

Overview

When writing the first draft of a research paper, you concentrate on including the essential information and using the correct format. The next step is to revise this draft many times to ensure that it presents a strong, clear argument using good scientific prose. In this session, you will learn how to revise the draft versions of your paper in a step-by-step manner, starting with content and structure and then looking at prose. You will also learn how to prepare the final manuscript of your paper, including references.

Learning objectives

After working through this session, you will be better able to:

- revise the content and structure of a draft research paper
- revise the prose of a draft research paper
- write the references for a research paper
- prepare the final manuscript of a research paper.

Planning your study

For this session you will be reading from one of your textbooks and some internet papers but most of the time you will be working on your earlier draft of the paper, ‘Childhood consultation rates in General Practice’

Your computer and word-processing software would be useful (but are not essential) for the activities in this session as you will be revising the draft paper you wrote in Session 8.

To complete the work in this session, you need:

- a hard copy of your draft research paper (produced in Session 8) ‘Childhood consultation rates in General Practice’ based on the research report by Saxena
Session 9: Revising drafts and preparing the final manuscript

- Saxena S. Do consultations for common childhood illness vary with social class? A descriptive study of General Practice in England and Wales (in the module Reader).

The ebook:

From the internet:
- BMJ information for authors: http://resources.bmj.com/bmj/authors

You should allow yourself approximately ten hours to complete this session. You will probably want to do the session in more than one sitting. You could take a break after each step of the editing. This should also help you to keep a clear head for each process.
Key terms

The corresponding author: the person who will have contact with the journal regarding the publication, and receive requests for reprints or questions from readers about the article once published (this is often the first author, but can be any of the co-authors).

Macro-edit: editing for content and structure but not detailed phrasing.

Micro-edit: editing for phrasing, words used, style of writing.

Revising your draft research paper

You have to revise draft versions of a research paper several times before the final manuscript is ready for submission to your target journal. In this session, you will first revise the content and structure of the paper, and then go on to revise the prose and style. Concentrating on style early on can lead to frustration if you find you have to change or replace large sections of the text.

The process of revision may seem long and tedious. However, it is important to see it as an essential part of the writing process. No one writes a perfect paper in one go; writing a good paper takes time and effort.

If you are the main author of a paper but have co-authors, it is advisable to do some editing on your own before asking your co-authors for comments.

Revising content and structure

When you revise the content and structure of your draft, you need to become a critic of your own work. You have to look at your paper as an editor, referee or reader would look at it. Specifically, you need to ensure that your paper presents a clear, convincing argument.

The mechanics of revision

Even if you are using a word processor, you will probably find it easier to read and revise a paper copy of your text, at least for the macro-editing and final run-through, rather than trying to do it on screen. Insert page numbers before you print it out, so that you won’t muddle it up if you drop it! Print out a copy of your paper with wide margins and wide spacing between the lines so that you can write comments alongside the text and between the lines.

Follow the activities below. This will involve going back to your word processor at various points and making some revisions. When you do so:

- give each draft a slightly different file name— for example “paper_dr1”, “paper_dr2” – putting the date in the file name or the header is often useful for keeping track of where you are.
use the “track changes” facility of your word processor to show the changes from one draft to the next, i.e., when starting draft 3, save a file with a name indicating it is draft 3, accept all the track changes you make in draft 2, and set up your word processor to show the new changes you make in draft 3.

Co-authors should also track changes when they comment on the paper. Before submitting to the journal, remember to remove any track changes or comments.

ACTIVITY 1

Read Albert from the beginning of Chapter 7 “Rewrite your draft”, up to the heading “Spelling and Grammar” pp. 57-64

After you have finished reading, answer the following questions:

1. What should you do after the first draft?
2. How do you stop the drafting going on endlessly?
3. What is the first type of edit?

Feedback

1. Take a step back – let it rest so you come to it fresh. Be prepared to need several drafts to get it right.
2. Have deadlines and stick to them.
3. Macro edit to see that the message and structure are right (getting the detail right comes later).

Revising the main text

The first time you re-read the main text (the IMRaD sections) of your paper, you should concentrate on assessing whether or not it presents a clear argument. The following checklist can help you decide if your paper contains the key elements of a critical argument.

Checklist for first reading (macro-edit content)

This list contains more than given by Albert – the section where you should be finding the information is given in brackets.

- Is your main message clear and prominent (Abstract and Discussion)?
- Is your research question explicit and unambiguous (Introduction)?
- Have you explained why that question is important (Introduction)?
- Have you presented adequate evidence to answer that question and “proven your message” (Results)?
- Have you presented information to enable the reader to judge the validity of the evidence (Methods and Results)?
- Have you discussed the implications of the evidence (Discussion)?
• Is your final answer to the research question convincing (Discussion/Conclusion)?

Checklist for second reading (macro-edit structure and tone)

• Are the sections roughly in the right balance (Albert recommends 2-7-7-6 paragraphs)?
• To see if there is a storyline;
• Does your first sentence grab your interest?
• Does the last sentence of your Introduction say what you did?
• Does the first sentence of your Discussion say what you found?
• Does the last sentence of your Discussion/Conclusion say what it means – give the message you want to get across?
• Does the paper start with an impact? Apply Albert’s six-word test (Fig 7.3, page 63)?
• Following Albert’s advice apply the ‘yellow marker’ test (page 62 and Fig 5.5, page 48);
• If your sentences are long or you have several three-syllable words in a paragraph, calculate the Fog Score (see Albert Fig 8.1 pp. 60-61) and make a note where you will need to simplify the text.

It is better to read through several times, each time looking for something specific than trying to spot too many things at once.

ACTIVITY 2

You should now undertake the macro-edit and revise the content and structure of your draft research paper on ‘Childhood consultation rates in General Practice’. Do not worry too much about details of style or accuracy of numbers yet – that comes later. Get the broad story and picture right at this stage.

Feedback

Next stage done – keep persevering.

Checklist for third reading (micro-edit accuracy and completeness)

As Albert said (p64) you should be painstaking about accuracy. People citing your results will unwittingly disseminate erroneous information; those wishing to replicate the study need to know exactly how it was done.

• Are the methods described correctly?
• Are your numbers correct? – check against your analysis output.
If you are reporting associations, are the directions of the associations clear, e.g. is the incidence rate of cancer greater or less the lower people’s education level – is there a gradient that extends across all levels of education, or is one group different from the rest?

Do data in the text agree with data in the tables?

Are the numbers in the tables coherent e.g. where you are showing a distribution do % add up to 100 (+/- 0.1%); are confidence intervals either side of the main estimate (e.g. OR 2.45 with 95% CI 1.97-2.33 does not make sense); are there any very surprising results – if so check that they are not a mistake.

At this stage also think about the following:

Is any needed content missing? – look at the relevant list – in this case STROBE;

Can any of the text be discarded? (Also see below under prose style.)

Have you cited unnecessary references? Have you omitted needed references?

Can you omit any of the tables or illustrations?

**ACTIVITY 3**

You should now revise for accuracy and completeness and make sure that your tables and figures are appropriate. You will tackle the prose style after this draft so do not worry too much about it at present.

**Feedback**

Later in this session you will have the chance to compare the structure and content of your paper with the structure and content of a published research paper based on the same research study. Do not look at this published paper yet.

**Revising prose style**

Once you are satisfied with the content and structure of your paper, you are ready to revise the prose style. You may feel that the style in which your paper is written is much less important than the content. It is true that a paper will not be published on the basis of style alone. However, good prose will ensure that your readers can easily follow your argument. Conversely, if your writing style is confusing and ambiguous, readers may fail to understand the content.

**ACTIVITY 4**

Read the rest of Albert Chapter 7 on ‘Microediting’, pages 65-72.

Make a note of his main messages.
Session 9: Revising drafts and preparing the final manuscript

Feedback

Use short words in short sentences.

Use active rather than passive tense¹.

Look at papers in your target journal and see what style they use.

He reminds us how styles of scientific papers have changed over the years.

ACTIVITY 5 (Advisable if not a native English speaker)

If you are not a native English speaker, look at the LSHTM in-house paper by Julia Mortimer: ‘How good is your academic English? Questions and answers’².

Use this opportunity to learn what you can about good scientific writing in English.

Ask someone who speaks better English than you to help you revise the prose style of your paper. However, do not do this for your assignment as we need to be sure that it is all your own work.

Revising prose style (continued-paragraphs)

- Start with the paragraphs and see how they fit together to make a story.
- Is the key sentence usually at the beginning of the paragraph?
- Does the last sentence of one paragraph link into the first sentence of the next?
- Where it is not possible to link sentences then the flow of the text may be helped by other means. For example, BMJ papers often have several headings (though other journals may not like this), or the sequence of reports of results may be foreshadowed by the way the analysis plan was described. The key sentences (usually the first sentence) should give the framework of a story if put together without the intervening text (the ‘yellow marker’ test (Albert page 62 and Figure 5.5, page 48).
- Are any paragraphs very long (no standard on this but one author suggests that 5 lines probably too short and 25 lines too many)? (Huth Writing and Publishing in Medicine page 174.)
- Within each paragraph is there a clear line of thought?
- Is there only one topic per paragraph?

¹ As mentioned in Session 8, the active voice should be the norm unless instructions for a journal (or recent examples in a journal) indicate otherwise. This does not mean that you have to write every phrase in this style; sometimes the passive voice will be more appropriate. However, your text will be shorter and clearer if you write primarily in the active voice.

² To be made available during 2011-12 academic year.
• Some paragraphs are narrative - it is usually sensible to arrange them in the order in which things happened (e.g. the order in which tests were taken). Other paragraphs are arguments – in this case one approach is to start with the question being debated, and to proceed through the evidence for and against, from the least convincing to most convincing, then rounding off by weighing the balance of evidence.

ACTIVITY 6

Read Albert on ‘Understanding the Paragraph’, pp. 41-43, for his suggestions on constructing paragraphs.

Revising prose style (continued-sentences and words)


Now look at the sentences and words:

• Are the sentences long? Apply the fog test again, as recommended by Albert.

• Do too many sentences have the same length and structure – go for variety e.g. a series of sentences beginning “Jones found that…., Evans found that… Gillett found that…” is tedious.

Similarly, a list of results can also be tedious “The odds ratio for heart attack comparing physically active with non physically active people was….; The odds ratio was … for people who were obese compared to those who had BMI in the range 20-25 kg/m2….”.

Instead you might write: “Physically active people were more likely to have a heart attack than those who were not (OR….), and obese people also had increased risk compared to those with BMI in the range 20-25 kg/m2 (OR…)”

• Is the use of connecting words like ‘and’, ‘but’, ‘although’, ‘however’, helpful and accurate? e.g. are the terms suggesting contrast (‘but’, ‘however’, ‘although’, ‘however’) really linking phrases that provide contrasts?

• Are there any abstract nouns where you could use verbs or simpler terms? e.g. “Stabilisation of the patient’s blood pressure was undertaken by the doctor” could be rewritten “The doctor stabilised the patient’s blood pressure.”

E.g. “He described the problematisation of the way that mental health conditions were becoming more common.” This could become: “He
described how the increasing prevalence of mental health conditions had become a problem”.

- Are there unnecessary words?
  e.g. “a young woman aged 20 years” – do you need the word ‘young’?
  
e.g. “In order to measure blood pressure, the nurse used a Brand X sphygmomanometer…” The phrase ‘in order to’ is unnecessary. The same information is given by saying: “The nurse used a Brand X sphygmomanometer to measure blood pressure”.
  
e.g. “High blood pressure, which is known to increase the risk of heart attack, remains undetected in many people.” This can be shortened to: “High blood pressure, a risk factor for heart attack, remains undetected in many people.”

- Are any of the words impolite or dehumanising or threatening or emotive?
  e.g. “The two cases with TB were tested for HIV”. The ‘cases’ are presumably people
  
e.g. “A pregnant female” is more politely rephrased as “a pregnant woman”
  
e.g. “A disabled person” is more politely rephrased as “a person with disabilities”
  
e.g. “A schizophrenic” is more politely rephrased as “a patient with schizophrenia”.

  In these last two examples, the first form of wording can be interpreted as reducing the person to an example of the condition whereas the second recognises that they are human beings who happen to have that condition as part of their lives. The terms ‘male’ and ‘female’ can be appropriate if you are referring to people of all ages (so neither ‘boy’ nor ‘man’ suffices) or be used as an adjective. The nouns ‘male’ and ‘female’ can be sensitive in some contexts but here we can do no more than alert you to this possibility.

- Emotive terms like “poorly administered”, “dishonestly practised”, “cruelly neglected” may be tempting so you can display your reaction to a situation. Emotive terms can be appropriate for some other forms of writing but in an epidemiological research paper you should be providing the evidence that will enable the reader to judge.

- Albert (page 70) gives some words to avoid and simpler alternatives.

Read the paper aloud – it may draw your attention to some awkward patches that you had not noticed previously.
Further checklist for revising for clarity

- **Sentence structure:**
  - move from ‘known information’ to ‘new information’
  - make topic of sentence clear at beginning.

- **Modifiers:**
  Modifiers are words or clauses or phrases that give a fuller definition of something. Examples are the words in italics in the following:
  
  The *nice* man came first
  
  The nurse, *who was fully trained*, took the blood pressure reading
  
  The *long-awaited* event happened on 3 March 2009
  
  - Try to avoid using compound terms made up of more than two modifiers
    e.g. “the revised party political statement” – it could be the party that is revised.
    
    If using terms with more than two modifiers, use hyphens to connect related terms
    e.g. “the revised party-political statement” or change it to “the revised statement of party politics…”
    
    - keep modifiers (including modifying phrases) close to what they modify.
      e.g. “One morning I shot an elephant in my pajamas. How he got into my pajamas I’ll never know. —Groucho Marx”[3]
      
      Presumably it was the speaker not the elephant who was in pajamas.
    
    - Make sure they modify something
      e.g. “Caring for the cancer patient, the treatment was successful”. The treatment was not doing the caring. Could rephrase “The treatment I used for the patient’s cancer was successful”.

- **Pronouns:**
  Do not use ambiguous pronouns: if in doubt, repeat the noun. When you use “he” “it” “they”, make sure it is clear to who or to what you are referring:
  
  e.g. “The nurses took blood pressure readings using X-brand sphygmomanometers. If they did not work, they tried again.” Was it the nurses not working or the sphygmomanometers – does the word ‘they’ refer to the same people or things on the two occasions it is used?
  
  This could be rewritten: “Each nurse used an X-brand sphygmomanometer to take blood pressure readings. If it did not work, the nurse tried again”
  
  Or “When taking blood pressure using X-brand sphygmomanometers, the nurses tried again if no reading registered”.

---

• Verb tense:
  Use tense consistent with sequence of events.
  e.g. “Participants ran 400 metres and their pulse was taken by nurses.” Was the pulse taken before, during, or after the running? If afterwards, the sentence could be rewritten “After participants had run 400 metres nurses took their pulse” or “The participants had run 400 metres before the nurses took their pulse”.

• Defining clauses:
  Commas are only used for non-defining clauses,
  e.g. “The participants who were local residents had a one-hour interview”;
  “The participants, who were local residents, had a one-hour interview”.
  The former is suggesting that one criterion for having a one-hour interview was being a local resident; i.e. other participants had a different kind of interview or procedure. The latter sentence tells you that all the participants had a one-hour interview; an extra bit of information about the participants is that they lived locally but this is not a distinguishing factor as to whether or not they had a one-hour interview.

ACTIVITY 7

Now revise the prose of your research paper on ‘Childhood consultation rates in General Practice’ using the information above to help you. You may want to annotate a paper copy (e.g. by underlining phrases you want to change) before changing the typed version. After each revision, read through and see if further change needed.

Feedback

Later in this session you will have the chance to compare the prose of your paper with the prose of a published research paper based on the same research study. Do not look at this published paper yet.

Additional elements

References

When you wrote the first draft of your paper, you may have used the name–year system (also called the author–date system) to cite references in the text. This system enables you to make changes to subsequent drafts of the paper without having to worry about the order of the citations. However, once you have finished revising your paper, you need to check which form of references and citation is required by your target journal.
ACTIVITY 8


When you have finished reading, answer the following questions:

1. What are the two common systems of citations and references used in biomedical journals?
2. How are citations written in the each of these systems?

Feedback

1. The two systems in common use are the Vancouver system (the citation–sequence system) and the Harvard system (name–year or author–date system). The Vancouver system is becoming the most popular system in biomedical journals.

2. In the Vancouver system, citations are Arabic numerals (1, 2, 3, 4, 5 etc.) within round brackets or parenthesis marks (). The numbers denote the sequence in which the references are first cited in the text. These numbers correspond to the references' numbers in the reference list.

In the Harvard system, citations include the author name(s) and year of publication within round brackets. References are listed at the end of the paper in alphabetical order determined by the surname of the first author.

Note, however, that journals do vary in specific details e.g. whether initials or first names are given, whether full stops are inserted after initials, whether journal names should be abbreviated and whether full page numbers should be given. Always check the style for your particular journal. Many of the software programs for managing references give a wide choice of styles fitted to specific journals and organisations. For some journals you can download their reference style from the journal website to your EndNote software (e.g. the Journal of Alzheimer’s Disease homepage http://www.j-alz.com/about/prepare.html) Wiley publishers also offer this service for their journals.

ACTIVITY 9

The following paper appeared on pages 37–41 of ‘Health Trends’ Volume 29, Number 2, 1997:

‘Trends in the need for services for people with learning difficulties: implications for primary care’ by Ross Lawrenson, Jenifer Rohde, Caroline Bott, Ian Hambleton, Richard Farmer.

Write this as a reference in the following formats:

• the Vancouver referencing system
• the Harvard referencing system.
Feedback

Your Vancouver reference should look like this:


Your Harvard reference should look like this:


At this stage, you should check that you have read all the papers that you cite as references and that you know exactly what they say. You should cite only references that directly support a statement that you have made in the text.

You should also check that the reference list at the end of your paper contains all the references that you cite, and no more.

Revising the Title

When you revise the title, you should check that it contains information on:

- the subject matter
- the study design
- the study population.

You should also bear in mind that the title is used for indexing purposes by electronic databases such as MEDLINE, so you should check that the specific words used in your title would enable the appropriate audience to retrieve your paper.

ACTIVITY 10

Review and if necessary revise the first draft of the title for your research paper on ‘Childhood consultation rates in General Practice’.

Feedback

You might wish to check your title against the style and format of titles required by your target journal (the BMJ) by looking at the titles of the articles by Smith et al. and Luo et al. on the BMJ website.
Revising the Abstract and adding key words

When you revise the Abstract, you should check that:

- it contains a brief summary of all the important points covered in your paper
- it is written in the correct order, following the IMRaD structure of the paper
- it fulfils all the requirements set out in the information-for-authors pages of your target journal.

The Abstract is also used for indexing purposes by electronic databases such as MEDLINE so, as with the title, you must ensure that the specific words used in your Abstract would enable the appropriate audience to retrieve your paper.

Some journals specifically require the inclusion of key words. The selection of keywords varies for different journals, so you should check with the specific journal you are submitting your article to on the need for and selection of the keywords. Unless the instructions for your particular journal guide you otherwise, you may select your keywords from MESH terms, which are described in Session 2, and are also available at [http://www.nlm.nih.gov/mesh/meshhome.html](http://www.nlm.nih.gov/mesh/meshhome.html).

A printed version of MESH terms is published regularly as a supplement to the Index Medicus. This is available in many medical libraries.

ACTIVITY 11

Read Albert on ‘The Abstract’, pp.82-83 and then read Vandenbroucke et al. section 1b ‘Provide in the abstract an informative and balanced summary of what was done and what was found’.

Revise the first draft of the Abstract for your research paper on ‘Childhood consultation rates in General Practice’.

Feedback

Again, you might wish to check your Abstract against the style and format of Abstracts required by the BMJ by looking at Abstracts of recent BMJ articles or of the two you looked at in Session 8 (Smith et al. and Luo et al.).

ACTIVITY 12

Suggest up to five keywords for the article. (You can browse the MESH terms on PubMed to help you find suitable ones – the training video is found on [http://www.nlm.nih.gov/bsd/viewlet/mesh/searching/mesh1.html](http://www.nlm.nih.gov/bsd/viewlet/mesh/searching/mesh1.html).)

---

3 Note that the National Library of Medicine (NLM) does not use author-ascribed keywords in its indexing for its data bases (e.g. PubMed) but other indexing systems may do so. For NLM databases a search should find your paper if the search term is in the title or abstract.
Feedback

Examples of keywords include the following, although you may have chosen different ones: morbidity; child; social class; health services; family practice; England; Wales; cohort studies.

Involving co-authors and others

Groups of authors will vary as to when they take part and your co-authors may have clear preferences on this. However, often the first author does some revision of the structure and content before circulating it for comment. Be prepared that some of your carefully-structured text may come under criticism. You do not have to accept all the suggestions made but you should be able to explain to your co-authors why you do not accept some. Eventually you all have to agree that the manuscript is ready to send to the journal.

It is also often helpful to ask someone who is not so familiar with your research topic to read through a draft. The unfamiliarity means that they may want clarification where you think it is very clear – this could be a sign that your journal readership would also want clarification. Also a fresh pair of eyes may notice some awkward phrasing or ambiguities or discontinuities that you miss because you know what you are trying to say.

Preparing the final draft

You are now ready to prepare the final manuscript of your paper. This is the version that you will send off to the editor of your target journal. The term manuscript means ‘written by hand’; these days the term continues to be used although in practice handwritten papers are not accepted.

To prepare this final version you need to:

- review the manuscript requirements of your target journal
- review the final version of your paper
- prepare the final manuscript in accordance with journal’s requirements
- check the final manuscript.

Review of the journal’s manuscript requirements

You have been consulting the information-for-authors pages of your target journal throughout the writing process. However, you still need to review the journal’s manuscript requirements thoroughly before you prepare your final version.

Many medical journals subscribe to the ‘Uniform Requirements for Manuscripts Submitted to Biomedical Journals’ (URM) produced by the International Committee of Medical Journal Editors. It is a good idea to download this now if you have not already done so.
If your target journal subscribes to these requirements, then it should say so in the information-for-authors pages. You may find that your target journal subscribes to these requirements, but has differing or additional requirements for certain sections of the manuscript. Again, this should be made clear in the information-for-authors pages.

Some journals have their own idiosyncratic manuscript requirements. If this is the case, then they should provide a list of these in their information-for-authors pages. If the information-for-authors pages do not specify any details of manuscript requirements, then it would be safest to follow the ‘Uniform Requirements for Manuscripts submitted to Biomedical Journals’.

Note that many journals now require a statement from the authors about conflict of interest, details of Ethics Committee approval for the study, and information about the procedures used for obtaining informed consent from study participants. It is also important to be aware early on in your preparation of accepted formats for electronic submissions and the preferred formats for tables and figures.

**ACTIVITY 13**

You have been preparing a paper on ‘Childhood consultation rates in General Practice’ for submission to the BMJ. This journal conforms to the ‘Uniform Requirements for Manuscripts submitted to Biomedical Journals’, but has several additional requirements.

Use the BMJ information for authors: [http://resources.bmj.com/bmj/authors/types-of-article/research](http://resources.bmj.com/bmj/authors/types-of-article/research). Scroll down to the part headed ‘How to prepare BMJ original research papers (full)’ and read until you reach the heading ‘What other information we need’. Then read the sections on ‘structured abstracts’, ‘What this paper adds box’ and ‘Summary statistics’. Also check through the house style requirements [http://resources.bmj.com/bmj/authors/bmj-house-style](http://resources.bmj.com/bmj/authors/bmj-house-style).

Identify additional requirements that are to do with the content and format of the manuscript. At present, do not include the checklists they mention. Other information that journals want, such as competing interests and supplemental files, is covered in Session 10.

Remember that you must always check the requirements for your particular journal.
Feedback

The requirements for the content and format of a manuscript submitted to the BMJ include:

- **Title page**
  - all authors should give their addresses and appointment at the time they did the work, and a current address. For the corresponding author an email address and the best contact address should be given.

- **Content:**
  - a structured abstract of 250-300 words with the following headings: objectives, design, setting, participants, (interventions where appropriate) main outcome measures, results, and conclusions (and trial registration where appropriate)
  - abide by STROBE, CONSORT etc
  - structured discussion with the following sequence: statement of principal findings; strengths and weaknesses of the study; strengths and weaknesses in relation to other studies; discussing important differences in results; meaning of the study; possible explanations and implications for clinicians and policymakers; unanswered questions and future research.
  - ‘What the paper adds’ box with two parts of 1-3 bullet points each: ‘what is already known’ and ‘what this study adds’. The papers by Smith et al. and Luo et al. give examples.
  - summary statistics: double check that you have the appropriate statistics for your study design.

- **Style:**
  - use a clear, direct and active style
  - abbreviations should be kept to a minimum
  - English spelling is used
  - raw numbers should be used alongside percentages
  - drugs should be referred to by their approved, not proprietary, names, and the source of any new or experimental preparations should be given
  - scientific measurements should be given in SI units, except for blood pressure which should be expressed in mm Hg.

- **Illustrations:**
  - these should be sent electronically
  - accepted formats are listed on the web page.

- **References:**
  - the Vancouver referencing system should be followed – up to 6 authors named.

Review of the final version of the paper

For your final manuscript, you should review the final version of your paper one last time. The aim of this revision is to check that your paper contains all the required sections (title page, abstract, text, references etc) and that these comply with the journal’s requirements.
ACTIVITY 14

Use the following checklist to make any final amendments to your draft version of your research paper on ‘Childhood consultation rates in General Practice’.

- Title page:
  - title: short, concise, contains key information of final draft
  - authors: all have approved final draft.

- Abstract page:
  - correct number for length of text and abstract length.

- Text pages:
  - headings and subheadings (first-order, second-order etc)
  - citation of references: correct system for target journal.

- Acknowledgements, with written consent.

- References:
  - order, content and format: correct system for target journal
  - submitted but unpublished papers, personal communications
  - verification.

- Tables:
  - correct number for length of text
  - cross-referenced in text.

- Adequate titles and footnotes.

- Illustrations: correct format.

- ‘What the paper adds’ box.

Tidying the final manuscript

ACTIVITY 15

You are now ready to tidy the final manuscript. Keep your drafts but now save a version without any tracking or comments, with the correct spacing and font size. The information-for-authors pages of your target journal will probably give some guidelines on layout requirements and whether you should number pages and/or lines.

Once you have produced the final manuscript, you should correct any typing errors (using the spell-checker facility on the word processor but note that this can mislead at times). You should then read through a hard copy of the manuscript at least twice more to check for any outstanding errors.
ACTIVITY 16

Now read the published research paper by Saxena et al. ‘Socioeconomic differences in childhood consultation rates in general practice in England and Wales: prospective cohort study’.

Feedback

Do not expect your paper to be the same as this published paper based on the same research study. You will probably have emphasized different points, and you may have interpreted the data slightly differently. You will also note that the data presented in the paper have been analysed in a different way from the data in the research report (rate differences have been calculated rather than rate ratios). However, you will probably find it useful to compare the content and style of your final manuscript with this successfully published paper.

You should now be ready to do FA2 on writing.

Summary

- Revising early drafts.
- Do macro-edits then micro-edits
  - check that you have a clear, convincing argument
  - check for any errors, omissions or excesses in structure or content. Accuracy is vital.
  - check that the prose is fluent and clear and does not contain over-emotive or degrading language
  - check that the citations and references comply with the requirements of the target journal.
- Preparing the final manuscript:
  - review the manuscript requirements of your target journal
  - review the final version of the paper
  - tidy up the final manuscript in accordance with journal’s requirements
  - check the final manuscript.

Optional additional practice

Using the BMJ references given above you can look at how certain features of their studies are treated:

e.g. Smith et al. had to give enough information about their trial for this paper but could refer to another paper with the full protocol; their sample size calculations take account of multiple outcomes; note how they discuss whether the non-
significant differences in the peer support intervention really mean it was no use (perhaps some author bias coming in here but also some good reasoning).

e.g. Luo et al. had secondary analyses – pick out how these were treated. Also note how they do not hide in their discussion that their results are different from most other studies and, although their finding regarding passive smoking was probably not the one they expected, they do not try to force a dose-response where there was not one.

As optional exercises you could try some of the tests mentioned in this session e.g. Albert’s ‘yellow marker’ test, on a section of one of these two BMJ articles (e.g. Introduction or Discussion) and then see if you could improve that section.

Further reading

Frequently asked questions on points of style from the American Psychological Association but more widely applicable: http://www.apastyle.org/learn/faqs/index.aspx

If you are not familiar with terms used in English grammar the following website has some guidance: http://owl.english.purdue.edu/owl/resource/678/01/

BMJ house style explains includes some tips on use of punctuation and how to obtain clarity. It is well worth looking at: http://resources.bmj.com/bmj/authors/bmj-house-style

Wager E., Godlee F., Jefferson T. How to survive peer review, BMJ books http://resources.bmj.com/bmj/pdfs/wager.pdf
Pages 23-27 also offer some advice on the last stages before submitting a paper.
Dealing with the journal

Overview

Once you have produced the final manuscript, you are ready to submit your research paper to your target journal. To do this, you will have to prepare a complete submission package, including a covering letter, the correct number of copies of your manuscript if it is not submitted electronically, and any additional items required by the journal. Your paper will then be assessed by the editor and, if appropriate, sent for peer reviewing. You will eventually receive a decision email/letter from the editor.

In this session, you will learn how to prepare a complete submission package, how to respond appropriately to an editor’s decision and how to proofread a manuscript prior to publication. You will also be reminded about what editors and peer reviewers look for when they assess a paper.

Learning objectives

After working through this session, you will be better able to:

- prepare a complete submission package
- respond appropriately to an editor’s decision
- correct a proof prior to publication.

Planning your study

For this session you will be reading from two of your textbooks, the BMJ website, and briefly refer to a couple of articles. You will carry out a number of activities related to your reading. To complete the session you need:

Book available online:


The ebook available via the LSHTM library:

and the following from the internet:

- **BMJ information for authors**
  [http://resources.bmj.com/bmj/authors/types-of-article/research](http://resources.bmj.com/bmj/authors/types-of-article/research) and
  [http://resources.bmj.com/bmj/authors/article-submission/article-requirements](http://resources.bmj.com/bmj/authors/article-submission/article-requirements)
  [http://www.bmj.com/content/342/bmj.d715.full](http://www.bmj.com/content/342/bmj.d715.full)
  [http://www.bmj.com/content/342/bmj.d1016.full](http://www.bmj.com/content/342/bmj.d1016.full)

You should allow yourself approximately three hours to complete this session.

### Key terms

**Guarantors** of a paper “are those people who have contributed substantially, but who have also made added efforts to ensure the integrity of the entire project. They organise, oversee, and double check, and must be prepared to be accountable for all parts of the completed manuscript, before and after publication.” Rennie D, Yank V, Emmanuel L. When authorship fails: a proposal to make contributors accountable. *JAMA* 1997; 278: 579-85.

**Open access journals or articles**: articles are open access when they can be accessed via the internet without a personal/institutional subscription.

### Preparing a submission package

There are several items that you need to include with your manuscript when you send it to your target journal. A complete submission package consists of:

- a covering letter.
- the correct number of copies of your manuscript in the correct medium
- any additional items required by your target journal.

The information-for-authors pages of your target journal should indicate whether you may submit the manuscript on paper or electronically. The BMJ, and many other journals, use a web-based submission system for which you upload one copy of the manuscript only. You will have to register with (create an account on) that system before you can use it. Make sure you follow the instructions on submission carefully, including the formats accepted by the journal. For example, at the time this session goes to print BMJ uses the ScholarOne Manuscripts system. The BMJ’s web-based submission system accepts common word processing formats for text and tables (preferring Word), and GIF, TIFF, EPS or JPEG files for images. On the
other hand, the BMJ does not accept Powerpoint or Excel files. BMJ likes to receive main text, tables and images in different files. The manuscript is then converted to PDF for review.

“The system can also accept supplemental files (for example: videos, datasets, research protocols and checklists or statements), related articles published or available elsewhere, articles in press elsewhere, permission letters, etc. These are files that normally do not appear with the print article, although they might accompany the final version of the paper online. Supplemental files are not converted to PDF but will be available to reviewers or editors exactly as you upload them.” (http://resources.bmj.com/bmj/authors/article-submission/Online%20Editorial%20Office%20Benchpress accessed March 2011.)

Several journals use the same web-based submission and review tool (e.g. ScholarOne, Benchpress, PeerTrack) but their requirements can still vary. For example, the IJE uses ScholarOne Manuscripts as well, allows Word , WordPerfect, txt, or PDF, but prefers PDF. They also use a wider range of formats for pictures, photos and figures. They prefer text, tables and images to be in one document, although they will accept figures separately. You may find, however, that you only need register once with a system and can then use if for all journals using that system.

The Journal of the American Medical Association (JAMA) accepts Word or WordPerfect documents and multiple formats for figures but warns that, although Excel is acceptable for tables, warn that they must not be in separate spreadsheets within a file. These journals convert most submissions to PDF format for the review process and do not want the first submission to be in PDF format already.

**Additional items**

The information-for-authors pages of your target journal will inform you of any additional items that should be sent with your manuscript. These additional items vary considerably from journal to journal, but may include copies of related papers that you have published, written consents from patients who may be identified from the paper, permissions for copyright of previously published illustrations, and so on.

For the BMJ and other journals you have to provide the word count for the main text (excluding the abstract, references, tables, boxes, and figures).

Several requirements are important to declare the integrity of the study (the statement of competing interests, the information on ethical approval, and the reassurance that all authors have had access to data and the independence of researchers). Some journals (e.g. the International Journal of Epidemiology) have specific forms for authors to complete regarding competing interests and the BMJ has one for the lead author to confirm that the criteria for authorship have been fulfilled. To give you an idea of the kinds of additional information needed, the requirements for the BMJ are reproduced overleaf.
## From the BMJ:
For original research study manuscripts in particular, please note that we need, as appropriate:

### In the manuscript:
- for an intervention study the manuscript should include enough information about the intervention(s) and comparator(s) (even if this was usual care) for reviewers and readers to understand fully what happened in the study. To enable readers to replicate your work or implement the interventions in their own practice please also provide (uploaded as one or more supplemental files) any relevant detailed descriptions and materials. Alternatively, please provide in the manuscript urls to openly accessible websites where these materials can be found.
- a competing interest declaration - This should be composed after each author has filled in the International Committee of Medical Journal Editors’ Unified Competing Interest form and the corresponding author should keep the completed forms in case they are required later. Please then add to the manuscript a statement in the following format:
  - “All authors have completed the Unified Competing Interest form at [www.icmje.org/coi_disclosure.pdf](http://resources.bmj.com/bmj/authors/types-of-article/research) (available on request from the corresponding author) and declare that (1) [initials of relevant authors] have support from [name of company] for the submitted work; (2) [initials of relevant authors] have [no or specified] relationships with [name of companies] that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have [specified] financial relationships that may be relevant to the submitted work; and (4) [initials of relevant authors] have no [or specified] non-financial interests that may be relevant to the submitted work.”
- details of contributors - giving their names and specific roles - and the name of the guarantor(s) for the study
- a statement that any identifiable patients have provided their signed consent to publication. Please submit, as a supplemental file, the signed BMJ patient consent form giving consent to publication in the BMJ of any information about identifiable individual patients. Publication of any personal information about a patient in the BMJ, for example in a case report or clinical photograph, will normally require the signed consent of the patient
- a statement that the study obtained ethics approval (or a statement that it was not required), including the name of the ethics committee or institutional review board and a statement that participants gave informed consent before taking part
- a statement giving the details of all sources of funding for the study
- description of the role of the study sponsor(s) or funder(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication
- a statement of the independence of researchers from funders
- a statement that all authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis
- a data sharing statement such as "Data sharing: technical appendix, statistical code, and dataset available from the corresponding author at <email address or url>. Participants gave informed consent for data sharing [or ...consent was not obtained but the presented data are anonymised and risk of identification is low... or consent was not obtained but the potential benefits of sharing these data outweigh the potential harms because...]”. If there are no such further data available, please use this wording: "Data sharing: no additional data available"
- trial registration number and name of register for a clinical trial – in the last line of the structured abstract
- registration number and name of register for any study type, if registered – in the last line of the structured abstract. We are keen to promote registration for observational studies
- for a clinical guidelines article explicit statements of the quality of evidence and strength of recommendations, preferably using the GRADE system (we encourage but do not insist on this)
- one or more references for the statistical package(s) used to analyse the data e.g. RevMan for a systematic review. There is no need to provide a formal reference for a very widely used package that will be very familiar to general readers e.g. STATA, but please say in the text which version you used.

Source: [http://resources.bmj.com/bmj/authors/types-of-article/research](http://resources.bmj.com/bmj/authors/types-of-article/research). Accessed March 2011.
ACTIVITY 1

Look at the two BMJ papers by Smith et al. and Luo et al. to see how the additional information is provided.

Supplemental files

The BMJ also lists a number of supplemental files (see below for those required at the time of printing this study guide). Some of these will help you to check that you have followed both ethical practice and advice on the information you should present. The list is not as daunting as it seems as not every item applies to every manuscript!

“As supplemental files:

- the original protocol for a clinical trial or, if the protocol has been published in an open access online journal, its reference and url
- for a randomised controlled trial, the appropriate completed CONSORT checklist showing on which page of your manuscript each checklist item appears, the CONSORT-style structured abstract, and the CONSORT flowchart (CONSORT has several extension statements e.g. for cluster RCTs, pragmatic trials)
- PRISMA checklist and flowchart for a systematic review or meta-analysis of randomised trials and other evaluation studies (the PRISMA guidelines have superseded the QUOROM guidelines)
- MOOSE checklist for a meta-analysis of observational studies
- STARD checklist and flowchart for a study of diagnostic accuracy
- STROBE checklist for an observational study
- for an economic evaluation (noting that we do not usually consider economic evaluations of clinical or health services research studies unless we have already published or are currently considering those primary studies) the BMJ health economics checklist
- original raw data if you think they will help our reviewers (and maybe readers), or if we specifically request them. Please note our policy on data sharing, explained above
- video and audio files that will add educational value to your article, for example by explaining the intervention in a trial
- copies of any non-standard questionnaires and assessment schedules used in the research
- copies of patient information sheets used to obtain informed consent for the study or to comprise or deliver the intervention in a clinical trial
- copies of closely related articles you have published (this is particularly important when details of the study methods are published elsewhere)
- copies of any previous reviewers' reports on this article. We appreciate that authors may have tried other journals before sending their work to the BMJ, and find it helpful if you let us know how you have responded to previous reviewers' comments"

Source: http://resources.bmj.com/bmj/authors/types-of-article/research

The covering letter

The covering letter, which should be short, introduces you to the editor and provides some initial information about your paper. It is the first impression the editor will have of you and your work. The information-for-authors pages of your target journal will provide details of what the editor of your chosen journal will expect to find in the covering letter.
ACTIVITY 2

Turn to Albert’s book and read pages 87-91 on the covering letter.

While you are reading, make a brief list of the issues that you should address in a covering letter.

What messages is he trying to get across?

Feedback

An important message, as stated in other sessions of this study guide, is that journals vary in their requirements. Another is to be positive and to be polite.

You have already seen that the BMJ asks for many of the details of ethics and authorship etc to be placed in the manuscript. However, they have some specific points for the covering letter too, notably that you should give details of previous publications from the same study and suggestions for peer reviewers. As an optional activity see Source: http://resources.bmj.com/bmj/authors/types-of-article/research for more detail.

Submission

Once you have prepared the complete submission package, you can send your manuscript to your target journal. You will find where and how to send your package in the information-for-authors pages. Don’t forget to keep full copies of everything that you include in your package. Having posted electronic copies on a website does not guarantee that the manuscript and accompanying documents will never be lost!

The editorial process

Once your manuscript has been received by your target journal, the journal’s editorial team will evaluate it. Although each journal has its own editorial process, most journals use similar general criteria to assess a manuscript. If you know what these criteria are likely to be, you will be better able to produce a document that satisfies them.

Editorial assessment

All submitted papers are read, usually by some mix of editors and associate editors. The main criteria used for assessment by editors do not generally vary much in their detail. Refer to Session 6 Activity 2 to remind yourselves of the different kinds of review systems that exist.

Most editors use the following criteria:

- Is the paper relevant to the journal’s audience?
- What is the importance of the main question to the journal audience? Is the answer addressed by the paper?
• Does the paper add to current knowledge or understanding (also, has it been published elsewhere?)
• What is the scientific validity of the evidence used to support the paper’s conclusions?
• What is the usefulness of the paper in helping the journal to publish on the range of topics that the editors wish to cover?
• Is the research ethical?

If the paper has satisfied these criteria, the editor is also likely to apply the following:
• effect of acceptance on journal’s backlog of already accepted papers
• presentation of the manuscript and extent of required revision.

ACTIVITY 3

Read Wager et al. on ‘What happens after you have submitted your paper’, pp.27-30.

What are the usual four forms of decision that editors use?

Peer reviewing was covered in Session 6. Without looking back, see what you can remember of the BMJ list for peer reviewers.

Feedback

The usual four forms are: Outright acceptance; conditional acceptance with minor revision; rejection but option to revise and resubmit; outright rejection.

Not stated in the reading from Wager, it is rare for the editors to accept without any changes. If the paper is rejected on the first screening then you may only receive a very brief statement of rejection; if it is rejected after a peer review you should receive more detailed comments on the main weaknesses or drawbacks for this journal (and there will probably be some favourable comments too – rejected papers are not necessarily without merit!).

ACTIVITY 4

See Session 6 Activity 7 for peer reviewer tasks.

Responding to editorial decisions

ACTIVITY 5

Using the information given in the reading from Activity 3, answer the following questions:

1. How should you respond to requests for revision of your manuscript?
2. What can you do if your paper is rejected?
Feedback

1. First make sure you have looked at the comments from the editor as well as all the reviewers.

How you respond to requests for revision depends on whether you agree with the reviewers’ recommendations or not:

- if you agree with a particular recommendation, you should modify your manuscript to comply with it
- if you do not agree with a particular recommendation, you should ensure that the issue has been clearly explained in your paper (you should also justify to the editor why you think that the particular change is not necessary when resubmitting the otherwise revised manuscript)
- when you resubmit your revised manuscript, you should send a letter giving a point-by-point explanation of how you have responded to each recommendation (including any not accepted)
- You may add other corrections or improvements that you would like to make – point these out to the editors. However, do not change your paper dramatically unless requested by the editor or reviewers.

Note that for resubmissions the formatting requirements sometimes differ from those allowed for the original submission.

2. If your paper is rejected, do not take the rejection personally. Most authors will have at least some of their papers rejected on first submission. You should try to analyse why the editors took that decision. If your paper is rejected, you have three main options:

(a) Appeal against the decision – only do this if you believe that your paper has been seriously misinterpreted or that you could revise it to overcome major criticisms;
(b) Rewrite the paper for a different target journal – use all the information gained from the reviewers’ comments and editor’s suggestions to define a new target journal for the paper, check that your co-authors agree on the new target journal, and revise your paper so that the content and presentation are appropriate for your new target journal;
(c) Give up trying to get the paper published – only consider this option if you are convinced that your paper has major flaws that cannot be overcome and that make it unsuitable for publication even in a less prestigious journal.

Involve your co-authors in deciding what to do next.

Correcting the proof

Once you have responded to any recommendations for changes or revisions, you should return your revised manuscript as soon as possible. Most journals specify that the revised manuscript must be submitted within 2 or 3 months (this varies so make sure you check the requirements for your target journal) but most authors will do so within a few weeks to avoid delay. You will then receive the final decision from the journal about whether your paper has been accepted. Sometimes the editors make this decision alone but the revised manuscript may be sent back to the reviewers to approve. It could therefore take several weeks before you hear. Shortly before your paper is due to be published, you will then receive a proof of the paper.
to read and correct. The usual turnaround time for this is only 48 hours so make sure you are available around the time you expect the proofs.

**ACTIVITY 6**

Read Wager *et al.* on ‘What happens after your paper has been accepted’, pages 30-32. This gives some tips on how to spot errors by looking at the text in unusual ways.

Then, using your imagination and common sense, make a list of the kinds of detail you think worth looking at specifically.

**Feedback**

Items you should check when reading an edited manuscript or proof:

- any queries from the manuscript editor – they must be answered
- that the manuscript editor has not changed the meaning of the text
- that nothing has been left out
- spellings
- word divisions (hyphenation)
- use of italics
- cross-check references and their citations in the text
- cross-check that numbers in the abstract, the text, the tables and the illustrations are consistent with each other
- table headings and data; in particular check that columns or rows of data have not become misaligned.
- illustrations (check for defects, lost data and orientation).

**Publication**

A final stage before publication may involve, if not previously done, signing forms assigning copyright and confirming authorship, paying fees for publication. Payment is increasingly common for online journals although check with your institution’s library to find out the arrangement they have with that journal. For example all the BMC journals are open-access online and charge a fee for publication but if the institution pays a membership fee to BMC this publication fee is usually waived.

The BMC also asks authors to sign an Open Access License agreement which allows anyone to copy the work and even make commercial use of it provided that they give credit to the original authors, and make clear to others receiving the document or its derivative what the license terms are. Authors can waive the conditions. See [http://www.biomedcentral.com/info/authors/license](http://www.biomedcentral.com/info/authors/license) for more detail.

Your paper will now appear in print. Congratulations!
ACTIVITY 7

Summary

- A complete submission package consists of:
  - the correct number of copies of your manuscript (text, tables, figures) in the correct medium
  - any additional items required by your target journal
  - a covering letter.

- Most editors assess a manuscript using the following criteria:
  - relevance to journal
  - importance of research question to journal audience
  - whether adds to knowledge and not available elsewhere
  - scientific validity of the evidence provided
  - helps balance the range of topics that the editors wish to cover
  - ethical criteria.

- Peer reviewers provide the editor with expert opinions on detailed aspects of the paper. The editor takes these opinions into account when making a decision.

- An editor will usually decide to immediately accept the manuscript, provisionally accept the manuscript, reject with option to resubmit, or reject the manuscript outright. Whatever decision is reached, the editor will usually recommend revisions to the manuscript or point out the main flaws. However, journals which have a first-pass screening of the papers, may only give a very brief statement of rejection.

- If you re-submit your manuscript to the same journal, you should send a letter that gives a point-by-point explanation of how you have responded to each recommendation. This letter should include your justifications for any changes not made.

- If your paper has been rejected, you have three main options:
  - appeal against the decision
  - rewrite your paper for a different target journal
  - give up trying to get the paper published.

- Before your paper is published, you will receive a proof copy for correction. You should read this proof carefully, looking for any errors. You may also have to complete forms assigning copyright and confirming authorship.