

# THE DOCTOR'S GUIDE TO CRITICAL APPRAISAL

## FOURTH EDITION

**Dr Narinder Kaur Gosall**

**BSc (Hons) PhD**

Lead Tutor, The Critical Appraisal Company

Director, Superego Cafe Limited

**Dr Gurpal Singh Gosall**

**MA MB BChir MRCPsych**

Consultant General Adult Psychiatrist

and Foundation Program Lead,

Lancashire Care NHS Foundation Trust

Director, Superego Cafe Limited

**Pastes<sup>+</sup>**

# CONTENTS

|  |           |
|--|-----------|
| About the authors                          | ix        |
| Introduction to the fourth edition         | x         |
| Acknowledgements                           | xi        |
| <b>SECTION A – EVIDENCE-BASED MEDICINE</b> | <b>1</b>  |
| Introducing critical appraisal             | 3         |
| Formulating a question                     | 8         |
| Search strategies                          | 10        |
| The journal                                | 13        |
| Organisation of the article                | 16        |
| <b>SECTION B – AIMS AND OBJECTIVES</b>     | <b>19</b> |
| The clinical question                      | 21        |
| Subgroup analysis                          | 23        |
| Introducing confounding                    | 25        |
| Introducing bias                           | 29        |
| <b>SECTION C – STUDY DESIGNS</b>           | <b>31</b> |
| Overview                                   | 33        |
| Observational descriptive studies          | 35        |
| Observational analytical studies           | 37        |
| Experimental studies                       | 43        |
| Other types of studies                     | 47        |
| Research pathway                           | 49        |
| <b>SECTION D – SELECTING SUBJECTS</b>      | <b>53</b> |
| Overview                                   | 55        |
| Populations and samples                    | 56        |
| Selection bias                             | 62        |
| Matching                                   | 68        |
| Randomisation                              | 71        |
| Concealed allocation                       | 80        |
| Propensity scoring                         | 84        |
| Baseline characteristics                   | 87        |
| <b>SECTION E – OBSERVING SUBJECTS</b>      | <b>91</b> |
| Overview                                   | 93        |
| The effects of expectation                 | 94        |
| Observation bias                           | 98        |

|  |            |
|--|------------|
| Blinding   | 100        |
| Endpoints  | 104        |
| Validity   | 109        |
| Reliability  | 111        |
| Bias revisited                                     | 118        |
| <b>SECTION F – INTERPRETING RESULTS</b>            | <b>119</b> |
| Overview   | 121        |
| Basic statistical terms                            | 122        |
| Epidemiology                                       | 124        |
| Types of data                                      | 129        |
| Measuring data                                     | 132        |
| Data distributions                                 | 135        |
| Summarising categorical data                       | 138        |
| Summarising normally distributed data              | 140        |
| Summarising non-normally distributed data          | 145        |
| Inferring population results from samples          | 149        |
| Patient flow                                       | 158        |
| Comparing groups – risks and odds                  | 167        |
| Comparing groups – the null hypothesis             | 177        |
| Comparing samples – statistical tests              | 190        |
| Correlation and regression                         | 200        |
| Interim analysis                                   | 209        |
| Non-inferiority and equivalence trials             | 210        |
| Confounding revisited                              | 212        |
| <b>SECTION G – CHECKLISTS</b>                      | <b>215</b> |
| Introduction to checklists                         | 217        |
| Aetiological studies                               | 218        |
| Diagnostic or screening studies                    | 220        |
| Treatment studies                                  | 229        |
| Prognostic studies                                 | 234        |
| Economic studies                                   | 240        |
| Qualitative research                               | 247        |
| Guidelines   | 254        |
| Systematic reviews and meta-analyses               | 256        |
| Systematic reviews – homogeneity and heterogeneity | 265        |
| Publication bias                                   | 269        |
| <b>SECTION H – APPLICABILITY</b>                   | <b>273</b> |
| The hierarchy of evidence                          | 275        |
| Critical thinking                                  | 278        |

---

|   |            |
|---|------------|
| <b>SECTION I – CRITICAL APPRAISAL IN PRACTICE</b> | <b>283</b> |
| Health information resources                      | 285        |
| Presenting at a journal club                      | 289        |
| Taking part in an audit meeting                   | 292        |
| Working with pharmaceutical representatives       | 294        |
| Further reading                                   | 298        |
| <b>A FINAL THOUGHT</b>                            | <b>301</b> |

# INTRODUCING CRITICAL APPRAISAL

## Scenario 1

Mr Lemming visited the car dealership. The salesman showed him to the new car. 'This is the latest and greatest,' explained the salesman. 'Faster, quieter and more efficient. The engine is revolutionary, the leather seats are suppler and the satellite navigation is outstanding.' Mr Lemming nodded in agreement as he flicked through the brochure. 'If you purchase this car,' said the salesman, 'you'll be the talk of the neighbourhood, sir.' Mr Lemming was convinced. Without a single question and without requesting a test drive, he immediately purchased the car and looked forward to his regular commute!

## Scenario 2

Dr Brown read the latest issue of the journal. A randomised controlled trial on a new treatment caught his eye. The results showed the new treatment was better than a placebo tablet. It helped patients to improve faster and with fewer side-effects. The authors of the article recommended the new treatment as the first-line intervention. Without a further thought, Dr Brown was convinced that his patients would benefit. He expected to achieve better outcomes than his colleagues. He would be the talk of the department! The next day Dr Brown began prescribing the new medication to his patients.

Every year, thousands of clinical papers are published in the medical press. The vast range of topics reflects the sheer complexity of the human body, with studies all fighting for our attention. Separating the wheat from the chaff is a daunting task for doctors, many of whom have to rely on others for expert guidance.

In 1972, the publication of Archie Cochrane's *Effectiveness and Efficiency: Random Reflections on Health Services*<sup>1</sup> made doctors realise how unaware they were of the effects of healthcare. Archie Cochrane, a British epidemiologist, went on to set up the Cochrane Collaboration in 1992. It is now an international organisation, committed to producing and disseminating systematic reviews of healthcare interventions. Bodies such as the Cochrane Collaboration have made the lives of doctors much easier, but the skill of evaluating evidence should be in the arsenal of every doctor.

1 Cochrane AL. *Effectiveness and Efficiency: Random Reflections on Health Services*. London: Royal Society of Medicine Press, 1999.

## Evidence-based medicine

**Evidence-based medicine** is the phrase used to describe the process of making clinical decisions about a patient's clinical state taking into account the best available research evidence, our clinical expertise and patient preferences<sup>1</sup>. As such, evidence-based medicine has had a tremendous impact on improving healthcare outcomes since its widespread adoption in the early 1990s.

The most widely quoted definition of evidence-based medicine is that it is '*the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient*'<sup>2</sup>. The practice of evidence-based medicine consists of five steps, shown in Table 1.

| EVIDENCE-BASED MEDICINE – THE FIVE STEPS |                    |   |
|--|--------------------|---|
| 1  | Question           | Formulate a precise, structured clinical question about an aspect of patient management   |
| 2  | Evidence           | Search for the best evidence with which to answer the question  |
| 3  | Critical appraisal | Evaluate the evidence, critically appraising the evidence for its validity, impact and applicability  |
| 4  | Application        | Apply the results to clinical practice, integrating the critical appraisal with clinical expertise and with patients' circumstances and views |
| 5  | Monitor            | Monitor the process, evaluating the effectiveness and efficacy of the whole process, and identifying ways of improving both for the future    |

**Table 1** Evidence-based medicine – the five steps

Evidence-based medicine begins with the formulation of a clinical question, such as '*What is the best treatment for carpal tunnel syndrome?*' This is followed by a search of the medical literature, looking for answers to the question. The evidence gathered is appraised and the recommendations from the best studies are applied to patients. The final step, which is often overlooked, is to monitor any changes and repeat the process. This may involve audits and surveys.

Although evidence-based medicine has led to a more consistent and uniform approach to clinical practice, it does not mean that clinicians practise identically.

1 Haynes RB, Devereaux PJ, Guyatt GH. Physicians' and patients' choices in evidence based practice. *BMJ* 2002; 324: 1350.

2 Sackett DL, Richardson WS, Rosenberg W, Haynes RB. *Evidence-based Medicine: How to Practise and Teach Evidence-based Medicine*. London: Churchill Livingstone, 1997.

Clinicians vary in their level of expertise, so not all the recommendations from clinical research can be followed. For example, the evidence might suggest that an intramuscular injection is the best treatment for a condition but the clinician might not have been trained to safely administer that treatment. In addition, patients differ in the interventions they find acceptable – some patients prefer not to have injections, for example, and interventions should be tailored to the needs of individual patients. Finally, a lack of resources can also restrict the choices available, particularly for new and expensive interventions.

## Critical appraisal

In the process of evidence-based medicine, why do we need a step of critical appraisal? Why not take all results at face value and apply all the findings to clinical practice? The first reason is that there might be conflicting conclusions drawn from different studies. Secondly, real-life medicine rarely follows the restrictive environments in which clinical trials take place. To apply, implement and monitor evidence, we need to ensure that the evidence we are looking at can be translated into our own clinical environment.

Critical appraisal is just one step in the process of evidence-based medicine. It allows doctors to assess the research they have found in their search and to decide which research evidence could have a clinically significant impact on their patients. Critical appraisal allows doctors to exclude research that is too poorly designed to inform medical practice. By itself, critical appraisal does not lead to improved outcomes. It is only when the conclusions drawn from critically appraised studies are applied to everyday practice and monitored that the outcomes for patients improve.

As with most subjects in medicine, it is not possible to learn about critical appraisal without coming across jargon. Wherever we start, we will come across words and phrases we do not understand. In this book we try to explain critical appraisal in a logical and easy-to-remember way. Anything unfamiliar will be explained in due course.

## Internal validity and external validity

Critical appraisal assesses the validity of the research and statistical techniques employed in studies and generates clinically useful information from them. It seeks to answer two major questions:

- Does the research have **internal validity** – to what extent does the study measure what it sets out to measure? We want to know how good the research methods used by the researchers are to answer the clinical question.

- Does the research have **external validity** – to what extent can the results from the study be generalised to a wider population? Studies are usually done in experimental and artificial settings – we want to know whether we will get the same results in real life settings.

If we change our practice based on a study with poor internal validity, we may have unrealistic expectations about our outcomes and be disappointed. We may also end up harming our patients by not offering alternative choices or by exposing them to new dangers.

Studies with good internal validity can have poor external validity, particularly if the conditions used in the study are far removed from everyday life. The challenge then is to find studies with good internal validity but with experimental conditions that mimic real clinical environments, so that the results can be applied to normal practice. As we shall see, as researchers implement methods to improve the internal validity, the external validity often suffers.

## Efficacy and effectiveness

Two words that are useful to define now are ‘efficacy’ and ‘effectiveness’. These words are sometimes used interchangeably but they have different meanings and consequences in the context of evidence-based medicine.

**Efficacy** describes the impact of interventions under optimal (trial) conditions.

**Effectiveness** is a different but related concept, describing whether the interventions have the intended or expected effect under ordinary (clinical) circumstances.

Efficacy shows that internal validity is present. Effectiveness shows that external validity (generalisability) is present.

The contrast between efficacy and effectiveness studies was first highlighted in 1967 by Schwartz and Lellouch<sup>1</sup>. Efficacy studies usually have the aim of seeking regulatory approval for licensing. The interventions in such studies tend to be strictly controlled and compared with placebo interventions. The people taking part in such studies tend to be a selective ‘eligible’ population. In contrast, effectiveness studies tend to be undertaken for formulary approval. Dosing regimens are usually more flexible and are compared with interventions already being used. Almost anyone is eligible to enter such trials.

It is not always easy and straightforward to translate the results from clinical

1 Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutical trials. *Journal of Chronic Diseases* 1967; 20: 637–48.



trials (efficacy data) to uncontrolled clinical settings (effectiveness data). The results achieved in everyday practice do not always mirror an intervention's published efficacy data and there are many reasons for this. The efficacy of an intervention is nearly always more impressive than its effectiveness.

### **Scenario 1 revisited**

*Mr Lemming's drive to work in his new car was a disappointing experience. The journey had taken the same duration as the previous week. He hadn't noticed an appreciable difference in acceleration. The fuel consumption appeared to be the same. The leather seats may have been a bit more comfortable but then again, Mr Lemming remembered, he had no complaints about the seats in his old car. Later that evening he conveyed his disappointment to his wife. She shook her head in dismay and said, 'Darling, you always fall for the glossy brochure.'*

### **Scenario 2 revisited**

*Dr Brown was called to the office of the Medical Director. An analysis of prescribing costs in his department showed his costs were much higher than his colleagues. 'For the last month you've been prescribing an expensive new treatment,' explained the Medical Director, 'but you're not getting better outcomes.' He was unwilling to concede to Dr Brown's request for more time. 'You've treated 50 patients so far with the new treatment,' he said, 'yet no more patients are being cured.' Dr Brown mentioned the journal article he had read but the Medical Director remained unimpressed. 'I read it too but I didn't alter my prescribing practice,' he said, shaking his head in dismay. 'It was obvious the efficacy data published in the trial was not going to translate into effectiveness data. It appears, Dr Brown, that my critical appraisal skills are better than yours.'*

# FORMULATING A QUESTION

The first step in adopting an evidence-based medicine approach is to formulate a precise, structured clinical question about an aspect of patient management.

## P.I.C.O.

The question should be directly relevant to the problem at hand<sup>1</sup>. Broad questions such as, 'How do I treat diabetes mellitus?' and 'What causes bowel cancer?' are easy to understand but return too many results on searching the medical literature. The acronym 'P.I.C.O.', explained in Table 2, can frame the question so that it directs the search to relevant and precise answers<sup>1</sup>.

|          |                    |  |
|----------|--------------------|--|
| <b>P</b> | Patient or problem | Describe your patient and their problem  |
| <b>I</b> | Intervention       | Describe the main intervention, exposure, test or prognostic factor under consideration                    |
| <b>C</b> | Comparison         | In the case of treatment, describe a comparative intervention (although a comparison is not always needed) |
| <b>O</b> | Outcome            | Describe what you hope to achieve, measure or affect   |

**Table 2** Introducing P.I.C.O.

For example, a doctor assesses a new patient presenting with depressive symptoms. The doctor decides to prescribe antidepressant medication. The patient is worried about side-effects and asks the doctor if there are any other treatment options. The doctor has heard that cognitive behavioural therapy is also used to treat depression. The doctor carries out a search of the medical literature using the P.I.C.O. search strategy shown in Table 3.

1 Richardson WS, Wilson MC, Nishikawa J, Hayward RS. The well-built clinical question: a key to evidence-based decisions. *ACP J Club* 1995; 123(3): A12-13.

|          |                    |   |
|----------|--------------------|---|
| <b>P</b> | Patient or problem | In a man with depression...                 |
| <b>I</b> | Intervention       | ...is cognitive behavioural therapy...      |
| <b>C</b> | Comparison         | ...compared to fluoxetine...                |
| <b>O</b> | Outcome            | ...better at improving depressive symptoms? |

**Table 3** An example of the P.I.C.O. framework

# SEARCH STRATEGIES

By adopting a sensible search technique you can dramatically improve the outcome of a search. You might begin by formulating a P.I.C.O. research question. This will enable you to perform a more structured search for the relevant information and will indicate where the information needs lie. Keywords, similar words or synonyms should then be identified, to search terms on the database.

When you start the search you want to ensure that the search is not too narrow – that is, that you get as many papers as possible to look at. This is done by **exploding your search**. This means that you can search for a keyword plus all the associated narrower terms simultaneously. As a result, all articles that have been indexed as narrow terms and that are listed below the broader term are included. If too many results are returned, you can refine the search and get more specific results – **focusing your search**. Filters can be used to increase the effectiveness of the search. Subheadings can be used alongside index terms to narrow the search. Indexers can assign keywords to an article. These words can also be weighted by labelling them as major headings. These are then used to represent the main concepts of an article. This can help focus the search even more.

Search engines are not normally case-sensitive – ‘*Diabetes*’ and ‘*diabetes*’ will return the same results. To search for a phrase, enclose it in **quotation marks** – ‘*treatment of diabetes mellitus*’ will only return items with that phrase, for example.

**Boolean operators** are used to combine together keywords and phrases in your search strategy:

- **AND** is used to link together different subjects. This is used when you are focusing your search and will retrieve fewer references. For example, ‘*diabetes*’ **AND** ‘*insulin inhalers*’ will return items containing both terms.
- **OR** is used to broaden your search. You would use **OR** to combine like subjects or synonyms. For example, ‘*diabetes*’ **OR** ‘*hyperglycaemia*’ will return items containing either term.
- **NOT** is used to exclude material from a search. For example, ‘*diabetes*’ **NOT** ‘*insipidus*’ will return items containing the first term and not the second.

**Parentheses (nesting):** This can be used to clarify relationships between search terms. For example, '(diabetes or hyperglycaemia)' AND 'inhalers' will return items containing either of the first two terms and the third.

**Truncation:** A **truncation** symbol at the end of a word returns any possible endings to that word. For example, 'cardio\*' will return 'cardiology', 'cardiovascular' and 'cardiothoracic'. There are a variety of truncation symbols in use, including a question mark (?), an asterisk (\*) and a plus sign (+).

**Wild cards:** A **wild card** symbol within a word will return the possible characters that can be substituted. For example, 'wom#n' will return 'woman' and 'women'. Common wild-card symbols include the hash (#) and the question mark (?).

**Stemming:** Most search engines will 'stem' search words. Stemming removes suffixes such as '-s', '-ing' and '-ed'. These variations are returned automatically when stem words are searched.

**Thesaurus:** This is used in some databases, such as MEDLINE, to help perform more effective searching. It is a controlled vocabulary and is used to index information from different journals. This is done by grouping related concepts under a single preferred term. As a result, all indexers use the same standard terms to describe a subject area, regardless of the term the author has chosen to use. It contains keywords, definitions of those keywords and cross-references between keywords. In healthcare, the National Library of Medicine uses a thesaurus called **Medical Subject Headings (MeSH)**. MeSH contains more than 27 000 terms<sup>1</sup>. Each of these keywords represents a single concept appearing in the medical literature. For most MeSH terms, there will be broader, narrower and related terms to consider for selection. MeSH can also be used by the indexers in putting together entries for MEDLINE databases.

**Synonyms:** Search engines might expand searches by using a thesaurus to match search words to other words with the same meaning.

**Plus (+) symbol:** Use a **plus (+)** symbol before a term that must appear in the search results. For example, '+glucophage diabetes' will return items that include the Glucophage brand name and diabetes rather than the generic name metformin.

**Stopwords:** Commonly found words, such as 'and', 'this' and 'also', are not indexed. These stop words are words that, if indexed, could potentially

1 U.S. National Library of Medicine. Medical Subject Headings (MeSH). 2014. Available: <http://www.nlm.nih.gov/pubs/factsheets/mesh.html>. Accessed 1 September 2014.

return every document in the database if the word was used in a search statement<sup>1</sup>.

### **Sources of information**

There is no single definitive source of medical information. A comprehensive search strategy will use a number of different sources to ensure that all relevant material is retrieved.

1 U.S. National Library of Medicine. Stopwords. 2014. Available: [http://www.nlm.nih.gov/bsd/disted/pubmedtutorial/020\\_170.html](http://www.nlm.nih.gov/bsd/disted/pubmedtutorial/020_170.html). Accessed 10 October 2014.

Not all journals are equal. Some journals are more prestigious than others. There can be many reasons for such prestige, including a long history in publishing, affiliation with an important medical organisation or a reputation for publishing important research. It is important to know which journal an article was published in – but remember, even the best journals sometimes publish poor articles and good papers can appear in the less prestigious journals.

## Peer-reviewed journals

A **peer-reviewed** journal is a publication that requires each submitted article to be independently examined by a panel of experts, who are non-editorial staff of the journal. To be considered for publication, articles need to be approved by the majority of peers. The process is usually anonymous, with the authors not knowing the identities of the peer reviewers. In double-blind peer review, neither the author nor the reviewers know the others' identities. Anonymity aids the feedback process.

The peer-review process forces authors to meet certain standards laid down by researchers and experts in that field. Peer review makes it more likely that mistakes or flaws in research are detected before publication. As a result of this quality assurance, peer-reviewed journals are held in greater esteem than non-peer-reviewed journals.

There are disadvantages to the peer-review process, however. Firstly, it adds a delay between the submission of an article and its publication. Secondly, the peer reviewers might guess the identity of the author(s), particularly in small, specialised fields, impairing the objectivity of their assessments. Thirdly, revolutionary or unpopular conclusions can face opposition within the peer-review process, leading to preservation of the status quo.

Finally, it is worth remembering that peer review does not guarantee that errors will not appear in the finished article or that fraudulent research will not be published. There have also been instances where the peer review process itself has been shown to be defective. For example, a spoof paper concocted by *Science* in 2013 revealed little or no scrutiny at many open-access journals<sup>1</sup>. Acceptance of the obviously flawed paper was the norm, not the exception. In 2014 two publishers announced they were removing more than 120 papers

1 Bohannon J. Who's afraid of peer review? *Science* 2013; 342(6154): 60–65.

from their subscription services after a researcher discovered that the works were computer-generated nonsense<sup>1</sup>.

## Journal impact factor

A high number of citations implies that a journal is found to be useful to others, suggesting that the research published in that journal is valuable. However, simply ranking a journal's importance by the number of times articles within that journal are cited by others would favour large journals over small journals and frequently issued journals over less frequently issued journals.

A **journal impact factor** provides a means of evaluating or comparing the performance of a journal relative to that of others in the same field. It ranks a journal's importance by measuring the frequency with which the average article in a journal has been cited in a particular year. Impact factors are calculated annually by Thomson Reuters (formerly known as the Institute for Scientific Information) and published in the *Journal Citation Report* (JCR).

The impact factor of a journal is calculated as the number of citations in the current year to articles published in the two previous years, divided by the total number of articles published in the two previous years<sup>2</sup>. In 2014 *The New England Journal of Medicine* had an impact factor of 54.42<sup>3</sup> (the highest among general medical journals) and *The BMJ* had an impact factor of 16.3<sup>4</sup>.

It is important to remember, in critical appraisal, that the journal impact factor cannot be used to assess the importance of any one article, as the impact factor is a property of the journal and is not specific to that article. Also, journal citation counts in JCR do not distinguish between letters, reviews or original research.

The **Immediacy Index** is another way from Thomson Reuters of evaluating journals. The Immediacy Index is the average number of times an article is cited in the year it is published<sup>5</sup>. It is calculated by dividing the number of citations

- 1 Van Noorden R. Publishers withdraw more than 120 gibberish papers. 2014. Available: <http://www.nature.com/news/publishers-withdraw-more-than-120-gibberish-papers-1.14763>. Accessed 1 September 2014.
- 2 Journal Citation Report (JCR). Philadelphia, USA. Thomson Institute for Scientific Information, 2005. JCR provides quantitative tools for ranking, evaluating, categorising and comparing journals.
- 3 NEJM. *Media Center Fact Sheet*. 2014. Available: <http://www.nejm.org/page/media-center/fact-sheet>. Accessed 1 September 2014.
- 4 The BMJ. *About The BMJ*. 2014. Available: <http://www.bmj.com/about-bmj>. Accessed 1 September 2014.
- 5 Thomson Reuters. *Immediacy Index*. 2012. Available: [http://admin-apps.webofknowledge.com/JCR/help/h\\_immedindex.htm](http://admin-apps.webofknowledge.com/JCR/help/h_immedindex.htm). Accessed 1 September 2014.



to articles published in a given year by the number of articles published in that year. This is useful for comparing journals specialising in cutting-edge research.

A journal can improve its impact factor by improving accessibility to its articles and publicising them more widely. In recent years there have been significant improvements in web-based access to journals and now some journals publish research articles online before they appear in print. Many journals issue press releases highlighting research findings and send frequent email alerts to subscribers. A rise in the percentage of review articles with citations to the journal itself can also boost a journal's impact factor. Review journals often occupy the first-ranked journal position in the JCR subject category listings.

As impact factors provide a quantitative measure of the quality of a journal it is perhaps not surprising that there have been scandals where impact factors have been manipulated. Some journal editors have engaged in coercive self-citation, pressurising researchers to add citations from the editor's journal, even when the manuscript was not lacking in attribution<sup>1</sup>.

## Ingelfinger rule

The Ingelfinger rule, named after Franz Ingelfinger, a former editor of *The New England Journal of Medicine*, stipulates that neither an original research article nor any of its pictures or tables may be published in more than one outlet<sup>2</sup>. This rule was originally implemented to protect the newsworthiness of the journal. It is now a widely adopted principle within the scientific community and serves to ensure research is subjected to peer review and published in the scientific literature before it is touted to the public or the profession.

- 1 Wilhite AW, Fong EA. Coercive citation in academic publishing. *Science* 2012; 335(6068): 542–43.
- 2 Relman AS. *The Ingelfinger Rule*. 1981. Available: <http://www.nejm.org/doi/full/10.1056/NEJM198110013051408>. Accessed 1 September 2014.

# ORGANISATION OF THE ARTICLE

The majority of published articles follow a similar structure.

**Title:** This should be concise and informative, but sometimes an attention-grabbing title is used to attract readers to an otherwise dull paper. The title can influence the number of people who read the article, which can in turn lead to increased citations.

**Author(s):** This should allow you to see if the authors have the appropriate academic and professional qualifications and experience. The institutions where the authors work might also be listed and can increase the credibility of the project if they have a good reputation for research in this field. Be wary of 'guest' or 'gift' authors who did not contribute to the article. These authors might have been added to make the list of authors appear more impressive or to enhance the authors' *curricula vitae*, often on a reciprocal basis. Conversely, a 'ghost' author is someone who contributed to a piece of work, but who is left uncredited despite qualifying for authorship. The International Committee of Medical Journal Editors (ICMJE) recommends that authorship be based on the following four criteria<sup>1</sup>:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.
2. Drafting the work or revising it critically for important intellectual content.
3. Final approval of the version to be published.
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged<sup>1</sup>.

**Abstract:** This summarises the research paper, briefly describing the reasons for doing the research, the methods used, the overall findings and the conclusions made. Reading the abstract is a quick way of getting to know the

1 Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals in <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>. December 2013. Accessed 10 October 2014.

article, but the brevity of the information provided in an abstract means that it is unlikely to reveal the strengths and weaknesses of the research. If the abstract is of interest to you, you must go on to read the rest of the article. Never rely on an abstract alone to inform your clinical practice!

**Introduction:** This explains what the research is about and why the study was carried out. A good introduction will include references to previous work related to the subject matter and describe the importance and limitations of what is already known.

**Method:** This section gives detailed information about how the study was actually carried out. Specific information is given on the study design, the population of interest, how the sample of the population was selected, the interventions offered and which outcomes were measured and how they were measured.

**Results:** This section shows what happened to the individuals studied. It might include raw data and might explain the statistical tests used to analyse the data. The results can be laid out in tables, diagrams and graphs.

**Conclusion / discussion:** This section discusses the results in the context of what is already known about the subject area and the clinical relevance of what has been found. It might include a discussion on the limitations of the research and suggestions on further research.

**Conflicts of interests:** Articles should be published on their scientific merit in order to maintain public trust in the scientific process<sup>1</sup>. A conflict of interest exists when professional judgment concerning a primary interest (such as how many subjects improve in a study) may be influenced by a secondary interest (such as financial gain)<sup>1</sup>. Perceptions of conflict of interest are as important as actual conflicts of interest<sup>1</sup>. Conflicts of interest can be held by anyone involved in the research project, from the formulation of a research proposal through to its publication, including authors, their employers, a sponsoring organisation, journal editors and peer reviewers. Conflicts of interest can be financial (eg research grants, honoraria for speaking at meetings), professional (eg being a member of an organisational body) or personal (eg a relationship with the journal's editor). Ideally, authors should disclose conflicts of interest when they submit their research work. **A conflict of interest does not necessarily mean that the results of a study are void.**

1 Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals in <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>. December 2013. Accessed 10 October 2014.

**Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children**

Wakefield AJ, Murch SH, Anthony A, et al. *Lancet* 1998; 351: 637–41.

This study raised the possibility of a link between the measles, mumps and rubella vaccine (MMR) given to children in their second year of life and inflammatory bowel disease and autism. This was widely reported by the media. The MMR scare reduced vaccination rates to 80% nationally, leading to a loss of herd immunity and measles outbreaks in the UK. Later it was revealed that the lead author was being funded through solicitors seeking evidence to use against vaccine manufacturers and he also had a patent for a single measles vaccine at the time of the study. Ten of the study's 13 authors later signed a formal retraction<sup>1</sup>. The editor of the *Lancet* said the research study would never have been published if he had known of a serious conflict of interest.

<sup>1</sup> Murch SH, Anthony A, Casson DH, et al. Retraction of an interpretation. *Lancet* 2004; 363: 750.