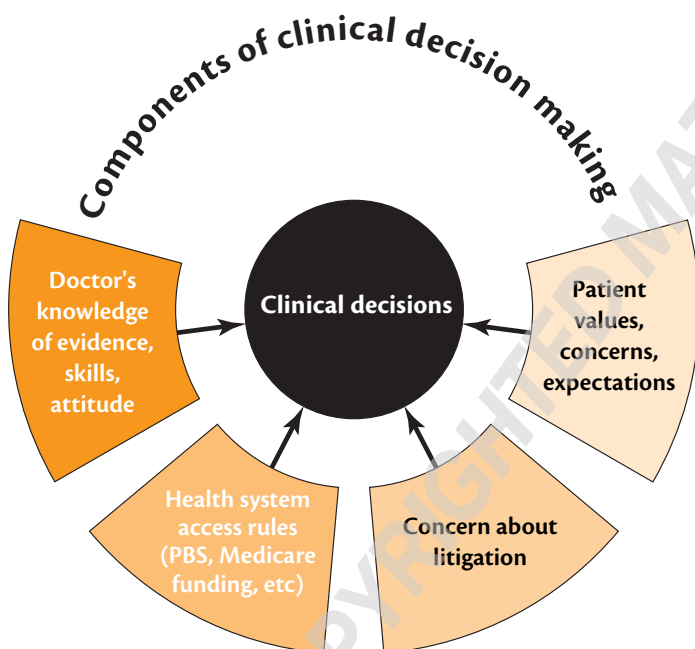


What is evidence-based practice?

Clinical practice is about making choices. Which test would be best to find out more about this condition? Which treatment would be the most effective for this patient? The answers to these questions depend on the practitioner's knowledge, skills and attitudes, the resources available and the patient's concerns, expectations and values.

In the early 1990s, David Sackett and his colleagues at McMaster University in Ontario, Canada, coined the term 'evidence-based medicine' to mean 'integrating individual clinical expertise with the best available external clinical evidence from systematic research' to achieve the best possible patient management. They have subsequently refined their definition to also take account of patient values (see box).

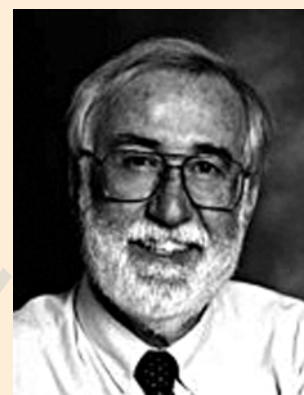


Thus, evidence-based medicine is about trying to improve the quality of the information on which health care decisions are based. It helps practitioners to avoid 'information overload' but, at the same time, to find and apply the most useful information.

The term 'evidence-based medicine', which has largely replaced the older term 'clinical epidemiology', is now often also referred to as 'evidence-based practice'. As well as being more inclusive of different areas of health care practice, the latter term highlights the important point that the 'evidence' that we are talking about is empirical evidence about what actually works or doesn't work in practice. It is not scientific evidence for a mechanism of action (such as a biochemical pathway, physiological effect or anatomical feature). Many factors affect the outcomes of clinical activities; the underlying mechanism is only one of them. Evidence-based practice (EBP) is concerned with actual clinical outcomes and is the term that we will use in this workbook.

"... the integration of **best research evidence** with **clinical expertise** and **patient values**"

– Dave Sackett



Reference:

Sackett DL, Strauss SE, Richardson WS, Rosengerg W, Haynes RB (2000). *Evidence-based Medicine: How to Practice and Teach EBM*, Churchill Livingstone, Edinburgh.

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Some essential elements of the EBP approach

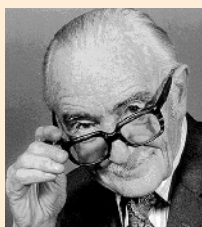
1. Recognise uncertainties in clinical knowledge
2. Use research information to reduce uncertainties
3. Discriminate between strong and weak evidence
4. Quantify and communicate uncertainties with probabilities

Why do we need EBP?

Unfortunately, there is a large though variable gap between what we know from research and what we do in clinical practice. Because so much research is published — some valid and some invalid — clinicians understandably are unaware of most of it, or do not have the ‘tools’ to assess its quality. Researchers, on the other hand, may not understand the information needs of clinicians and often present their work in a way that is not easily accessible to busy practitioners. In 1972, British epidemiologist Archie Cochrane highlighted the fact that most treatment-related decisions were not based on a systematic review of clinical research. Rather, they were based on an ad hoc selection of information from the vast and variable quality scientific literature, on expert opinion or, worst of all, on trial and error.

Who was Archie Cochrane?

Professor Archie Cochrane was a medical researcher in the United Kingdom who contributed to the development of epidemiology as a science. In an influential book published in 1972, *Effectiveness and Efficiency*, he drew attention to the great collective ignorance at that time about the effects of health care. He recognised that doctors did not have ready access to reliable reviews of available evidence. In a 1979 article, he said:

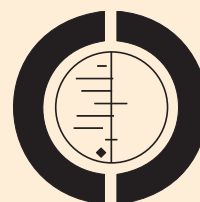


‘It is surely a great criticism of our profession that we have not organised a critical summary, by speciality or subspeciality, adapted periodically, of all relevant randomised controlled trials.’

References:

- Cochrane AL (1972). *Effectiveness and Efficiency: Random Reflections on Health Services*, Nuffield Provincial Hospital Trust, London (reprinted in 1989 in association with the *British Medical Journal*).
- Cochrane AL (1979). 1931–1971: A critical review, with particular reference to the medical profession. In: *Medicines for the Year 2000*, Office of Health Economics, London.

Cochrane proposed that researchers and practitioners should collaborate internationally to systematically review all the best clinical trials (that is, randomised controlled trials, or RCTs), specialty by specialty. His ideas were taken up during the 1980s by Iain Chalmers who persuaded colleagues to join him and make care during pregnancy and childbirth the first area of clinical practice to be reviewed in this way. Systematic reviews of RCTs of different aspects of obstetric care soon showed some anomalies between the clinical trial evidence and established practice. This highlighted the gaps that existed between research and clinical practice and started to convince some doctors of the benefits of an evidence-based approach to bridge this gap.



THE COCHRANE
COLLABORATION®

The ‘pilot’ of Effective Care in Pregnancy and Childbirth then led to an international collaboration being established in response to Archie Cochrane’s call for systematic, up-to-date reviews of all relevant randomised controlled trials of health care. In the early 1990s, funds were provided by the UK National Health Service to establish a Cochrane Centre in Oxford. The approach was further outlined at an international meeting organised by the New York Academy of Sciences in 1993 and at the first Cochrane Colloquium in October 1993, when ‘The Cochrane Collaboration’ was founded.

<http://www.cochrane.org>

The Cochrane logo has been reproduced with permission from The Cochrane Collaboration.

This work has been continued through The Cochrane Collaboration (see box), which publishes systematic reviews of RCTs electronically in the Cochrane Database of Systematic Reviews, within The Cochrane Library. Access to The Cochrane Library is available free online in many countries.

Go to **<http://www.cochrane.org>** and follow the prompts for The Cochrane Library.

CORTICOSTEROIDS FOR PRETERM BIRTH

1972

An RCT was published that showed improved outcomes for preterm babies when mothers were given a short course of corticosteroids before the birth.

1972–89

Six more RCTs were published, all confirming the 1972 findings.

During this time, most obstetricians were still unaware that corticosteroid treatment was effective and so did not treat women who were about to have a preterm birth with corticosteroids.

1989

The first systematic review of corticosteroid treatment was published.

1989–91

Seven more studies were published.

Conclusion

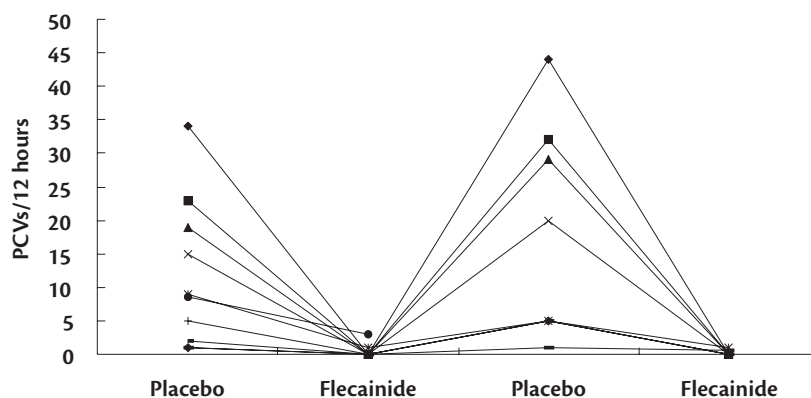
Corticosteroid treatment reduces the odds of babies dying from complications of immaturity by 30 to 50%, but thousands of babies have died or suffered unnecessarily since 1972 because doctors did not know about the effectiveness of the treatment shown in the 1972 trial, and were misled by subsequent smaller trials until these were combined ('meta-analysed').

The flecainide story

The history of the use of the drug flecainide to treat heart attacks in the United States in the 1980s is a dramatic example of the gap between research and clinical practice, and of the reliance on evidence of a mechanism rather than an outcome. In 1979, the developer of the defibrillator, Bernard Lown, pointed out in an address to the American College of Cardiology that one of the biggest causes of death was heart attack, particularly among young and middle-aged men (20–64-year-olds). People had a heart attack, developed arrhythmia and died from the arrhythmia. He suggested that a 'safe and long-acting antiarrhythmic drug that protects against ventricular fibrillation' would save millions of lives.

In response to this challenge, a paper was published in the *New England Journal of Medicine* introducing a new drug called flecainide — a local anesthetic derivative that suppresses arrhythmia. The paper described a study in which patients who had just had heart attacks were randomly assigned to groups to receive either a placebo or flecainide and were then switched from one group to the other (a cross-over trial). The researchers counted the number of premature ventricular contractions (PVCs) as a measure of arrhythmias. The patients on flecainide had fewer PVCs than the patients on placebo. When the flecainide patients were 'crossed over' to the placebo treatment, the PVCs increased again.

Suppression of arrhythmias in nine patients
(Each line represents one patient)

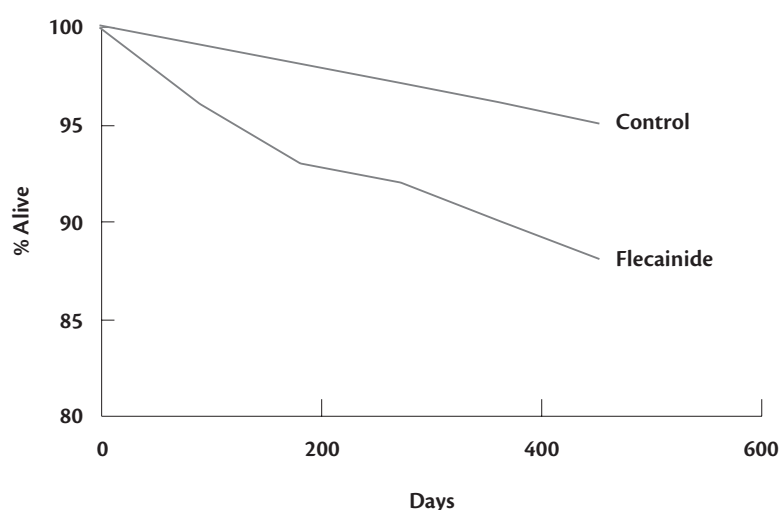


The conclusion was straightforward: flecainide reduces arrhythmias, arrhythmias cause heart attacks (the mechanism); therefore, people who have had heart attacks should be given flecainide. After the results were published, flecainide was approved by the United States Food and Drug Administration and became fairly standard treatment for heart attack in the United States (although it did not catch on in Europe or Australia).

Almost immediately after the first trials were complete, however, other researchers had started gathering information on the survival of the patients

(the outcome) instead of the PVC rate (the mechanism). This showed that over the 18 months following treatment, more than 10% of people who were given flecainide died, which was double the rate of deaths among a placebo group. In other words, despite a perfectly good mechanism for the usefulness of flecainide (it reduces arrhythmias), the drug was clearly toxic and, overall, did more harm than good.

Cardiac arrhythmia suppression trial



Unfortunately, because the initial studies had been widely published in medical texts, it was a long time before doctors caught up with the subsequent data showing poor outcomes, which did not attract as much attention. Meanwhile, by 1989, about 200,000 people were being treated with flecainide in the United States. Based on the trial evidence, this would have caused tens of thousands of additional heart attack deaths due to the use of flecainide. Although there was published information, doctors were systematically killing people with flecainide because they did not know about the good-quality outcome-based research.

What does the flecainide example tell us?

In the flecainide example, the initial research was widely disseminated because it was based on a traditional mechanistic approach to medicine, and because it offered a 'cure'. The subsequent outcomes research may not have been widely disseminated because it was counterintuitive and negative in terms of a potential treatment. Doctors continued to prescribe flecainide because they believed that it worked. They did not know that they needed to look for additional information.

Key issues

Overall, the flecainide story raises two important issues:

- We need a better way to find information, even when we do not know that we need it. In other words, up-to-date, good-quality research findings need to be available to all medical practitioners on a routine basis.
- The type of research is important. We must move away from a traditional mechanistic approach and look for empirical evidence of effectiveness using a clinically relevant outcome (such as survival, improved quality of life).

References:

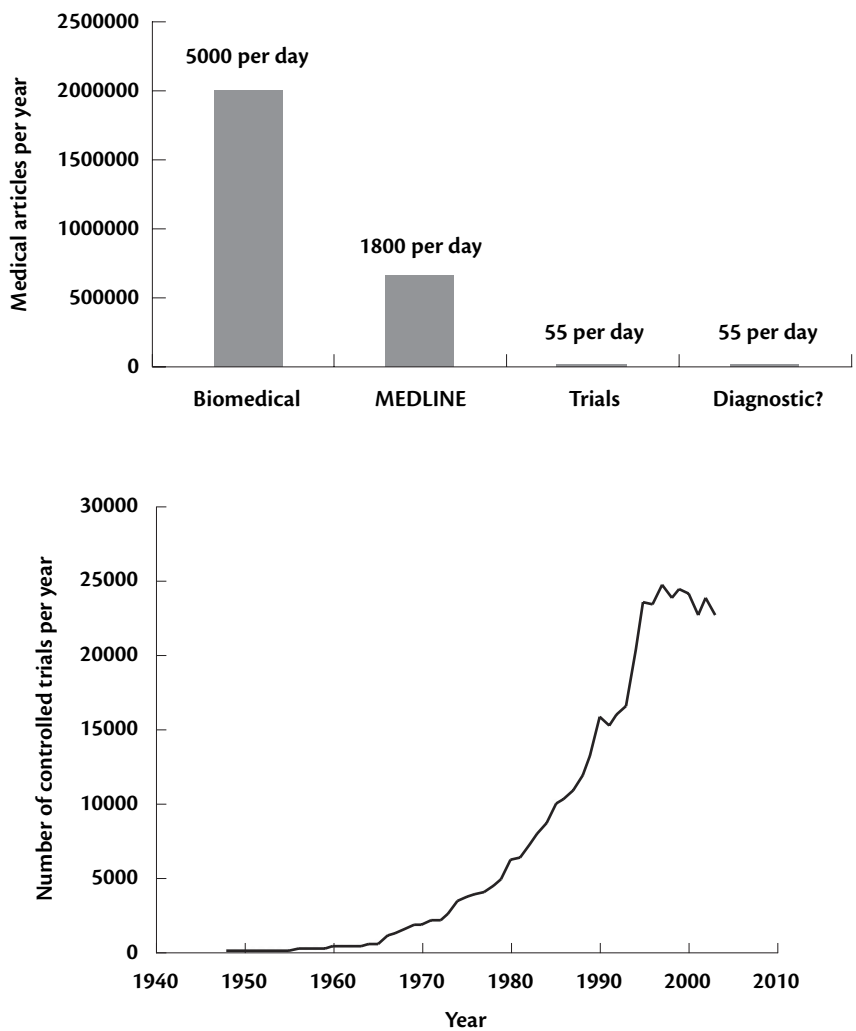
- Anderson JL, Stewart JR, Perry BA et al (1981). Oral flecainide acetate for the treatment of ventricular arrhythmias. *New England Journal of Medicine* 305:473–477.
- Echt DS, Liebson PR, Mitchell LB et al (1991). Mortality and morbidity in patients receiving ecainide, flecainide, or placebo. The Cardiac Arrhythmia Suppression Trial. *New England Journal of Medicine* 324:781–788.
- Moore TJ (1995). *Deadly Medicine*, Simon and Schuster, New York.

So much evidence, so little time

Doctors need to be linked to the medical research literature in a way that allows them to routinely obtain up-to-date, outcomes-based information. However, most medical practitioners, particularly GPs, are overloaded with information. Unsolicited information received though the mail alone can amount to kilograms per month and most of it ends up in the bin.

The total number of RCTs published has increased exponentially since the 1940s. A total of 20,000 trials are published each year (with more than 400,000 trials in total). In 2005, approximately 55 new trials were published every day. Therefore, to keep up to date with RCTs alone, a GP would have to read more than one study report every half hour, day and night. In addition to RCTs, in 2005, about 1800 papers were also indexed daily on MEDLINE from a total of probably 5000 journal articles published each day.

The amount of medical research



'Kill as few patients as possible'

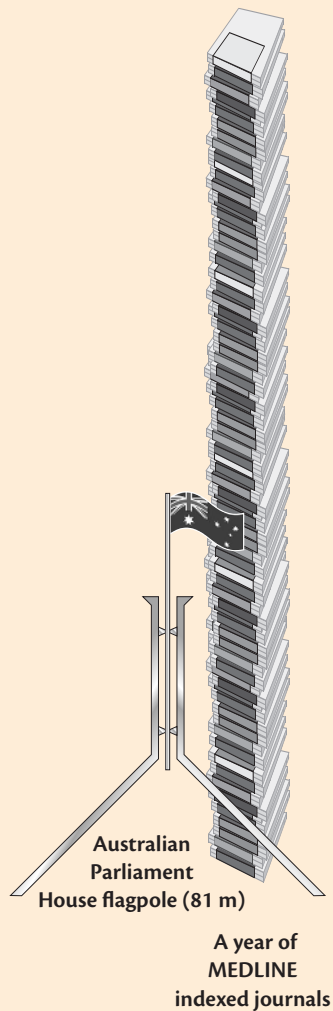
A book by physician and medical humorist Oscar London, called *Kill as Few Patients as Possible*, gives a set of 'rules' for clinical practice.

Rule 31 offers some advice on how to keep up to date with medical research:

'Review the world literature fortnightly'

Reference:

London O (1987). *Kill as Few Patients as Possible: And 56 Other Essays on How to Be the World's Best Doctor*, Edition 2, Ten Speed Press, Berkeley, California, USA.



At best, most GPs give a selective sample of the literature a cursory review, but very little is properly assessed and almost none influences what they do in practice.

Doctors may feel guilty, anxious or inadequate because of this (see box on the JASPA criteria), but it is not their fault — there is just too much information. There needs to be a better way.

JASPA criteria (journal-associated score of personal angst)

Can you answer these five simple questions:

- J** Are you ambivalent about renewing your **journal** subscriptions?
- A** Do you feel **anger** towards particular authors?
- S** Do you use journals to help you **sleep**?
- P** Are you surrounded by piles of **periodicals**?
- A** Do you feel **anxious** when another one comes through the letterbox?

Score (Yes = 1; No = 0):

- 0 anyone who scores zero is probably a liar!
- 1–3 normal range
- >3 sick, at risk for 'polythemia gravis' and related conditions

Reference:

Modified from 'Polythemia gravis: the downside of evidence-based medicine.' *British Medical Journal* (1995) 311:1666–1668.

How do doctors try to overcome information overload?

Write down some education activities that you and your organisation engage in and how much time you spend on them.

Rank your activities from most to least time.

Then for your top activities/sources, ask yourself the following questions:
Where do questions come from? How is the information selected? Is the information appraised (or do you appraise it)?

Your education activities	How much time do you spend on each?	Rank

You have probably included a selection of activities including attending lectures and conferences, reading journals and ‘throwaways’, textbooks and clinical practice guidelines, electronic searching, clinical attachments, and small-group learning.

You may also have included talking to colleagues or specialists. But everyone has the same problem of keeping up to date and your colleagues may be out of date or just plain wrong. If they have got the information from somewhere else, you need to know where they got it so that you can check how good it is. Textbooks are always about 5–10 years out of date.

Faced with all the alternatives, how do you actually choose what to do in your continuing education time? If you are honest, your choice probably depends on what you are already most interested in rather than what you don't know about.

Continuing medical education (CME) has been a mainstay of doctors' professional development but no-one has ever shown that it works. When doctors choose their courses, they choose things that they think they need to know about. But as we have seen, the most important information is what they don't know they need! In other words, we need a system to tell us we need to know something.

In a trial of CME, a random sample of GPs were asked to rank 18 selected conditions into either a 'high preference' set for which they wanted to receive CME, or a 'low preference set' for which they did not want further education. Physicians with similar rankings were paired and randomised to either:

- a control group, whose CME was postponed for 18 months; or
- an experimental group, who received CME at once for their high preference topics and were provided with training materials for their low preference topics, which they were asked to promise to study.

The outcomes were measured in terms of the quality of clinical care (QOC) provided by each of the physicians before and after CME (determined from clinical records). The results showed that although the knowledge of the physicians in the experimental group rose after their CME, the effects on QOC were disappointing with a similar (small) increase in QOC for both the experimental and control groups for their high preference conditions.

By contrast, for low preference conditions, QOC rose significantly for the experimental physicians but fell for the control group.

A review of didactic CME by Davis et al (1999) also concluded that formal sessions are not effective in changing physician performance.

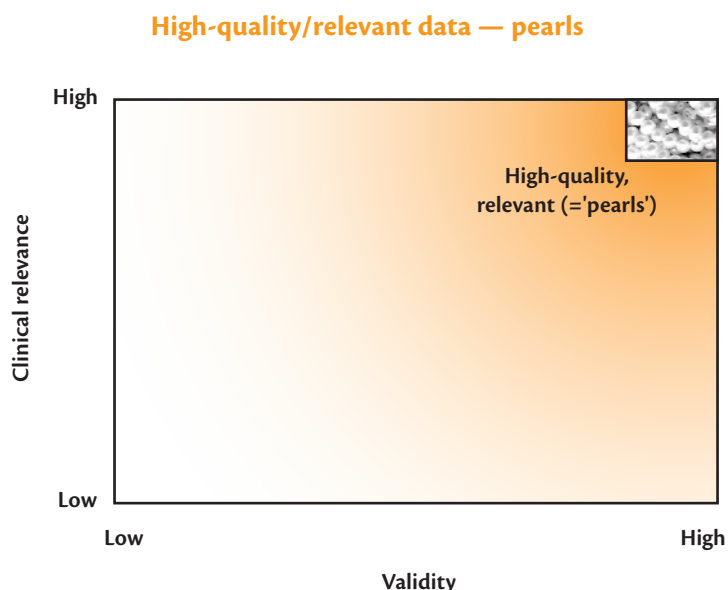
Conclusions of CME trial

1. If you want CME on a topic, you don't need it.
2. CME on a topic only works when you don't want it.
3. CME does not cause general improvements in the quality of care.

References:

- Sibley JC, Sackett DL, Neufeld V et al (1982). A randomised trial of continuing medical education. *New England Journal of Medicine* 306:511–515.
- Davis D, O'Brien MA, Freemantle N et al (1999). Impact of formal continuing medical education: do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? *JAMA* 282(9):867–874.

Overall, as we have seen, there is too much information but we still need it. The quality of most of this information is very poor: most published information is irrelevant and/or the methods are not good. Finding the high-quality evidence is like trying to sip pure water from a hose pumping dirty water, or looking for 'rare pearls'.



How many questions can doctors answer each day?

Many questions arise every day as a result of seeing people in clinical practice. Two papers have been published on this: one of interns in a hospital setting and one of GPs. In both cases, the researchers asked the doctors to note every time a question arose and what information they needed.

The study of 100 GPs showed that they each wrote down about 10 questions over a 2.5-day period. The GPs tried to find answers for about half of these. The most critical factor influencing which questions they followed up was how long they thought it would take to get an answer. If the doctor thought the answer would be available in less than a couple of minutes, they were prepared to look for it. If they thought it would take longer, they would not bother. Only two questions in the whole study (ie 2/1000) were followed up using a proper electronic search.

Doctors' information needs

Study 1 (interns)

- 64 residents in 2 hospitals were interviewed after 401 consultations
- They asked an average of 280 questions (2 questions for every 3 patients seen)
- At interview two weeks later, they had followed up an answer for only 80 questions (29%)
- Other questions were not pursued:
 - because of lack of time, or
 - because they forgot the question
- Sources of answers to questions were:
 - textbooks (31%)
 - articles (21%)
 - consultants (17%)

Study 2 (GPs)

- 103 GPs in Iowa collected questions over 2.5 days
- A total of 1101 questions were collected
- Pursued answers in 702 (64%)
- Spent less than 2 minutes pursuing an answer using readily available print and human resources
- Only 2 questions (0.2%) led to a formal literature search

References:

- Green ML, Ciampi MA and Ellis PJ (2000). Residents' medical information needs in clinic: are they being met? *American Journal of Medicine* 109:218–233.
- Ely JW, Osherooff JA, Ebell MH et al (1999). Analysis of questions asked by family doctors regarding patient care. *British Medical Journal* 319: 358–361.

Information gathering

There are two ways in which we all get information:

- just in case — in an ad hoc way from the vast amount of information that crosses our desk or arrives in our inbox daily ('push'), or
- just in time — in a targeted way, by seeking out information in response to a specific question ('pull').

'Push' new relevant and valid results

For EBP, the best sources for the 'push' approach to improving knowledge ('just-in-case' learning) are where the 'pearls' have already been selected from the rest of the lower-quality literature. Some good sources of information where this has been done include:

Evidence-Based Medicine — one of several 'evidence-based' journals that scan more than 100 journals for valid articles and then have clinicians around the world assess their clinical relevance and importance to clinical practice. The EBM journal is published every two months and has no original articles, but gives a condensed version of the original paper.

The journal is also available on the internet at:
<http://www.evidence-basedmedicine.com>

Clinical Evidence — a compendium of evidence-based literature searches. It is updated and published every 6 months as a book and CD. Information is arranged by specialty and just states the best existing evidence for an intervention. If there is no evidence, it says so. It does not include opinions or consensus guidelines. The editors decide what questions are relevant but the book is based on what doctors need. Doctors can look up information when they need it (the 'pull' method of obtaining information).

Clinical Evidence is available on the internet at:
<http://www.clinicalevidence.com>

'Pull' answers in less than 2 minutes

In this workbook, we will focus on learning how to formulate questions and 'pull' answers out of the literature in less than 2 minutes! This is sometimes called 'just-in-time' learning.

In the next few pages we will look at some case studies where EBP methods were used.

Balance your information: 'push' and 'pull'



'Push' (or 'just-in-case' learning) is when we receive information from a variety of sources and on a variety of topics and extract what we think we need for our practice.



'Pull' (or 'just-in-time' learning) is when we deliberately seek information to answer a specific question.