Getting a better grip on research: A simple system that works

A complex system that works is invariably found to have evolved from a simple system that works.

John Gaule. Church of England clergyman and author (1603/4-1687)

his is the third paper in a series of five describing the use of evidence to support decisions made in clinical practice.

GP curriculum box

Statement 2: The general practice consultation

Demonstrate understanding of the context in which the consultation happens by

• Negotiating a shared understanding of the problem and its management with the patient, so that he or she is empowered to look after his or her own health

Demonstrating familiarity with basic concepts in medical ethics such as confidentiality, consent, resource allocation and truth telling by

• Demonstrating an ability to reflect on how particular clinical decisions have been informed by these concepts

Statement 3.3: Clinical ethics and vales-based practice

• Demonstrate the knowledge skills and attitudes for effective communication in eliciting and understanding the values of patients, negotiating an acceptable course of action and justifying that course of action

Statement 3.5: Evidence-based practice

All GPs should be able to

- Ask the 'right questions'
- Find the appropriate literature from the widest available sources
- Apply rigour in appraising the literature
- Place the answers in the appropriate context

GPs should have the ability to

- Demonstrate that they base their treatment and referral decisions on best available evidence
- Apply rigour to scientific research to decide whether evidence is applicable to the primary care setting and appropriate to the individual
- Demonstrate sufficient knowledge of the breadth of scientific evidence in order to provide the best information for the individual and his or her illness
- Demonstrate the ability to communicate risks and benefits in a way that is meaningful to patients
- Demonstrate that they base their treatment and referral decisions on best available evidence
- Demonstrate understanding that evidence needs to be gathered from the most appropriate, rather than the most readily available source. GPs should be able to determine whether evidence presented to them is sufficient and rigorous enough to be analysed in the context of a patient.

© The Author 2009. Published by Oxford University Press on behalf of the RCGP. All rights reserved. For permissions please e-mail: journals.permissions@oxfordjournals.org In the 21st century, health care clinicians, managers and patients expect to see the findings of research incorporated into clinical practice, taking into account the needs and wishes of individual patients. In this series, we are examining why that happens—and often does not happen—and what clinicians and managers can do to improve the use of evidence in consultations.

Papers 1 and 2 are based on comprehensive literature searches undertaken as part of a programme that started in 2002 by the National Prescribing Centre. These two papers outlined the background to the science of evidence-based medicine and considered the extent to which it informs practice. This paper, Paper 3 describes the tools-the underrecognized but evidence-based, pragmatic approaches that can enable high-quality research findings to be identified, considered and where appropriate incorporated more often and with less difficulty into routine clinical practice. This paper also contains details of materials for further study for generalists and especially GP registrars. Paper 4 is based on a published systematic review. It describes the characteristics and actions associated with more successful adoption of change and the implications for health care organizations such as hospital trusts, primary care trusts and practicebased commissioning groups and their equivalents in other health systems. The final paper describes a clinician's progress on a journey to meet the real-world challenges of using evidence in medical practice, using a narrative approach.

Evidence, decisions and organisations

In the first two papers in this series, we described some of the difficulties of using evidence-based medicine (EBM) in the clinical setting, so that it can fulfil its potential of supporting optimal practice. The EBM movement came about in part because it had become clear that interventions that were likely to be beneficial were not being taken into clinical practice and those which were of low value or even harmful persisted. There was also a growing awareness of the limitations of many of the sources of advice and guidance in which practicing clinicians placed their trust. Yet, despite two decades of work still these problems persist, and we gave some examples in the first paper in this series. NPCi, a virtual learning environment (www. npci.org.uk), contains data-focussed commentaries for more than 30 common therapeutic topics. These compare recent prescribing data with the current evidence base; each one highlights that important evidence is not routinely reflected in prescribing practice. What are the obstacles that prevent the products of high-quality research being used in practice?

The first we have identified is the failure to recognize the importance of the human nature of decision making. *Homo sapiens* cannot all think like Albert Einstein, store as much information as IBM's Big Blue computer and exercise the willpower of Mahatma Gandhi (Thaler and Sunstein, 2008). Humans make decisions based on their own mind map and construct that pattern largely from brief reading and talking

to other people. Pattern recognition or System 1 processing is the normal approach to decision making. A System 2 approach involving detailed analysis of all the evidence and the available options may be intellectually and emotionally more attractive as a basis for decision making. But it is unrealistic in terms of the time available to make most decisions in health care and, in addition, it fails to chime with the way humans naturally interact and decide (Gigerenzer *et al.*, 2008). We described these issues in more detail in Paper 2.

The second difficulty is that the skills required to practise EBM as it is currently often taught also do not chime with natural decision making and the skills that do—Information Mastery and communicating risks and benefits to patients in terms they can understand—are less well recognized and taught. It is this area we will expand on in this paper; these skills are especially relevant to general practitioners in training.

Finally, the third difficulty is that there are both individual behavioural and organizational dimensions of change. This means that introducing an evidence-based change may still fail or result in incomplete adoption even if the first and second difficulties are overcome. Implementing and sustaining innovations in service delivery and organization are like raising a child—it is an art as much as a science, and the principles of complexity theory apply (Plsek and Greenhalgh 2001; Plsek, 2003). Although there are some evidence-based principles, the success of any change project remains (and always will remain) largely unpredictable, depending as it does on judicious appraisal of the local situation and the continuous evaluation of emerging data. We cover this in detail in Paper 4 of this series.

Information mastery

In many people's minds, EBM is about a cycle in which individual clinicians formulate a clinical question, search for the best available research evidence, employ critical appraisal skills to evaluate it and use that which is most valid to guide practice and then perform a check to ensure that implementation in practice of the new data has indeed been successful. See Fig. 1 (Sackett et al., 1991). This is System 2 processing. If you ask doctors, they say they need information in order to be able to manage a clinical problem about once a week and, if that were truly the extent of their information need, activating this cycle once a week might be a practical proposition. However, if you debrief doctors more intensively, they raise about two questions for every three patients (Covell 1985; Ely 1999). Answering that volume of guestions with the traditional five-step EBM process is incompatible with the pace of clinical practice, and it is not surprising that answers to most questions are not immediately pursued. When they are, an average of less than 2 minutes is spent pursuing an answer, and readily available printed material or colleagues are the usual sources of information accessed.

Searching computerized databases of published research (e.g. Medline) and critical appraisal of the identified research are now widely taught in undergraduate and postgraduate

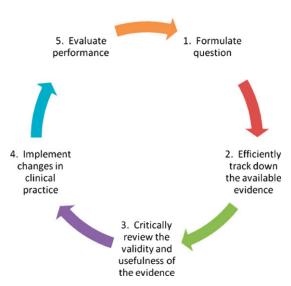


Figure 1. The five steps of the traditional approach to evidencebased practice. This graphic encapsulates the key approach clinicians are encouraged to use when practising traditional EBM. The clinical question requiring an answer is created—preferably with a definition of the patients characteristics—for example, over 65 years or teenage boys; the intervention and control or comparison treatments are defined and finally the outcomes were are interested in. The acronym PICO for patients intervention control and outcomes is used. The clinician then tracks down the best available evidence, critically appraises that evidence and implements changess in his or her clinical practice. Finally, there is an evaluation of performance to check if changes in practice are required that they have been implemented. We have been following this model for more than 20 years-teaching Medline searching and critical appraisal are key features of most undergraduate and postgraduate EBM courses.

Sackett, D.L., Haynes, R.B., Tugwell, P., Guyatt, G. Clinical epidemiology: a basic science for clinical medicine. 2nd edition. Lippincott Williams and Wilkins (1991).

courses for health care professionals. But the skills are not intuitive to many biological scientists, and like any skills, they atrophy rapidly with disuse. And there is a massive amount of new information published each week. In 2002, it was estimated that 7287 articles potentially relevant to primary care are published each month. Physicians trained in critical appraisal would take an estimated 628 hours per month to evaluate the articles (Alper *et al.*, 2004).

But worse, if a clinician reads a journal or searches and finds a paper relevant to their practice, how do they know if that one paper represents 'the truth' or whether it is an aberrant individual piece of research and that there are half a dozen other papers all showing they should do the opposite of what it indicates? Very rarely will one paper tell the whole story by setting its results in the context of the rest of the evidence (Clarke and Chalmers, 1998; Clarke *et al.*, 2002). And that volume of material is before we include guidelines, local clinical initiatives and important non-clinical information such as new contracts and policies from the Department of Health. So, hoping to keep up-to-date solely by reading research in journals is an unattainable goal.

System 1 processing dominates human decision making, and no one should feel guilty about using it when making decisions

in health care. System 2 processing is difficult and time consuming. Many health professionals feel that they ought to practice system 2 EBM, but realizing they have neither the time nor the skills to apply System 2 processing, they revert to System 1 processing—relying on brief and unstructured reading, professional networks and the advice of experts. System 1 approaches can be superior to System 2 in some circumstances (Gigerenzer *et al.*, 2008), but the gaps between evidence and practice we described in Paper 1 indicate that this is far from the case in many areas of health care. How can we reconcile that on the one hand System 1 processing is the way we will continue to acquire and use information to make decisions because we are human and on the other that we need to base our practice on the best available evidence?

Foraging, hunting and hot-synching

The first Information Mastery paper was published in 1994 (Slawson *et al.*, 1994). Originally, there were two components to Information Mastery—hunting and foraging. Patients and their health care practitioners rate being up to date with recently published research very highly. In order to meet this need a 'foraging' service is required—a service that surveys the literature (and other sources of information) and alerts health professionals to that new information which is both important and likely to be useful to them. For medicines, the National Prescribing Centre's Current Awareness Bulletin (www.npc.co.uk) together with a blog service that appraises and sets two or three key papers each week in the context of the rest of the evidence base (www.npci.org.uk) may meet those requirements.

In addition to foraging, clinicians need an approach to finding information when it is needed, that is when they are 'stuck'. In Information Mastery language, this is called 'hunting'; an approach which enables health professionals to find useful information rapidly when they need it and also enables them to know that they have found the best answer not just an answer.

There is a third element to add to these initial two-'hotsynching'. It is unrealistic to expect clinicians to be up to date with conditions they rarely see-the volume of material is too large to handle and by the time they see a condition, it is likely they will have forgotten what they learnt—or even worse remember what they learned incorrectly. So it is unreasonable to expect a GP to know without checking how to manage hypertrophic cardiomyopathy, but entirely reasonable to expect this of a tertiary centre cardiologist. Similarly, it is unreasonable to expect a cardiologist to be up to date in managing otitis media, but you would expect a GP to be on the button. The information which comprises being 'on the button' is unconsciously and automatically combined into a mind map which is activated, again automatically, most of the time for both diagnosis and management. The data which informs the mind map comes from brief reading and talking to other people—so called 'trusted sources' (Gabbay and le May, 2004). The important conclusion is that these trusted sources should

be informed by the least biased, highest quality forms of evidence. Information coming directly from other human beings requires careful assessment to reduce bias to a minimum.

So what do we mean by hot-synching? The evidence is that busy NHS professionals spend up to an hour most weeks on continuing professional development (CPD). Many will not spend longer than an hour on CPD—they do not have the time. But it is not unreasonable to expect generalist clinicians to be right up to date with what actually is the best evidence for the management of asthma, diabetes, depression, common infections and so on—not what they think is the evidence.

So just as we might 'hot-synch' our Blackberry with our emails, appointments and contacts—or our iPod with our music playlists—we can do the same for the evidence we need to know to be able to manage the conditions we see commonly. Instead of random reading or attending teaching sessions with a generic curriculum, this 'golden hour' can be spent reviewing summaries of evidence produced by trusted, public sector organizations covering just the conditions the individual practitioner commonly sees. Hot-synching is realistic for busy clinicians and fits with the human dimensions of information acquisition and decision making. It enables them to continue to use the rapid and efficient System 1 processing in the health care setting because the information in their mindline is based on the best available evidence.

So what information is likely to be the best clinicians can find, whether foraging, hot-synching or hunting? The answer is expressed in the usefulness equation (see Box 1). The usefulness of a piece of information is directly proportional to its relevance and its validity and inversely proportional to the amount of work we have to do to find it. A piece of information, which is both highly relevant and highly valid and which we find easily, is likely to be extremely useful. That same piece of information would be less useful if we have to do a lot of work and hunting to find it. Equally, a piece of information which is readily available but is not very relevant and not very valid is also not very useful. In fact, it might be positively unhelpful.

Whether foraging, hot-synching or hunting, the information pyramid applies (see Fig. 2). A key feature of this approach to using high-quality information to inform practice is that

Box 1. Usefulness equation

Usefulness of a piece of clinical information=

work required^c

a. Examples of information which may not be relevant to front line care include that which is upstream to clinical decisions being made, for example animal or *in vitro* studies or where study populations and/or settings do not reflect question type, practice population and settings.

1

- b. The information may not be valid due to, for example, poor study design, bias and confounding, invalid measurements and insufficient statistical power.
- c. This is the work required to find the information and by extension, the work required to establish its relevance and validity.

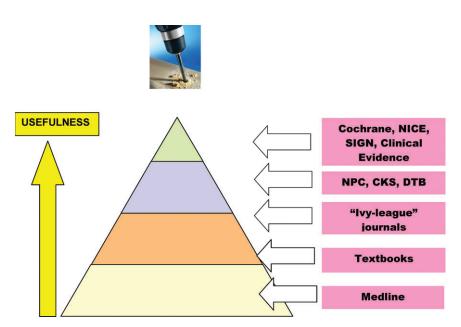


Figure 2. Slawson, D.C., Shaughnessy, A.F. The Information Mastery Pyramid.

someone else other than busy front line clinicians - preferably a trusted public sector organization - does the selection and critical appraisal. The most useful information sources are at the top of the pyramid. Medline and Google Scholar and similar sources at the bottom will provide lots of information, but the usefulness is quite low because it takes a lot of work to filter out the relevant and valid information. Textbooks are easier to access, but the validity may not be so high: they might present information selectively and the information may be out of date. Resources such as the Cochrane Library, Clinical Evidence, clinical knowledge summaries (formerly Prodigy) and similar synthesized sources of information, produced by trusted and trustworthy providers of information in a timely and up to date manner, are most useful. We need a better way of drilling through that pyramid and finding the information we need. Collations of information sources exist and they can help clinicians answer clinical questions (Alper et al., 2001), but none of them are a complete solution when hunting. Hunting is the most difficult of these three approaches and the one clinicians still find most difficult to use in practice despite having previous teaching in searching and critical appraisal. The paradox is that most of the evidence-based movement has concentrated resources almost entirely on teaching the most difficult of these three approaches, rather than a more balanced skill set to enable foraging and hot-synching, as well as hunting.

Relevance before validity

Despite having a foraging service and using the hot-synching approach to CPD, clinicians will find themselves hunting. And if they do not find an answer in the higher levels of the information pyramid, they will find themselves assessing individual studies. What is the fast and frugal approach here? A few simple rules can help. Firstly, screening a piece of information for relevance can be done quickly and easily and can be done before assessing validity. Despite the validity limitations of data in some abstracts for relevance, we probably need to only look at the title and skim the abstract of a paper. The FOCC mnemonic can be helpful for the majority of health professionals involved in delivery of patient care (see Box 2). If the information is not relevant, we need to go no further. We might choose to read it out of general interest, but it should not have a high priority.

If evidence passes the relevance test, screening for validity is more difficult and requires some expertise and also time and frequent practice. There are numerous options for practitioners to acquire and develop these basic skills (see Box 3). However, it is reasonably easy to spot the common fatal flaws in randomized controlled trials. These are simple rules of thumb and further reading is advised.

Box 2. Screening for relevance: the FOCC mnemonic

Feasible: the intervention is feasible in our clinical practice.

Outcomes: the study reports patient-orientated outcomes (POOs).

Common: the condition or clinical situation is common in our clinical practice.

Change: a change in practice might be required if this information is valid and is in keeping with the rest of the evidence base.

A POO is an outcome which is important to patients. For example, a reduction in the rate of heart attacks and strokes, a reduction in the development of diabetic foot ulcers or a reduction in night time wakenings in people with asthma. This is in contrast to disease-orientated outcomes: these do not directly tell us if the intervention helps patients to live longer or live better. They are surrogate markers and are often laboratory tests. Examples include reductions in blood pressure (compared with reductions in clinical cardiovascular end points such as heart attack or stroke), HbA_{1c} in type 2 diabetes and peak expiratory flow volume in asthma. These may be useful surrogate measures, which indicate a benefit to patients, but equally they may not and indeed sometimes can mislead (NPC, 2005).

Box 3. EBM further reading and critical appraisal resources

Centre for Evidence-based Medicine, Oxford, Accessed via www.cebm.net

Critical Appraisal Skills Programme. Accessed via www.phru.nhs.uk/Pages/PHD/CASP.htm [date last accessed 17.03.2009]

Greenhalgh, T. *How to read a paper: the basics of evidence-based medicine* (2006) 3rd edition. Oxford: Blackwell ISBN-13: 978-1-4051-3976-2.

MeRec Briefing (2004). Using evidence to guide practice. Accessed via www.npc.co.uk/MeReC_Briefings/2004/ briefing_no_30.pdf and www.npc.co.uk/MeReC_Briefings/2004/briefing_no_30_supplement.pdf [date last accessed 17.03.2009]

National Prescribing Centre. Information Mastery Skills. Accessed via www.npci.org.uk

Is it a high level of evidence?

Wherever possible, we should use evidence based on a randomized controlled trial or a systematic review and meta analysis of randomized controlled trials (see Box 4).

Box 4. The hierarchy of evidence

Well conducted meta-analysis of several, similar, large, well-designed randomized controlled trials (RCTs)

- Large well-designed randomized control trials (RCTs)
- Meta-analysis of smaller RCTs
- Case control and cohort studies
- Case reports and case series
- Consensus from expert panels
- I think

Source: Greenhalgh T. *How to read a paper: the basics of evidence-based medicine* (2006). 3rd edition. Blackwell ISBN-13: 978-1-4051-3976-2.

Is it statistically significant?

It is conventionally determined that if a result could occur by chance less than one time in 20 (or 5 in 100, 0.05), then we accept that result. So, if the P value is very small, then it is likely that the result we are seeing is not due to chance. But the closer it gets to 0.05, the brows start to furrow and, certainly, above 0.05 that single piece of research is not useful to the busy clinician.

Is it clinically significant?

It is possible for a study to produce a highly statistically significant result which has very limited clinical value. For example, the time taken for someone with osteoarthritis to walk 50 yards is reduced with an non-steroidal anti-inflammatory drug instead of paracetamol (P < 0.001). However, the actual clinical benefit was 0.7 seconds—statistically significant but clinically insignificant (Wegman *et al.*, 2004).

Do you understand what the numbers tell you?

There will be a key expression of difference in the results relative risk, relative risk reduction, absolute risk reduction, odds ratio and hazard ratios. There is no shortcut to developing the skill required to understand what those terms mean. (see Box 5)

Were there enough people in the study for long enough?

It is possible to obtain false-positive or false-negative results with a small randomized controlled trial undertaken for a short period. How many people are required for how long is determined statistically by an approach termed a power calculation. It is not necessary to understand how to calculate a power calculation to know that it is important. Two rules of thumb: if you do not see a power calculation be concerned and if the number of people in the study is fewer than 300 (certainly less than 200), then there might be some concerns about the validity of the result.

Was the allocation concealed?

The importance of allocation concealment has only recently been recognized. Again, it is not necessary to understand the details of allocation concealment to know that it is important, but in essence, the study investigators should not know to which group the potential subject would be assigned before enrolling them. It is not the same as blinding. Trials with unconcealed allocation consistently overestimate benefit by about 40%. Where allocation was not concealed investigators in trials have admitted 'altering enrolment or allocations ... after decoding future assignments, which were ... visible through translucent envelopes held up to bright lights, opening, unsealed assignment envelopes, sensing the differential weight of envelopes and opening unnumbered envelopes until they found a desired treatment' (Schulz *et al.*, 1995; Schulz and Grimes, 2002).

Rather than just trying to keep critical appraisal skills honed, with limited time in which to use them, it is more important that health professionals appreciate 'how' they use information to make decisions, use a foraging service and a hot-synching approach and also hunt for information when they need to find an answer to a clinical question. The main skill required to get research into practice as part of an evidence-based approach then becomes understanding what a summary of evidence is saying—relative risk, NNT, *P* values, confidence intervals, etc. within the framework of the hierarchy of evidence. This is in contrast to the traditional EBM approach focussed on searching Medline and critical appraisal.

Innumeracy and statistical illiteracy

Poor numeracy impairs understanding and communication of health risks and benefits. For example, 46% of New England veterans were unable to convert 1% to 10 in 1000, 80% were unable to convert 1 in 1000 to 0.1% and 46% were unable to correctly estimate how many times a coin would come up heads in 1000 flips. Just 6% of women answering one of these questions correctly could correctly interpret the benefit of mammography after being presented with standard risk reduction information, whereas 40% of those answering all three questions correctly could accurately interpret the data (Schwartz et al., 1997). In our extensive experience of teaching Information Mastery in workshops, a small percentage of health care professionals who attend, perhaps 5–10%, need some remedial work on converting simple fractions to percentages and in recognizing that a relative risk of 0.99 equates to a reduction of 0.01, a hundredth or 1% in relative terms.

Collective statistical illiteracy refers to the widespread inability to understand the meaning of numbers (Gigerenzer, 2008). The result is that few people are aware that if 1000 people at 20% cardiovascular risk take a statin, then the number of people who avoid having a cardiovascular event per year is just five or that the statement that mammography screening reduces the risk of dying from breast cancer by 25% means that one less woman out of 1000 screened will die of the disease. This often occurs unintentionally as a

Box 5. Expressions of difference used in studies

In a randomized controlled trial lasting 1 year, 40% of people taking the control treatment died. Only 30% of people taking the experimental treatment died over the same period. How do we describe the difference between the treatments?

The difference is 10%. (Control rate – experimental rate = 40% – 30% = 10%)

This is the 'absolute risk reduction' (ARR), also sometimes called the risk difference.

'The relative risk reduction' (RRR) is calculated by dividing the difference between the control and experimental rate by the control rate ((control rate - experimental rate) ÷ control rate).'

Control rate - experimental rate/control rate;

40% - 30%/40% = 10%/40% = 1/4 = 25%.

This is the **'relative risk reduction' (RRR)**. RRR can sound impressive, but only sometimes is. If you could take a medicine which gave you a 25% reduction in your chance of being struck by lightening this means you had a very small chance of being struck by lightening and that is still now the case. Millions of people would have to take that medicine for one person to avoid a lightening strike; no doubt, side effects would affect some of them and then there would be the cost and inconvenience of medicine taking. Absolute difference is required as well as relative in order to assess the usefulness of a medicine.

Absolute difference can also be expressed as a **'number needed to treat' (NNT)**—the number of people who need to take the treatment rather than the control for one to benefit. The sum to calculate this is

NNT=100/ARR(%):

In this case, 100/10=10.

For every 10 people who takes the new treatment for one year, one benefits who would not have done had they all taken control.

Sometimes the difference is expressed as a **'relative risk'** (also sometimes termed risk ratio). This is a simple sum: experimental rate \div control rate. So in this example, it is: $30 \div 40 = 0.75$.

Note that no difference in rates between experimental and control treatments would have given a relative risk of 1.0. So a reduction from 1.0 to 0.75 is 0.25 which can be expressed as 25 hundredths or 25% (the RRR). It is easy to calculate the RRR from the relative risk in this way.

Odds are sometimes the only way to describe differences, rather than rates. And the way to compare odds is in an **'odds ratio'**. We would not expect to see an odds ratio as the expression of difference in a randomized controlled trial written up appropriately. But the odds ratio would be appropriate and used in a case control study, for example.

In our example, the odds of dying with the experimental treatment is 30:70, and the odds of dying with control treatment is 40:60; 30÷70 divided by 40÷60 gives an odds ratio of 0.65.

Note that the odds ratio is smaller and therefore potentially more impressive than the risk ratio (relative risk). What we have done in the odds ratio is compare the number of people having an event with those not having an event who have the treatment. What we have done in the risk ratio (relative risk) is compare the number of people having an event with the total number of people getting that treatment. So if an event is reasonably common, the odds ratio will be smaller than the risk ratio. For rare events, they will be the same or nearly the same because the numerator will be very small, and whatever the denominator is the result of the sum will be very similar or identical.

And finally, **'hazard ratio'**. This expression of difference cannot be calculated from event rates. It takes into account that during the study, events may not occur at the same rate over time or at the same rate in either group. If there were 100 people taking control treatment, the first event in that group would have an impact of 1/100 on the population, the second event 1/99 and so by the time there were 90 events, the 91st would have an impact of 1/10. The hazard ratio is calculated by a computer programme using the time and number of events as they occurred during the study. It should be thought of as broadly equivalent to relative risk, although the hazard ratio may be smaller than relative risk, again providing to the unwary an impression of a more impressive benefit than some other expressions of difference.

result of the inappropriate and non-transparent framing of information but also can be the result of intentional efforts to manipulate or persuade.

Statistical literacy—or more simply, understanding what the numbers in a summary of evidence are saying—is a necessary requirement for 21st century health care. The skill was not required when the doctor—patient relationship was dominated by the health care professional's paternalism and the patient's complete trust in authority. It was not required when physicians were expected to determine the causes and simply advise on therapy, rather than advise as accurately and in as unbiased a way as is possible on the risks and benefits of different management options. And, it was not required when patients and doctors believed in an illusion of causation and certainty. None of those circumstances now applies.

Without understanding the numbers involved, professionals and the public are susceptible to manipulations of their concerns and hopes. In turn, this undermines the goals of informed consent and shared decision making.

Communicating risks and benefits

A patient recently discharged from hospital brings to his general practitioner his list of medication and, in particular, queries the benefits of adding clopidogrel to his previous antiplatelet agent, aspirin. Helpfully, your patient has found you the key trial and has highlighted the key results sentence:

The primary outcome—a composite of death from CV causes, nonfatal MI or stroke—occurred in 9.3% of the patients in the clopidogrel [plus aspirin] group and 11.4% of the patients in the [aspirin plus] placebo group (RR 0.80, 95% CI 0.72 to 0.90; P < 0.001) (CURE, 2001).

He asks you to explain the benefits he will get from taking this extra tablet. Can you translate these data into terms he can understand?

Using the simple sums to decode the expressions of difference, we can quickly conclude that the absolute difference is 2.1%, the RRR is 20% and the NNT is 49; the patient pointing out that the average duration of treatment in this trial was 9 months. But what evidence is there about how to communicate risks and benefits optimally?

The basic principles are straightforward (Paling, 2003). Firstly, we should communicate the trade off between benefits. We should avoid purely descriptive terms of risk, for example 'low risk' and use natural frequencies (not percentages) and a consistent denominator, for example 1 in 100, 5 in 100; not 1 in 100, 1 in 20. Then, we should use absolute (not relative) numbers and finally use visual aids and probabilities.

So, we might say something like 'If there were 100 people like you and we just gave them aspirin for nine months then 89 people would be fine. Unfortunately 11 of them would have a heart attack or a stroke or die from one of those. However, if we give the 100 people aspirin plus clopidogrel 91 people now are fine at nine months, and nine have heart attack or a stroke or die from one of those. We can't predict at this stage whether you will be one of the 89 who would be fine on just aspirin, one of the two who is prevented from having a heart attack or a stroke or die from one of those, or whether you would be one of the nine who unfortunately has a heart attack or a stroke or die from one of those despite taking aspirin and clopidogrel.' (see Fig. 3).

If that was not too much information, we could go on and show similar visual aids demonstrating the harms. In this case, that would be three people out of 100 having a major bleed on aspirin and four people having a major bleed on dual therapy.

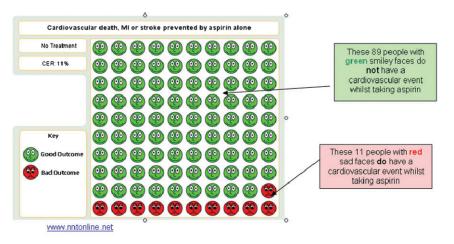
Visual aids of this kind are relatively new and the science continues to develop. There are some caveats, notably about the baseline risk of the individual patient compared to the population in the study. A patient at higher risk than those in the study might have a greater chance of benefiting than indicated by the study population average and someone at lower baseline risk less chance of benefiting, with the risks of harm probably being unchanged in either case. Some adjustment according to the characteristics of the individual when compared to the average of the population in the study is probably required on some occasions, but necessarily will be an estimate.

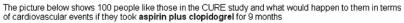
The Cochrane review of patient decision aids found that, compared to usual care, decision aids perform better in terms of greater knowledge, more realistic expectations, lower decisional conflict related to feeling informed, an increased proportion of people active in decision making and a reduced post-intervention. When simpler aids were compared to more detailed decision aids, the relative improvement was significant in knowledge, more realistic expectations and greater agreement between values and choice. Decision aids appeared to do no better than the comparators in affecting satisfaction with decision making, anxiety and health outcomes, and decision aids had a variable effect on which healthcare options were selected (O'Connor, 2003).

If now you have a fairer, more accurate and more balanced mind map of the benefits and risks of aspirin and clopidogrel compared to aspirin in acute coronary syndrome ... then you may agree with us that decision aids are worth exploring for the common conditions presenting to you (see, e.g. the patient decision aids in www.npci.org.uk). But do not expect them to fix a dysfunctional consultation, and the new skills brings new challenges—it is necessary to find out whether the patient wants help to make the decision, wants you to make the decision or wants you to provide the information, so that they can make the decision themselves.

Becoming an Information Master

Setting out to work in this new paradigm is not easy. Some of this approach can seem daunting and complex, so we





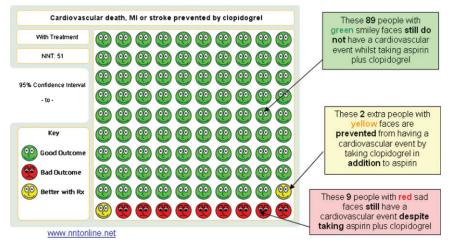


Figure 3. Decision aid to explain the results of Cure Study Investigators. Effects of clopidogrel in addition to aspirin in patients with acute coronary syndromes without S-T segment elevation.

New England Journal of Medicine (2001); 345:494-502. See www.npci.org.uk.

offer three simple steps to guide aspiring information masters.

Orientation

An element of 'buying in' to the EBM approach is initially required. There is a need to accept that 'the judicious use of the best available evidence, moderated by patient circumstances and preferences, to guide our practice to improve the quality of clinical judgements and facilitate effective healthcare' is preferable to alternative approaches (Sackett *et al.*, 1991). Intimately associated with this approach is the acceptance that using the hierarchy of information can make patient care more logical, objective and more cost-effective, but only if patient circumstances and preferences are fully taken into account.

Essential to the orientation is some understanding of how humans make decisions. Understanding our own responses to data, especially new data, and recognizing the reasons why others react to new data in different ways from ourselves is a constant challenge, surprise and occasional delight.

Skills

The hierarchy of the information pyramid, the importance of screening evidence for relevance first, then validity and basic numeracy ought not to seriously challenge an aspiring information master. But some work is required to become familiar and confident with the expressions of difference and simple statistical terms.

Information Mastery in action

Then, the fun starts. Foraging, hot-synching and hunting can be combined with exploring the use of patient decision aids, again all in the context of the needs and preferences of individual patients.

The next paper in this series will discuss the challenges of getting research into practice at an organizational level.

Key points

- Humans make decisions based on their own mind map and construct that pattern largely from brief reading and talking to other people. Pattern recognition or System 1 processing is the normal approach to decision making.
- If you ask doctors, they say they need information in order to be able to manage a clinical problem about once a week, and if that were truly the extent of their information need, activating this cycle once a week might be a practical proposition. However, if you debrief doctors more intensively, they raise about two questions for every three patients.
- Patients and their health care practitioners rate being up to date with recently published research very highly. In order to meet this need, a foraging service is required—a service that surveys the literature (and other sources of information) and alerts health professionals to that new information which is both important and likely to be useful to them.
- Clinicians need an approach to finding information when it is needed, that is when they are 'stuck'. In Information Mastery language, this is called hunting; an approach which enables health professionals to find useful information rapidly when they need it, and also enables them to know that they have found the best answer, not just an answer.
- Instead of random reading or attending teaching sessions with a generic curriculum, the hour per week of professional development can be spent hotsynching—reviewing summaries of evidence produced by trusted, public sector organizations covering just the conditions the individual practitioner commonly sees.
- Statistical literacy—or more simply, understanding what the numbers in a summary of evidence are saying—is a necessary requirement for 21st century health care.
- Without understanding the numbers involved, professionals and the public are susceptible to manipulations of their concerns and hopes. In turn, this undermines the goals of informed consent and shared decision making.

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