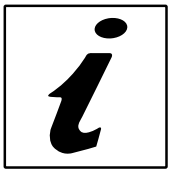

Information in practice

Communicating the risk reduction achieved by cholesterol reducing drugs

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"When the facts change, I change my mind. What do you do?" asked Professor Michael Oliver at a presentation held in Stockholm on 6 June 1996. This is what readers of the *New England Journal of Medicine* were told in an advertisement for the cholesterol lowering drug simvastatin during the winter of 1996-7. Oliver's statement is accompanied in the advertisement by the following facts: "In post MI and angina patients with cholesterol levels in the range of 5.5 to 8.0 mmol/l (212-309 mg/dl). Proven to reduce the risk of total mortality by 30% (P = 0.0003),[1] coronary mortality by 42% (P = 0.00001).[2]" These facts are followed by another statement from Oliver et al: "Lower patients' cholesterol now."[3] This second statement represents Oliver's change of mind since he, in 1992, stated his "Doubts about preventing coronary heart disease: multiple interventions in middle aged men may do more harm than good,"[4] which contributed to the controversy over the importance of lowering serum cholesterol concentrations.[5]

In a similar advertisement, readers of the *Lancet* have been informed of the same facts, but unaccompanied by Professor Oliver's statements. Instead, these readers are provided with more facts: "Projected 6-year benefits in 1000 patients with coronary heart disease (CHD). 35 lives saved, 67 MIs prevented, 59 procedures avoided."

At first sight, a negative response to Oliver's rhetorical question may seem perverse or prejudiced. On second thoughts, given its rhetorical nature and considering that it is being used in a commercial presentation, you might suspect that there is something more to it. Indeed there is, and the aim of this article is to shed some light on the presentation of facts from clinical trials like the Scandinavian simvastatin survival study (4S) and the West of Scotland coronary prevention study (WOSCOPS).[6]

Facts from WOSCOPS were presented in a press release on 15 November 1995: "People with high cholesterol can rapidly reduce their risk of having a first-time heart attack by 31 per cent and their risk of death by 22 per cent, by taking a widely prescribed drug called pravastatin sodium. This is the conclusion of a landmark study presented today at the annual meeting of the American Heart Association. The results appear in the 16th November edition of the *New England Journal of Medicine*" (available on URL: http://www.gla.uk/Acad/PathBio/press_release.html).

Summary points

Perceptions of risks and benefits, by both lay people and doctors, are strongly influenced by the way data are presented

In the case of possible benefits of cholesterol lowering drugs on the risk of coronary heart disease, the difference between reporting relative or absolute risk reductions can greatly influence this perception

Accordingly, data from randomised trials of such drugs can be presented in different ways

Doctors should be aware of these perception biases when studying information about drug effectiveness and when making decisions on treatment and communicating with patients

In communications with individual patients, doctors should also acknowledge that effectiveness at the group level may mean uncertainty at the individual level

Before moving on, the reader would do well to note that none of the above statements contains anything that is not true. There are, however, other facts, just as true, that may give a somewhat different impression.

When the stating of the facts change, you change your mind

Both the advertisements and the press release are based on relative risk estimates. This is an estimate that has been shown repeatedly to give a more favourable impression of the effectiveness of a drug than absolute risk estimates.[7–13] These latter estimates can be found in the original articles, but, unfortunately, these are rarely read by the physicians prescribing the drugs. Table 1 gives some examples of possible combinations of absolute and relative risk reductions and shows that the relative risk reduction may remain stable across a set of various trial outcomes. It also remains true in all these examples that the risk in the placebo group is twice that in the treatment group. The real impact of the

treatment, however, can only be seen by also reviewing the absolute risk reductions.

Table 2 shows some absolute risk estimates from the 4S and WOSCOPS. If the relative risk numbers in the original WOSCOPS press release were replaced with absolute risk numbers, it would then read: "People with high cholesterol can rapidly reduce their [absolute] risk of having a first time heart attack by 1.9 per cent and their [absolute] risk of death by 0.9 per cent, by taking a widely prescribed drug called pravastatin sodium." Likewise, the effectiveness of simvastatin could be stated as: "Proven to reduce the [absolute] risk of total mortality by 3.3% (P = 0.0003), coronary mortality by 3.5% (P = 0.00001)." Yet another way of stating the facts would be to say that patients with angina or after a myocardial infarction may improve their probability of avoiding coronary death from 91.5% to 95% by taking simvastatin, while people without prior coronary disease may improve their probability from 98.3% to 98.8% by taking pravastatin. From earlier studies,[7–13] it would seem a fair guess that these statements would leave different impressions than the original ones.

At this point it should also be added that the WOSCOPS group, a year after publishing their original study and releasing the news of their study to the press, published an article wherein they stated their belief in absolute risk estimates as the better estimate of the benefits of treatment.[14] This article also contained absolute risk estimates for various subgroups in the study, calculated in an attempt to identify high risk individuals who should be subject to statin treatment. This strategy for selection of high risk patients was attributed to evidence that hypercholesterolaemia alone was not a good indication for statin treatment and that a population based strategy would prove too costly for countries with restricted healthcare budgets. This statement that hypercholesterolaemia alone is an insufficient indication for treatment may lead people to see the press release's primary focus on risk reduction in people with high serum cholesterol as a generous interpretation of the facts.

One for all, all for one

Another point that can be made about the original statements is the phenomenon called pseudocertainty—that is, that "outcomes that are merely probable are underweighed in comparison with outcomes that are obtained with certainty."[15]

"Proven to reduce the risk…" and "People with high cholesterol can rapidly reduce their risk…" may easily be understood to mean guaranteed improvements rather than improved probabilities. There is, on the contrary, considerable uncertainty with regard to which individuals will benefit from statin treatment. As it is, some people taking statins will suffer a coronary death, just as most people not taking them will live. Apart from taking in these implications of the risk estimates, this uncertainty is further illustrated by the number needed to treat (table 3).[16]

Prescriptions of cholesterol reducing drugs have risen explosively in recent years. One reason for this may well be messages attributing certainty when uncertainty prevails. To illuminate the mechanisms of the explosion, we have calculated the number of tablets needed to be taken (suggested abbreviation TNT) to save one life (table 4). Based on the number needed to treat and the number of tablets needed to be taken, we are able to state that, based on data from WOSCOPS, "Medicine is not an exact science. Therefore, 200 men without any prior heart disease have to swallow 357 700 tablets over five years to save one of them from dying from coronary heart disease. This is due to the fact that no exact knowledge exists as to whom of these 200 will benefit from the treatment."

Another mechanism involved here is that of overconfidence in current scientific knowledge.[15] An example of this is the statement of the editor of the *American Journal of Cardiology* that statins are miracle drugs that "are to atherosclerosis what penicillin was to infectious diseases."[17] Despite whatever present argument exists over the long term effects of penicillin and other antibiotics, their effectiveness was never based on treating hundreds of patient daily for half a decade to cure the infection in one of them. Such overconfidence may easily be built on relative risk estimates, but also on a failure to acknowledge that the aetiology of coronary heart disease still has many unknown components. Indeed, if the recent attention to the possible contribution of infections to coronary heart disease proves to be right,[18–21] then the statement may be that penicillin is to atherosclerosis what it was to other infectious diseases.

One way of informing patients has been suggested by Hanne Hollnagel, professor of general practice in Copenhagen.[22] Her strategy is based on the principles

Table 1 Some simple examples of combinations of relative and absolute risks

Treatment group		Placebo group		Relative risk reduction (%)	Absolute risk reduction (%)
Survivals	Mortalities	Survivals	Mortalities		
9000	1000	8000	2000	50	10
9900	100	9800	200	50	1
9990	10	9980	20	50	0.1
9999	1	9998	2	50	0.01

Table 2 Estimates of absolute risk of coronary and total mortality from data from the 4S[1 2] and WOSCOPS[6] studies (values are percentages)

	4S		WOSCOPS	
Outcome	Placebo	Simvastatin	Placebo	Pravastatin
Coronary mortality	8.5	5.0	1.7	1.2
Total mortality	11.5	8.2	4.1	3.2

Table 3 Number needed to treat* to save one life estimated from data in the studies 4S[1 2] and WOSCOPS[6]

	Number needed to treat	
Outcome	4S	WOSCOPS
Coronary mortality	29	200
Total mortality	30	111

*1/(absolute risk reduction).

Table 4 Tablets needed to be taken* to save one life estimated from data in the studies 4S[1 2] and WOSCOPS[6]

	Tablets needed to be taken	
Outcome	4S	WOSCOPS
Coronary mortality	57 159	357 700
Total mortality	59 130	198 524

*Number needed to treat×365×daily dose×average number of treatment years (5.4 years for 4S, 4.9 years for WOSCOPS).

of acknowledging that there is uncertainty involved, avoiding value laden words such as "risk" or "chance," using absolute estimates, and avoiding relative estimates. For a patient fitting the inclusion criteria for the 4S, her message would then be: "If 100 people like you are given no treatment for five years 92 will live and eight will die. Whether you are one of the 92 or one the eight, I do not know. Then, if 100 people like you take a certain drug every day for five years 95 will live and five will die. Again, I do not know whether you are one of the 95 or one of the five."

Men only?

Another issue is the sex of the beneficiaries of statin treatment. Surely, it seems reasonable for readers of the advertisements and the press release to assume that "patients" and "people" include both sexes. However, WOSCOPS was strictly men only, and, although 4S included women, there was no reduction of total mortality for the female patients in the study while their absolute risk of a coronary death was reduced from 4.0% to 3.1%.[1] It would, of course, be premature to say that women will not benefit from statin treatment, but it should be acknowledged that such benefits have not been shown by these two studies.

Another question is whether people and patients mean individuals or groups. "People with high cholesterol can rapidly reduce their risk of having a first-time heart attack by 31 per cent," may be interpreted as all individuals taking the drug will have a 31% reduction of their personal risk. However, this statement is true only for groups of men, a fact that should not be forgotten in consultations with individual patients.

Discussion

Considering that "the public has a right to information and to be involved in the choice of treatment,"[23] doctors have to communicate the risk reduction achieved by cholesterol reducing drugs to their patients. Advocating patient autonomy may not be done with a light heart, however, as a patient's choice may not always be what a doctor would like it to be. Belief in patient autonomy may indeed prove to be a bitter pill for doctors to swallow when they consider that "How people perceive health issues and risk and how they make choices about their own behaviour do not always fall into a rational pattern."[23] If a doctor further believes that a patient's need for statin treatment is a result of irrational lifestyle choices it would seem paradoxical to give the patient the freedom of choice with regard to treatment. On this issue, the doctor has no option, however, as the decision on whether to swallow a pill always lies with the patient.

Then again, what exactly is a rational choice in these matters? A possible answer is that there are several rationalities involved, reflecting various interests. In this case there are at least those of the individual patient, of public health, of the medical profession, and of the pharmaceutical industry. What makes the choice difficult is that it is hard to tell when these interests overlap and when they do not.

In the era of evidence based medicine it is no surprise that measures of clinical effectiveness are focused in drug advertisements. Indeed, this is a most rational strategy given the circumstances. As has been shown, however, we would do well to look beyond the face value of facts stated as relative risk reductions and keep in mind that effectiveness at the group level may mean uncertainty at the individual level.

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Endpiece

Alternative definitions

Friendship: A ship big enough to carry two in fair weather, but none in foul.

Ambrose Bierce, *The Cynic's Word Book* (1906), subsequently titled *The Devil's Dictionary*

Evaluating information technology in health care: barriers and challenges

Heather Heathfield, David Pitty, Rudolph Hanka

There is strong push for clinical leadership in the development and procurement of information technology in health care.[1] The lack of clinical input to date has been cited as a major factor in the failure of information technology in health services[2] and has prompted many clinicians to become involved in such endeavours. Furthermore, there are various clinical decision support systems available, the merits of which clinicians are expected to judge (such as Prodigy[3] and Capsule[4]).

It is essential that clinicians have a knowledge of evaluation issues in order that they can assess the strengths and weaknesses of evaluation studies and thus interpret their results meaningfully, and also contribute to the design and implementation of such studies to provide them with useful information.

Summary points

- Clinicians are becoming increasingly involved in the development and procurement of information technology in health care, yet evaluation studies have provided little useful information to assist them
- Evaluations by means of randomised controlled trials have not yet provided any major indication of improved patient outcomes or cost effectiveness, are difficult to generalise, and do not provide the scope or detail necessary to inform decision making
- Clinical information systems are a different kind of intervention from drugs, and techniques used to evaluate drugs (particularly randomised controlled trials) are not always appropriate
- The challenge for clinical informatics is to develop multi-perspective evaluations that integrate quantitative and qualitative methods
- Evaluation is not just for accountability but to improve our understanding of the role of information technology in health care and our ability to deliver systems that offer a wide range of clinical and economic benefits

The evaluation dilemma

Decision makers may be swayed by the general presumption that technology is of benefit to health care and should be wholeheartedly embraced. This view is supported by assertions such as that general practitioner computing is seen "as an integral part of the NHS IT strategy,"[5] the US Institute of Medicine's statement that computing is "an essential technology for healthcare,"[6] and the increasingly high levels of spending on healthcare information technology. On the other hand, decision makers may support the argument that procurement of information technology should be based on the demonstration, in randomised controlled trials, of economic benefits or positive effects on patient outcomes.[7–12]).

Regardless of which view you take, evidence is scarce. Large scale pilot initiatives such as the NHS electronic patient record project have yielded only anecdotal evidence, with little or no credence given to results of external evaluation ("We now know how to do it and it is achievable in the NHS"[13]). Results from economic analyses and randomised controlled trials of healthcare systems are emerging, but these studies cover only a small fraction of the total number of healthcare applications developed and address a limited number of questions, and most show no benefits to patient outcomes (D L Hunt et al, Proceedings of the 5th Cochrane Colloquium, Amsterdam, October 1997).[14]

Those who base their judgment on the failure of randomised controlled trials to show improved outcomes may cause important projects to be prematurely abandoned and funding to be discontinued. In contrast, those who heed the proponents of healthcare information technology and base their decisions on unsubstantiated reports of projects, written without external verification, may waste precious NHS resources through the inappropriate and uninformed application of information technology. This is likely to result in repeated failure without retrospective insight, and so does nothing to further the science of system development and deployment. The problem is confounded by the fact that negative results are seen as unacceptable and do not generally become public, thus failing to facilitate knowledge for future developments.

Problems with inappropriate evaluations

Evaluation can be viewed as having a severe negative impact on the progress of clinical information technology because, in our opinion, many evaluation studies ask inappropriate questions, apply unsuitable methods, and incorrectly interpret results. The evaluation questions most often asked include those concerning economic benefits and clinical outcomes, despite the lack of strong evidence of such and the recognition of the difficulty of applying results in other contexts.[15] The misplaced notion that clinical information technology is comparable to a drug and should be evaluated as one has led to the idea that the randomised controlled trial is the optimal method of investigation.[16] While a major deterrent to the use of randomised controlled trials has been their cost, they are also vulnerable with respect to external validity: trial results may not be relevant to the full range of subjects (that is, specific

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SIS

implementations of a healthcare application) or typical uses of a system in day to day practice, and they are likely to cover only a small proportion of the wide range of potential healthcare applications. Furthermore, negative results from such trials cannot help us understand the effects of clinical systems or build better ones in the future.

New directions in evaluation

New perspectives on evaluation are emerging in the domain of health care. Most important is the recognition that randomised controlled trials cannot address all issues of evaluation and that a range of approaches is desirable (Heathfield et al, Proceedings of HC96, Harrogate, 1996).[17] As pointed out by McManus, "Can we imagine how randomised controlled trials would ensure the quality and safety of modern air travel . . .? Whenever aeroplane manufacturers wanted to change a design feature . . . they would make a new batch of planes, half with the feature and half without, taking care not to let the pilot know which features were present."[18] Others have sought to find surrogate process measures that may be used instead of "prohibitive" outcome measures, thus making randomised controlled trials more cost effective.[19]

Likewise, workers in clinical informatics have questioned the usefulness of conducting randomised controlled trials on clinical systems. The demonstration of quantifiable benefits in a randomised controlled trial does not necessarily mean that end users will accept a system into their working practices. Research shows that satisfaction with information technology is more correlated with users' perceptions about a system's effects on productivity than its effect on quality of care.[20–22]

These insights have highlighted the need to examine professional and organisational factors in system evaluation and have led to the concept of multi-perspective, multi-method evaluations, which seek to address a number of issues with multiple methods and with evaluators from different backgrounds working together to produce an integrated evaluation. This is coupled with an awareness of the importance of qualitative methods in system evaluation.[23–26] The NHS electronic patient record project is an example of a large, multi-perspective evaluation, which includes social scientists, health economists, computer scientists, health service managers, and psychologists and uses a wide range of different methods. However, the problems of conducting large scale evaluations of this type show the need for careful planning in such studies.[27]

Challenges for evaluating information technology in health care

Clinical systems are embedded social systems with different people, institutions, providers, settings, and so on. While it is important that we search for causal mechanisms that lead to clinical outcomes, the investigation and, possibly, classification of such contexts is essential. This will help us to understand and predict the behaviour of systems and provide important knowledge to inform further developments. This form of research will be facilitated by refocusing attention from debates about specific methods towards issues of multi-method evaluation and the integration of methods and results.

Conclusions

The arguments for performing multi-method evaluations must be acknowledged and progressed within the community. Information technology is not a drug and should not be evaluated as such. We should look to the wider field of evaluation disciplines, in which many of the issues now facing clinical informatics have been addressed.

The current political context in which healthcare applications are evaluated emphasises economic gains rather than quality of life. Thus, the role of evaluation has been to justify past expenditures to taxpayers, managers, etc, and so evaluation becomes a way of trying to rebuild lost public trust. This is short sighted. Evaluation is not just for accountability, but for development and knowledge building in order to improve our understanding of the role of information technology in health care and our ability to deliver high quality systems that offer a wide range of clinical and economic benefits.

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Netlines

Wired in Lytham

• Internet-savvy patients in Lytham St Annes, Lancashire, can now access all the information they could possibly want about the local general practice Holland House Medical Centre via the surgery's website (**http://ourworld.compuserve.com/homepages/Nick_Lowe/pracbook.htm**). The site is nicely laid out and covers everything from repeat prescriptions to the out of hours service and from medical certificates to childhood immunisations, although I wonder how much of their advice on self treatment of common disorders is evidence based.

WebDoctor

• WebDoctor (**http://www.gretmar.com/webdoctor/**) is a comprehensive index of medical resources on the internet produced in Canada. The site includes introductory articles about the internet for doctors, covering topics like "Working with the internet-literate patient," links to electronic medical journals, and interactive discussion forums.

Fifty years of the NHS

• This site (**http://www.nhs50.nhs.uk/**) has been set up to commemorate the 50th anniversary of the NHS. It describes the past, present, and future of the NHS and includes features such as "Today in 1948" and a critique of the successes and failures of the service.

Plague genome

• The Wellcome Trust (**http://www.wellcome.ac.uk**), through a new initiative, Beowulf Genomics (**http://www.beowulf.org.uk**), is funding the sequencing of several microbial genomes, including that of *Yersinia pestis*, the causative agent of bubonic plague. Sequencing and annotation will be carried out at the Sanger Centre, near Cambridge, (**http://www.sanger.ac.uk/Projects/Y_pestis/**). Further information on the project and links to online information about *Y pestis* and plague can be found on a website in my department (**http://www.medmicro.mds.qmw.ac.uk/yersinia/**), which also features information about St Bartholomew's Hospital and the Plague of 1665 (**http://www.medmicro.mds.qmw.ac.uk/yersinia/Plague_history.html**).

Research misconduct

• Following the discussion of this topic in a recent issue of the *BMJ* (6 June), I searched the web for further information. Walter W Stewart's Site on Scientific Misconduct (**http://www.nyx.net/~wstewart/main.ssi**) provides a wealth of information and links, including documents and discussions relating to notorious cases (Darsee, Baltimore, etc). Brian Martin in Australia has produced a site on "suppression of dissent" in science (**http://www.uow.edu.au/arts/sts/bmartin/dissent/**), while the UK organisation for whisteblowers, Freedom To Care, has a site on **http://members.aol.com/FreeCare/Info.htm**. The Department of Chemistry at Virginia Tech has put together an Ethics in Science page (**http://www.chem.vt.edu/ethics/ethics.html**), with links to useful resources, including an excellent guide to scientific conduct by the National Institutes of Health, *On Being a Scientist* (**http://www.nap.edu/readingroom/books/obas/**). The Medical Research Council's scientific misconduct policy and procedure can be obtained in Adobe Acrobat format from **http://www.mrc.ac.uk/mis_con.pdf** (to read this, you will need Acrobat Reader **http://www.adobe.com/prodindex/acrobat/readstep.html**).

• To protect yourself against false accusations, you should read the British Technology Group's guide to keeping a laboratory notebook on **http://www.btgplc.com/lit/lit2fr.htm**. And if you have been wrongly or maliciously accused of research misconduct, you can find your union on the web: the BMA's website is on **http://www.bma.org.uk/**, while non-clinical researchers can find the AUT on **http://www.aut.org.uk** and MSF on **http://www.msf.org.uk**.

Respiratory Infection Website

• Clinicians or microbiologists interested in respiratory infection should visit this excellent new website (**http://www.respiratory.infection.org**), which contains well written articles on many aspects of respiratory infections and allows readers to comment on what they read through an online discussion group. The only drawback is that you have to register before you can access the site.

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