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A matter of heart: the general practitioner consultation in an evidence-based world

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This article is based on a keynote presentation at the 12th Nordic Congress in General Practice in Trondheim, Norway in September 2002. The aim was to demonstrate the strengths and limitations of evidence-based medicine (EBM) in a primary healthcare setting. The presentation comprised two separate lectures discussing an authentic case history from everyday practice that had been presented to the authors by the congress organisers. Initially, Peter Nilsson overviews the correct approach to the situation as described according to EBM. Subsequently, Linn Getz questions whether we can be sure that application of EBM is necessarily in this particular patient's best interests. The title of the presentation, 'A matter of heart', has a double meaning. On the one hand it indicates an update on preventive cardiology, on the other it addresses the importance of academic courage (coeur = heart) among members of the medical

community. The general practitioner is in a unique position to observe the interaction between the scientific paradigm of biomedicine and individuals, whether suffering from ill health or considering themselves healthy. It is our privilege and professional duty to reflect upon clinical experience and be open to critical debate.

Key words: general practice, evidence-based medicine, unrecognised myocardial infarction, human sciences, ethics, concept of risk, risk perception, emotional health.

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CASE HISTORY

The patient is a 70-year-old healthy male who, because of his age, needs a health certificate in order to have his driving licence renewed. He thus comes to see his general practitioner for the first time since he enlisted at the practice 8 years previously. He informs the doctor that he is healthy and emphasises the fact that he has always been healthy. Clinical examination reveals no sign of pathology, except for his heartbeat appearing somewhat irregular. The doctor thus orders an electrocardiogram (ECG), which shows no pathological arrhythmia. However, there is indication of an old coronary infarction in the ECG.

The doctor hesitates. She recognises that being 'of strong health' may be important to this man's identity. On the other hand, several scientific studies indicate that, compared to the general population, he is at increased risk of future coronary events. Furthermore, it is a medical duty not to withhold diagnostic information from patients. Choosing her words carefully, so as not to upset him, the doctor informs the man about the finding in the ECG. She asks him to make a new appointment so that his condition can be evaluated further. She then completes the certificate confirming that she considers him medically fit to drive a car and hands it over with a smile. She tells the man not to worry about his

heart. The patient nevertheless appears hesitant and troubled as he leaves her office.

Despite having performed her task according to existing medical guidelines, the doctor is left with a feeling of unease, as if she has made a mistake.

Evidence-based medicine – the narrow road

PETER M. NILSSON

Why is evidence-based medicine (EBM) a narrow road? Even though we try to apply EBM in our daily clinical practice, we have to admit that the findings are generally based on randomised controlled trials (RCTs) and mean effects on a group basis (1). Any conclusions must therefore be translated to the individual level relative to age, gender, ethnic background and other relevant medical problems of the patient involved. Furthermore, EBM is often difficult to remember in all its aspects and it changes in focus and content. We therefore need continuous medical education as well as technical support through reliable information systems, e.g. easy computer access to MEDLINE/Pubmed and other relevant databases in the clinical office. Even if there are many inherent problems and shortcomings with EBM, it is a lifeboat

on a stormy sea of medical problems and ignorance, but it does not always reach harbour, for example when the patient suffers a morbid event or dies in spite of all good intentions and efforts.

Is a silent myocardial infarction (MI) in a 70-year-old man something to bother about or not? According to observational epidemiological data from the Framingham study, based on 708 MI cases among 5127 participants, more than 25% were detected by annual ECG check-up only (2), and more than half of these were "silent", especially in women and elderly men. After a follow-up period, it was concluded that a silent MI implied a similar risk for cardiovascular complications as a clinical MI (2). The risk associated with a silent MI cannot therefore be ignored and should be categorised as a triggering event for starting secondary prevention of coronary heart disease (CHD).

Can the physician confirm a diagnosis of silent MI? The first step would be to compare an abnormal current ECG with previous ECGs, if possible, to prove changes. Other technical options, not all of them necessary or needed in every case, are the following: a myocardial scintigram for evaluation of myocardial damage; an echocardiography for evaluation of cardiac failure and decreased ejection fraction; or a bicycle ergometry test for evaluation of coronary ischaemia. In addition to these investigations, the full cardiovascular risk factor profile should be evaluated, including family history, medical history, lifestyle, blood pressure and blood sampling (fasting lipids, glucose). Balanced advice for an improved lifestyle (stopping smoking, increasing physical activity, proper diet) could be offered to all patients regardless of how well proven the cardiac damage is or is not – this is a message for everyone!

The five cornerstones for EBM in the secondary prevention of CHD/MI are: (a) improved lifestyle, (b) lipid lowering by statin use (based on the trials 4S, HPS, CARE and LIPID) or fibrate use (VA-HIT trial), (c) ACE inhibition (HOPE trial), (d) beta-receptor blockers (several trials) and (e) low-dose aspirin (several trials). These interventions should be discussed with the patient, not forced upon him/her, and ranked according to cost of intervention (Table I). In the recent Heart Protection Study, which included 19,000 high-risk individuals, the relative risk reduction (RRR) of acute MI was 24% by added-on simvastatin treatment compared to placebo and was not dependent on baseline LDL-cholesterol level (3). If all EBM proven therapies in secondary prevention could be jointly and successfully applied, a much higher RRR could be expected, as high as 80% according to some authors (4).

What about numbers needed to treat (NNT) in secondary prevention? This should be based on data

Table I. Evidence-based medicine (EBM) measures in secondary prevention of coronary heart disease, stratified for cost of intervention.

Low-cost interventions
Smoking cessation
Physical training
Low-dose aspirin
Medium-cost interventions
Beta-receptor blocker therapy
ACE inhibitor (generics) therapy
Statin (generics) and fibrate therapy
High-cost interventions
ACE inhibitor (non-generic) therapy
Statin (non-generic) therapy
Revascularisation (CABG/PTCA) procedures

from trials. In the Scandinavian Simvastatin Survival Study (4S), risk reduction during the trial was related to the absolute risk at baseline. In the 4S, the RRRs were 38%, 39% and 42% in patients at low, medium and high baseline risk. The absolute risk reduction (ARR) varied between 8% and 16% according to risk category (5). This corresponds to NNT (1/ARR) of 6 (95% CI: 4–11) to 11 (7–25) and 13 (8–34) patients for 6 years in order to prevent one cardiovascular event (5).

How can the quality of secondary prevention for CHD be improved? In Sweden, a national project for better quality in secondary prevention has been on-going for 6 years based on a joint collaboration between the Swedish Society for Cardiology, the Swedish Society for General Medicine and the Swedish Federation for Health Care Staff in Cardiology. One of the findings, based on data from almost 30,000 patient visits, is that gender-equal care has been established for secondary prevention, as mirrored by similar lipid levels and drug treatment profiles in male and female patients after 1 year of follow-up, post-MI or following a revascularisation procedure (6).

The well-proven facts of EBM in secondary prevention should be acknowledged and not ignored, otherwise the doctor runs the risk of working in an unprofessional, unethical and non-legal way, at least according to Swedish recommendations (7,8), and most importantly the Health Care Legislation Act from 1980. This Act states that the patient should have the right to an informed choice whenever possible. However, no prevention should be forced on the patient; the crucial point is that it takes information and mutual communication between the doctor and the patient to make real the goal of an informed choice. Otherwise the doctor is working in a God-like manner, prohibiting the patient, an adult person, from making use of the relevant medical information for a personal choice (9). Therefore, we should all reflect

Table II. Which kind of GP doctor are you? A personal test for self-reflection.

<i>The sphinx-like GP</i> – knows everything, but says nothing.
<i>The God-like GP</i> – knows everything, but says only partly and wants the patient to be obedient and thankful whatever is said and done.
<i>The charlatan GP</i> – knows little, says anything.
<i>The anxious GP</i> – says little, makes a referral to hospital.
<i>The ultra-democratic GP</i> – knows something, asks the patient and relatives for a joint majority decision on what to do.
<i>The “normal” GP</i> – knows something, tries to balance evidence-based medicine with narrative medicine = consultation skills.

upon the kind of doctor/GP we would like to be – in our own view and in the eyes of the patient (Table II).

In conclusion, the EBM-believing physician should consider the absolute (total) risk of a cardiovascular event in the next 10-year period, and base treatment recommendations on this estimation according to current European (10) and national recommendations. In the case history presented here, all relevant risk factors should be evaluated and discussed for possible treatment. The patient should be an active partner in this process, and relevant information should be available from the physician or from recommended literature. If the patient in the end declares that he or she will not take medication, this is based on an informed choice and should be respected. To put it in another way: when mother EBM meets father narrative medicine (11–13), the two happy parents (14) will have a beautiful child called consultation skills. No child can be born without the interaction of two parents – a simple fact of life!

What kind of evidence is relevant to clinical decision-making?

LINN GETZ

Despite convincing evidence that men who have undergone a MI may benefit from secondary prevention, I am not fully convinced that the medical encounter described in this case was health-promoting. Consider the outcome of the consultation: the patient appears hesitant and troubled as he leaves the office. The doctor is left with a feeling of unease, as if she has made a mistake. Is something of clinical and scientific significance going on? I see crucial questions in relation to several topics. These include:

- the validity of EBM to this particular man
- the significant correlation between emotions and cardiovascular health

- the fact that general practitioners show limited concordance with clinical guidelines in the field of preventive medicine
- issues related to philosophy, theory of science and medical ethics.

Connecting these diverse issues together in one argument is tricky. Medical reasoning, the way we have been taught to understand the physical heart of a patient, is detached from the human sciences that enable us to analyse the person's life-world. If we intend to apply a truly scientific approach, the case should be evaluated at the crossroads between these approaches. Biomedicine's inability to explain the placebo effect, however, documents that the paradigm cannot encompass the fundamental fact that human experience of meaning has profound effects on the physical body (15).

Is biomedicine in accordance with common sense?

I have presented this case history to several scholars. It tends to evoke one of two distinct responses. To illustrate these, I present an authentic dialogue between an American professor of medicine and his wife, a researcher in ancient history. This short dialogue (Table III) highlights three key issues: firstly, we see that from a traditional biomedical standpoint there appears to be no doubt as to whether the medical professional is doing good by *transforming a healthy person into a patient*. Secondly, it illustrates a statement recently put forward by David Sackett in his paper “The arrogance of preventive medicine” (16). Sackett states that *preventive medicine displays all three elements of arrogance*; aggressive assertiveness, presumptuousness and use of forcible arguments. Thirdly, I choose to believe that the opinion of the historian-wife reflects her knowledge that in Antiquity medicine was intertwined with philosophy, *the two disciplines together serving a common aim – the relief of human suffering*.

How exact is the evidence?

Unrecognised MIs may be present in about 3.5% of 70-year-old men in the general population (17). Studies indicate that their prognosis does not differ significantly from that of patients with recognised infarctions (17–19). Evidence-based calculations of

Table III. Dialogue illustrating two typical but differing views of how to handle the case in question.

<i>Accompanying wife/historian:</i>
“Of course it is best not to tell the patient”
<i>Professor of medicine:</i>
“But, darling, it is a matter of saving his life! ”
<i>Wife:</i>
“Oh...”

the potential benefits of therapy for a patient like our man come from a heterogeneous mixture of studies, mostly related to patients with symptomatic heart disease. There is reason to ask whether the term 'evidence-based' may give the pretence of high scientific certainty, which in fact does not apply in this particular case. Table IV presents some 'best estimates' of the prognosis (17–19) and potential theoretical benefits of intervention (20).

Deducing from the group to the particular

Let us presume that the estimates (Table IV) are indeed valid for a group of men like our man. We intend to inform him about his personal risks and the potential benefits of therapy. However, as we counsel him on the basis of group-based data, we in fact commit a logical error, according to scholars of the theory of science (21,22). We choose to ignore individual variation and diversity, crucial phenomena in human biology. It should not therefore come as a surprise when epidemiological studies confirm that "The prediction of coronary heart disease risk in individuals is an imprecise science" (23).

Dealing with the concept of risk

During recent decades, there has been a steadily increasing focus on *risk* in Western societies (24–27). Adoption of the risk concept as a basis for preventive medicine on a large scale has taken place

Table IV. Some "best estimates" of medical risks and potential benefits of therapy for the man in the case story. Estimates of therapeutical benefit are based on a number of intervention studies (included 4S) indicating a potential for 30–40% relative risk reduction for each drug prescribed for secondary prevention after a myocardial infarction.

No intervention (natural prognosis): 96–97% of 70-year-old men like this man are likely to survive each of the years to come, i.e. mortality in this group is 3–4% per year or 30–40% in the next 10 years (17,18).

Intervention may statistically reduce the mortality in this group somewhere between 1.5% and 2.5% per year. The maximum estimate presumes intervention with 3 or 4 drugs according to EBM, and furthermore presupposes that each drug will subsequently contribute a 30–40% relative risk reduction in relation to fatal CV events. Additive effects of several drugs, however, have not been documented scientifically.

Number needed to treat (NNT): If you intensively treat 40–60 patients like this man for 1 year, you might prevent 1 man from dying a cardiovascular (CV) death. After 10 years of treatment, 1 CV death may have been prevented for every 4–6 men.

Impact of diagnosis and therapy on quality of life in a group of patients like this:

There appears to be very little applicable evidence.

without much analysis and debate (25). The goals of medicine have expanded from the curative to the preventive sphere, a development that carries fundamental philosophical and ethical implications (25,27). The process of critical reflection in relation to risk intervention is still in its early stages.

For once, there is a problem related to *the communication of risk and treatment effects* (28,29). Doctors and patients tend to make different therapeutic considerations, depending on the way risk estimates are presented, i.e. what statistical model is used (29,30). Our man may be greatly interested in achieving a 40% reduction in the relative risk for a disease event during the next year, but reluctant if told that it is 98% likely that therapy will not affect his prognosis during the next year. The underlying data are the same. When can we say that a person makes an autonomous, informed choice?

Another issue yet to be explored is *how people experience the state of being 'at-risk'* (24,25,31,32). A philosopher reminds us how knowledge about medical risk may connect directly to the depths of our existence; our mortality, vulnerability and dependence (Arne Johan Vetlesen, pers. comm., 2002). As professionals we need to consider how this particular man may feel about the information he receives. Does his perception of his body change? What does he do, or stop doing? What will he tell his wife? What will she think if one day he looks a bit tired?

There are relatively few empirical studies on human experience of being labelled as 'at risk'. The results are contradictory and reveal what appear to be several paradoxes. The professional's preconception is of course that information about risk will increase people's sense of control over their lives and ultimately their quality of life. However, studies indicate that knowledge about medical risk may come to echo in people's minds in daily life. Food may become connected to ambivalence and guilt, innocent bodily symptoms to anxiety. There are empirical data indicating that knowledge about risk may cast shadows of doubt and insecurity over people's lives. One individual who was diagnosed as 'at risk' as he participated in a population study on cardiovascular disease worded this experience: "the fear is always there with you" (32). Despite the absolute risk of disease being relatively low, people also report that if you don't truly believe the statistics relate to you personally, there is no motivation to comply. Consequently, prevention may become a question of "complying or dying" (32). Are we setting up an emotional trap? It is not easy to say; research shows that many people express satisfaction with screening programmes and gratitude for the "gift of knowing" (33).

Emotional well-being and cardiovascular health

There is much evidence that changes in emotional life may affect the cardiovascular disease process itself for better or for worse (34–36). Depression may be associated with a twofold to threefold increase of cardiovascular mortality (36,37). A sense of hopelessness, defined as feeling unable to reach one's goals in life, has been shown to be predictive of a threefold increase in the incidence of hypertension in the near future, as well as worsening of overall cardiovascular status (38,39). We have no direct evidence that emotional stress related to information about medical risk can aggravate the disease process itself, but such a link appears biologically plausible.

The man in our case told his doctor that he considered himself "a man of strong health". However, subjective experience of this kind is not considered worthy of inclusion in cardiovascular risk estimates. There is much evidence that a subjective perception of good health is a strong predictor of survival (40–42). Our particular man may have a considerably better prognosis than estimated by so-called EBM.

Biomedical data – the ultimate truth?

The doctor in our case hesitates for a moment before allowing a diagnostic test result to overrule our man's subjective experience of being "a man of strong health". Her feeling of unease reflects an ethical dilemma necessary to discuss. The biomedical approach to the human being rests on systematic separations between 'normal' and 'deviant' findings, based on definitions made by the healthcare system itself. As medical professionals, we have a moral obligation "to tell the truth" to our patients. By tradition, the results of medical diagnostic tests have come to represent *ultimate truths* about the human condition, and thus something to be communicated irrespective of the context in which the results arise. In his 1973 analysis of the history of medical perception, social philosopher Michel Foucault describes the historical context in which *the clinical gaze* evolved, and how this gaze came to represent "a separating agent of truths" (43). As diagnostic technology becomes ever more widespread and refined, the professional's dilemma of having to communicate medical 'truths', despite considerable scientific uncertainty about their significance for the particular individual involved, appears to arise ever more frequently (44,45).

Limited concordance with clinical guidelines – what lies beneath?

Several studies indicate that general practitioners show limited adherence to clinical guidelines (46,47). Organ experts tend to indicate that the reason may be

either ignorance or paternalism among GPs and consider it a violation of patient autonomy not to offer state-of-the-art medical intervention. In discussions of the present case, the question of autonomy typically arises at the final stage of the consultation, to emphasise the patient's democratic right to consider further diagnosis and therapy. But at that point a violation of our patient's autonomy has already taken place: our man never asked for a cardiovascular risk evaluation, his interest was driving his car. What is medical paternalism if not the use of medical technology in a somewhat arbitrary fashion on a healthy individual who is not asking for medical advice? Being aware of the scientific uncertainties outlined above *we cannot know that we are not doing more harm than good by imposing information about risk on this particular man*. Remember the prime principle of medical ethics – *primum non nocere* (first of all, do no harm) (9).

Whether analysing the case history from a biomedical or a humanistic perspective, the doctor in our case may find considerable theoretical and empirical support for her feeling of unease. Can it thus be that among general practitioners who show limited adherence to medical guidelines in the preventive sphere, there are doctors who actually show respect for a 'scientific truth' about their patient's condition that penetrates deeper than EBM (48)?

Humane doctoring

The medical practitioner who strives to combine biomedical evidence derived from group data (EBM) with a humanistic approach to the particular individual can be designated a *humane* doctor. Humane doctors hesitate *before* applying ECG electrodes to the chest of elderly gentlemen of very strong health. This is due not to ignorance in relation to medical guidelines (humane doctors do not hesitate to perform literature searches), but because a humane doctor acknowledges that the biomedical paradigm has fundamental shortcomings when it comes to explaining human health and suffering (49). With reference to the literature on empowerment and health, a humane doctor might deliberately choose to exclude the measurement of body mass index (BMI) in an overweight patient, despite this being part of a state-of-the-art risk evaluation. Making a point of excess body fat may sometimes be counterproductive to the symmetrical dialogue about health resources and future possibilities (50) which may facilitate constructive and lasting changes in a person's life.

Being a professional is not simply a question of commanding the various tools of medicine, such as medical guidelines. A medical professional also acknowledges that the use of reductionist medical tech-

nology may carry unintended side effects (22,44,45), and thus makes sure that its application is truly warranted in the first place. The decision of when to perform a diagnostic test and when to refrain from testing has to rest on scientific considerations that transcend the biomedical paradigm. As pointed out by Haynes, EBM does not make clinical decisions. People do (48).

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