

Epistemology of Evidence Based Medicine

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Abstract

Clinically relevant attitudes and guidelines issued by a rational evidence based medicine (EBM) approach integrate individual clinical expertise with the best available external clinical evidence from systematic research. However, many physicians, while considering the ultraliberal world they are practising in and fearing that the primary goal of managed care in a market environment is reducing cost in order to make profit or decrease spending, remain suspicious of this kind of tentative protocol driven medicine when applied to medical and surgical practice. If physicians want to develop a health policy agenda that emphasises patient care issues above providers' or payers' interests, they should share a common semantics (i.e. understand the *words* and the *numbers*), enhance education programmes, improve continuing objective assessment of the way medicine and surgery are performed, face moral issues raised by innovation, and assume an increased leadership role in sound critical evaluation of non-validated new techniques. They should no longer consider EBM as a weapon turned against the medical profession, but rather see it as a tool that may provide some answers to chronically unresolved questions in the evolving art of Medicine and Surgery. (*Acta gastroenterol. belg.*, 2006, 69, 238-246).

Key words : EBM, Evidence Based Medicine, efficiency, effectiveness, innovation, bioethics.

The idea that clinical practice should be rigorously based on the best scientific evidence is not new (1). What has been new over the past three decades is the ever increasing pressure to contain the inflationary growth of health care costs. Until relatively recently, attempts to restrain this growth had only minimal or transient effects and the failure to control costs has led to the current climate, one that attempts to control unit price and question the effectiveness and/or the efficiency of care. In such a climate, *cost effectiveness*, *cost benefit*, *cost analysis*, and *Evidence Based Medicine* (EBM) are sometimes just buzzwords that disguise the slipperiness of key concepts that bedevil clinical decision making. Indeed, the key unanswered question is still : to what extent is current clinical practice, taken as a whole, actually supported by satisfactory scientific evidence ?

This paper is dealing with the varieties, sources, ethical ground, socio-economic context, and validity of EBM knowledge as well as with its application in daily clinical practice. Which is actually what **epistemology** of any science is all about.

Is EBM really a new concept ?

Mythology

When one brings forth a new concept or revives a rather old one – which is the case with EBM –, one

should turn to the ancient mythology because there is always a good metaphor to describe how we are, in fact, rediscovering the wheel.

In Greek legend the robber Procrustes mutilated his victims in order to make them fit the length of one of his two beds. He forced the tall travellers to lie down in the short bed and the small ones to lie down in the long bed. Then, he cut the arms and legs of the tall travellers and he stretched the arms and legs of the small travellers out. Ultimately, Theseus tortured him the same way. Well, EBM can sometimes be somewhat compared to forcing clinicians into the Procrustean bed of “protocol driven medicine”.

History

But let's move up to the decade 1818-1827 – which was a golden decade for Medicine – : Louis Pasteur, Joseph Lister and Ignac Semmelweis were born during this decade. Pasteur, who initiated the concept of modern bacteriology, specified what can be considered as two basic principles of EBM : (1) Discovery by sheer chance happens only to well prepared minds ; (2) Our experience is the sum of our errors.

At almost the same time, Lister introduced the antiseptics at the Royal Infirmary of Glasgow where he treated the first compound fracture with antiseptic surgical technique. Lister delayed publishing his results until a total of eleven patients had been managed by the antiseptic technique. His study entitled “*On a new method of treating compound fracture, abscesses with observations on the conditions of suppuration*” was published in The Lancet in five successive issues from March 16 to July 27, 1867. Those were happy times for EBM experts who could get five papers published in The Lancet with a series of eleven patients !

Already as a young student in Vienna, Semmelweis was deeply moved by the ravages of puerperal fever. In 1842 as much as 30% of all parturients had died because of the so-called child-bed fever at the Allgemeines Krankenhaus in Vienna. However, the maternal death rate was significantly higher in the Students' ward (1st Clinic) compared with the Midwives' ward (2nd Clinic).

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Submission date : 12/02/2006.

Acceptance date : 24/04/2006.

In April 1847, Semmelweis friend, Kolletschka, professor of forensic medicine died. During an autopsy his finger had been cut by a medical student's knife. Semmelweis studied the record made of Kolletschka's post-mortem. He was shocked because he realised that the findings were identical with the findings from those women who had died of puerperal fever. Eventually, Semmelweis concluded that the infectious material which caused cadaver fever caused also puerperal fever and that the causes were in both cases one and the same, i.e. "the cadaver particles were introduced into the blood-vascular system". The particles were taken over to the parturients by the examining physicians and medical students who did post-mortem examinations and were constantly dealing with cadavers. Consequently, Semmelweis made chlorinated lime hand-wash compulsory between each examination. The routine execution of chlorinated lime hand-wash resulted in a great reduction in the mortality rate in the 1st Clinic, and in March and August 1848 nobody died in the Clinic. The Semmelweis-doctrine was born: he clearly defined the aetiology of the disease and the ways and means for its prevention, which is nothing else than asepsis, the prophylaxis of infection. One should also recognise that Semmelweis' doctrine was the starting point of another collateral progress: the concept of nosocomial infection. The simple truth, however, proved for many not to be easily accepted. Semmelweis was sharply attacked by leading members of the profession, most notably: Klein, director of the 1st Clinic of the Allgemeines Krankenhaus in Vienna, Simpson in Edinburgh, Scanzoni in Würzburg, Dubois in Paris, Kiwisch in Prague, Virchow and the French Academy of Medicine. Already at this time, sound EBM was not easily integrated by the medical profession! But Semmelweis made a fatal mistake by omitting to publish rapidly his discovery in a full authentic text. He wrote only private letters about it to his friends, because as he said later: "*My whole nature repulses from any kind of paper warfare*". Finally, Semmelweis published a full paper in German in 1861 in Leipzig. This paper is a basic and thorough medical work, an exact statistical document with refined irony at the same time. But few things can result in anyone losing his temper more than the continual lack of comprehension. Semmelweis tone became more and more sarcastic; this is demonstrated by an excerpt of a 1861 letter: "In a new hospital accommodated with the most modern furnishing and appliances, a good deal of homicide can be committed, providing one has the indispensable talent to carry it out". Such a statement is still true in 2006 particularly for the outbreak of nosocomial infection. So much for the expertise and the so-called expertness.

The sins of expertness and a proposal for redemption

About expertise and expertness, David Sackett (2), the founding father of modern EBM, once wrote – in a self deprecating article entitled "The sins of expertness

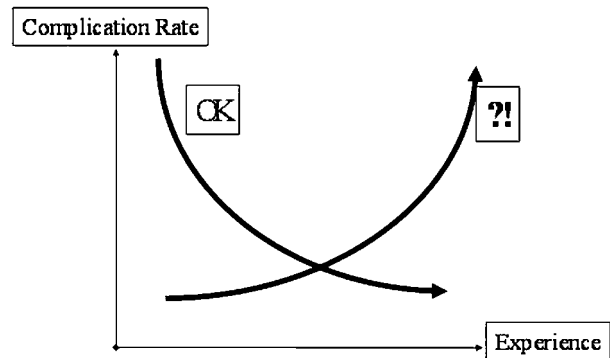


Fig. 1. — Learning curve

and a proposal for redemption" –: "*There are still far more experts (sometimes self appointed) around than is healthy for the advancement of clinical science. The first sin committed by experts consists in adding their prestige and their position to their opinions, which give the latter far greater persuasive power than they deserve on scientific grounds alone*". If we do not commit this sin, then redemption is possible for us in the realm of Evidence Based Medicine! To do so, we have to discuss the facts and fallacies about the learning process which is fed more and more – often indiscriminately – by EBM knowledge while confusing often the varieties, sources, grounds, and validity of this knowledge as well as its application in daily clinical practice. Again, this is by definition what an epistemological analysis could help avoiding.

The Learning Curve: another artifice?

A learning curve is a graphic representation of the relationship between experience with a new procedure or a new technique and an outcome variable, e.g. operative time, complication rate, hospital stay or mortality (Fig. 1). The learning (performance) curve is steep in its early part. As experience accumulates, the curve becomes flatter, with less marginal improvement with each additional experience because expertise has been gained. However, the shape (steep or slow rising slope) of the learning curve is, as would be expected, different according to the learner and the task. Furthermore, clinicians are hardly ever in full control of events; even if occasionally they are in a position to deflect them to their advantage. And this is more likely to happen if one has an updated knowledge of these "events". On the contrary, clinicians who are in real trouble will demonstrate a learning curve rising from left to right instead of dropping from left to right (Fig. 1).

Cyclical pattern of adult learning

Learning can not be restricted to the learning curve paradigm. Learning is a *process*, not an *event*. In other words, one does not become competent once and for all.

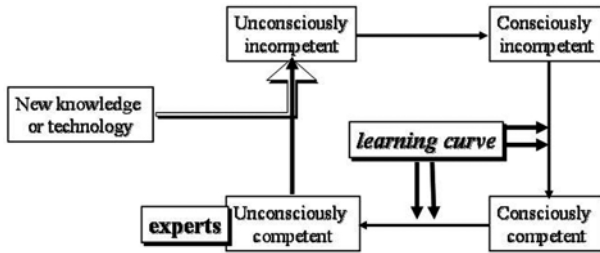


Fig. 2. — Cyclical pattern of learning

In fact, adult learning follows a *cyclical* pattern (Fig. 2). Before one is aware of the changes in knowledge or the apparition of an innovative technology, one is *unconsciously incompetent* about it. When one becomes aware of this innovation, one becomes conscious of the innovation but one is still incompetent with it: one is then *consciously incompetent*. Then, experience accumulates with practice and the individual becomes progressively *consciously competent*. Later on, with even more practice, mastery develops and the individual becomes *unconsciously competent* because he is so well familiarised with the new technique that using it is just a matter of simple routine. In other words he is now...an expert!

But the continuous development of new data, new hypothesis and techniques make the maintenance of competence a moving target. The clinician who just became an expert in a specific technique may not sit down on his expertness while preferring static and secure knowledge once and for all. In our preoccupation with innovation we should not lose sight of ideas and techniques, which have proved their worth and stood the test of time. As a consequence, continuing learning must be seen also as a routine part of daily practice. If not, from being initially unconsciously competent, the expert will rapidly become unconsciously incompetent again (Fig. 2).

Changes of norms and standards : moral skepticism in the current hospital and health care environment

The state of flux in modern medicine is not restricted only to innovative techniques and knowledge. The probabilistic (not quite sure) atmosphere is also challenging and fascinating for the practitioner at the social, economical, political, and moral level.

Those who cherish values and hold fast to moral norms and standards are not always reliable: we know that moral norms and standards can be changed overnight, and that all that then will be left is the mere habit of holding fast to something. Much more reliable will be the doubters and skeptics, not because skepticism is good or doubting wholesome, but because they are used to examine things and to make up their own minds. Best of all will be those who know only one thing

for certain: that whatever else happens, as long as we live we shall have to live together with ourselves. This evidence fits pretty well the description of physicians practising in the current hospital environment with its overnight changes of norms and standards, with its collapse of respectability, with its doubters and skeptics – either constructive or destructive –, with those people who do not care to live together with themselves, with those people who wash their hands of what is going on all around them. Or in a laconic phrasing: the hyper-individualism searching for instant gratification.

The Physician as the constant gardener of health care numbers and words

If we are to enter an era of constant change of norms and standards in the health care industry, we must comply with what could be considered as two other basic principles of EBM: that have been illustrated in politics and more recently by the US military involvement in Irak.

1. An *error* does not become a *mistake* until one has decided not to correct it (John Fitzgerald Kennedy, 1962)
2. *Discipline* is doing what is right when nobody is watching (Four Stars General Schumacker, US Marine Corp - May 7, 2004 at the US. Senate hearing about the army personnel misconduct in Irak)

Those two basic and simple principles are particularly useful considering the indiscriminate use of *words* and *numbers* as far as health care business is concerned (3,4). In other words, the loose and variable use of terms and numbers can interfere with discussion of the real issues.

Numbers

Numbers never make sense by themselves. To make sense, it takes at least that numbers were enlightened by a *comparison*. For instance, 10 billions Euros have been collected in some weeks for the casualties of the December 2004 Tsunami. It is altogether a huge amount of money and rather pathetic when compared to the overall World Ground Product of 36,000 billions Euros.

100 billions US.\$ have been dedicated for the 2005 New Orleans disaster by the federal government. It is a good move but a tiny one when compared to the 11,684 billions \$ US.2004 GNP. But it is really trivial when compared with the total US military spending for 2004: 502 billions \$! Indeed, we clearly have to relativize numbers. The real problem is the choice of society, thus political choices that should not be hidden behind selected numbers. And the problem is the same for the health care industry when we are told over and over that we are spending too much for it. We can do better to fairly allocate the spending, but is the overall cost of health care in modern societies really too high?

In 1942, Lord William Beveridge wrote in his plan for Social Security: "A social security system having respect for the value of liberty and in which each actor faces up his own responsibility". This was a three parameters equation: security (in front of the risk of diseases), liberty (of choice) and responsibility (of the health care providers and consumers). At the same time, Lord Anthony Eden wrote about the Beveridge's plan conclusions: "In time of crisis, anybody could favour general restrictions. But at the same time each one of us would tolerate special spending when it is in his own favour". Eden's sentence can be rephrased in 2006 as: "While we understand the need for belt-tightening, let's start with the other guy first".

This brings us back to the fact that *discipline* is doing what is right when nobody is watching. A sense of responsibility leading to genuine discipline is the only way to find the balance between «*what to pay for*» and «*who will pay for*». Because to skip parts of such a sensitive issue will call into question the baseline of solidarity, which is actually the cornerstone of our health care system.

Words

Confusion and misuse of words are the source of misunderstanding, mistrust, suspicion and conflict of interests between the numerous actors – who ideally should be partners – of the health care system (politicians, economists, doctors, nurses, paramedics). If we are to use the same words – such as quality, efficacy, effectiveness, efficiency – then it is worth giving them precise definition (3,5,6,7,8).

The *quality* of an health care intervention reflects its result in terms of health improvement; not only physical improvement but also social and psychical improvement, or to put it in other words: the improvement in terms of prevention as well as treatment of diseases.

A treatment will be defined as *efficacious* if its effects are demonstrated in the laboratory setting or, more widely, in a yet experimental environment which includes the clinical research setting. Efficacy deals with the potential effects of a treatment. In a strictly controlled research setting, efficacy allows to demonstrate that such a treatment produces a definite effect, often on an intermediate parameter (e.g. the volume decrease of a tumour in a mouse; the normalisation of the blood pressure or the glycemia in a clinical research setting about a new drug).

The *effectiveness-effectivity* bring us a step forward: a treatment is efficacious in a controlled research setting, but this treatment will be declared effective only if its efficacy is confirmed when the patient receives it in a setting of daily clinical practice (and no more in a research environment). Therefore, an effective treatment (or an effective diagnostic tool) is the one that has demonstrated its effects outside the strictly controlled research setting while reaching a practical clinical objective bringing eventually an improvement in the quality of care.

The difference between efficacy and effectiveness is important, because whether it is rather easy to demonstrate that a new chemotherapy (efficacious in a controlled research setting on mice) might well reduce the size of a tumour, on the other hand, to prove that this treatment is effective in patients as far as increased survival is concerned will often demand large scale and long survey (5). Furthermore, in these surveys, the final assessment criteria (end points) should also be qualitatively relevant from the patient viewpoint (life expectancy, comfort and quality of survival).

Such a treatment will be defined as *efficient* if it reaches its goal at the lowest financial cost. The efficiency is the ratio between: the allocated means (i.e. financial spending, technological investments) and the clinical results obtained (i.e. the effectivity). Efficiency is somewhat the ratio between the input and the output. "Efficient health care" means grosso modo effective care reached at the lowest cost and for the minimal spending.

Economical rationality versus clinical rationality

Efficiency is an economical concept, effectivity is a clinical concept.

However, according to the physician and/or the patient's viewpoint it can be judicious to choose the more expensive treatment because it is the more effective, despite the fact that it is less efficient according to the health care economist or manager viewpoint.

If the economical efficiency can be considered as a tool for saving in an environment of limited resources allocation, efficiency leads sometimes to suboptimal care in an era where economical rationality takes over clinical rationality. And as far as efficiency is concerned the control of spending and cost in one sector of health care often means displacement of cost and spending toward an other sector. Which can be summarised as «*cost containment is often just cost displacement*», without even knowing what is happening to the *quality* of care provided to the patients. An economical rationality that remains unaware of the clinical rationality – and vice versa – leads to irrationality in both fields.

The recent medical and surgical literature provides several examples of studies showing that innovative diagnostic testing or treatment were efficacious in the clinical research setting but did not remain effective in daily clinical practice. In addition, the use of those new techniques providing no effective benefit increases the total cost, hence the efficiency decreases.

The EBM tool is first of all a clinical tool. It should not be manipulated as an economical and/or political tool. This risk of manipulation will be illustrated in the next four paragraphs.

Relationship between cost and quality of care: positive or negative?

Early attempts to control health care costs were unsuccessful, in large part, because it was believed that

the relationship between cost and quality was strictly *positive*. In such a model, reducing health care expenditures would only reduce quality. Defining quality in health care was (and still is), however, somewhat elusive. Health care providers, including physicians and hospitals, claim high quality; yet similar claims are accompanied by significant variations in actual cost. Health care payers then reason that if the providers claim equal quality, they would simply practice good business by purchasing quality from the least expensive providers. As a consequence, the current belief of health care payers is that the relationship between quality and cost can also have a *negative* component and thus that quality and cost can move in opposite directions (5,6,7). However, while the same health care payers proclaim that they are as motivated as physicians by their concern for patients, asserting that reduced cost is simply a by-product of good management efforts (6), in fact their main goal is often cost containment, irrespective of potential drawbacks for patients (7,8).

Cost effectiveness analysis, quality of care and EBM

In line with this current belief, the use of *cost effectiveness analysis* – a method for plotting points on a curve and quantifying the direction of change in quality and cost that occurs with new or alternative modes of diagnosis or treatment – has been a foundation for health care policy changes, ignoring – too often – two essential patient centred concerns :

1. What is best for this patient ?
2. How should we distribute limited health care resources fairly ?

For the clinician, the method of health care policy making is overtly focused on patient care. The currently accepted method of *evidence based medicine* (9) – defined as the integration of individual clinical expertise with the best available external evidence and patient's values and expectations – has been accepted as a reasonable and rational way of making decisions about the care of a specific patient. Although this method seems straightforward, the devil is in the details because for most medical decisions, clear answer or guidance are not available, and the limited scope and ambiguous nature of available evidence introduce ethical concerns about the use of the evidence based framework for "decision making" in the quickly evolving art and science of medicine and surgery. These concerns arise from the types of decisions to be made, the type of practice within which they are to be made, and the nature of the evidence available and required for the decision making process.

What is clear is that in both managerial and clinical medicine, it is important – in applying *cost containment choices*, *cost effectiveness analysis* and the *evidence based medicine approach* to either clinical practice or health care policy – to avoid the twin pitfalls of hastily

rejecting the unproven and of creating a straightjacket of protocol driven medicine, thus arresting future progress. In the ultraliberal world physicians live in, this kind of seemingly protocol driven medicine, when applied to daily clinical practice, can be rather appropriately described by using *market metaphors* : now a good physician in the managed care paradigm is no longer a physician who successfully performs expensive and difficult tests or operations in high risk patients. A "good" physician performs only profitable techniques, balancing the budget of the health maintenance organisation (HMO) to which he belongs. In other words, from a managerial point of view, a good physician is one who is not spending the resources of the HMO, whose primary goal in a market environment is reducing cost in order to make a profit, or in a nationalised health care system (which in Europe is functioning more and more as an HMO) is saving public money by reducing spending. Physicians may be resisting EBM because they feel it is often guided by business tenets meant to manage costs, not care (6).

Cost effectiveness analysis and the EBM are nevertheless here to stay, but their potential to distort the doctor patient relationship is another cause for concern and an additional source of clinical risk. Historically, the physician has been the advocate of the patient (i.e. the personalized approach). The physician's top priority is to act in the best interest of the patient, acknowledging fully the importance of the patient's own values and perception of his or her health and decisions regarding it. Within this framework, EBM can be useful to the doctor and patient so long as it remains a tool that helps inform their decision making with only the patient's health in mind. However, when EBM is used only to evaluate decisions about resource allocation (i.e. the collective approach), there is a risk of EBM becoming a potent force that transforms the physician into an agent of the health service and the patient into a consumer (8). At such a system level, the physician becomes a double agent since one person's health care is another person's health cost – a double agent keeping his left eye on patient's needs and his right eye on the health care cost containment indicators. Furthermore, when the EBM approach is blindly linked to cost effective/benefit analysis it can lead to the routine rejection of the unproven and in the current market driven climate lead to cost containment to the detriment of the patients.

However, the tool of EBM can lead also to a more "rational" provision of diagnostic and therapeutic services, since it provides a focused and more efficient approach to the interpretation of research findings and translates them into clinical options. Consequently, EBM can provide the physician with a valuable tool for managing the knowledge base of medicine or surgery. This EBM approach focuses, nevertheless, on average and mean effects and rarely provides clear-cut guidance to help the physician tailor care and surgical intervention to the individual patient. Even more rarely does EBM provide guidance about how to respond to an individual

patient's values, priorities, and cultural needs. The potential role of EBM in resource allocation and health service management must be recognised by physician as that of a *tool*, which can enlighten their decisions and show reasonable trends for health care cost containment. It should not be seen as a *standard* by which decisions about the allocation of health service resources and the crafting of clinical research agendas and priorities are to be made. In other words, physicians should not become so bemused by analytical and statistical techniques applied to large amount of data and patients – for the purposes of EBM – that sight of a simple rule is lost : each patient should always be assessed and treated individually.

Border between macroeconomics and microeconomics : clinical effectiveness versus economical efficiency

To put it bluntly : even if there is no *rational* incompatibility between the components of the trilogy resulting from the fair and efficient containment of costs in health care, the evidence based medicine approach and the effective care of patients, it is obvious that the interconnection between these three issues is hedged about with the difficulties of defining, with transparency and coherence, what is the *reasonable* border between macroeconomics (which has to deal with political choices and economical feasibility) and microeconomics (which is confronted at the grass roots level with the ethical and deontological obligations of the clinician). Again, part of those difficulties are illustrated by the unconscious – but sometimes deliberate – confusion (3,7) of the concept of *efficiency* (which is an economical concept) with the concept of *effectiveness* (which is a clinical concept).

Nevertheless, we should neither put all the blame on incoherence between the micro and macroeconomics of health care resource allocations, nor confuse deliberately the semantics of buzzwords coined by and for the health care complex. It is precisely here that we have to resort to sound medical mystique, which does not mean an atmosphere of mystery and veneration investing the art of medicine and surgery or any professional skill designed to mystify and impress the lay person. But rather a mystique whose main feature is honest self criticism about the way clinical results are evaluated, the way innovations are introduced and validated, and about the way clinical and ethical principles are applied more or less strictly to some people or situations than to others, which is exactly how double standards arise.

Political responsibility versus clinical responsibility : the “cog-theory”

Hannah Arent (10) once made one concession to the reproach of irresponsibility levelled against the people who washed their hands of what was going on all around them, when she wrote : “I think we shall have to admit

that there exist extreme situations in which responsibility for the world, which is primarily political, cannot be assumed because political responsibility always presupposes at least a minimum of political power. Impotence or complete powerlessness is, I think, a valid excuse”. Here, physicians can share the analogy with Arendt's thoughts because, in the current health care world, they often have to assume personal responsibilities heavier than ever while they are more and more powerless at the political front. Furthermore, too often *personal* responsibility is confused with *political* responsibility. Personal responsibility must be understood in contrast to political responsibility which every government assumes for its deeds and misdeeds as well as for those of its predecessors. We would also agree that “the validity of the excuse of powerlessness is all the stronger as it seems to require a certain moral quality even to recognise powerlessness, the good will and good faith to face realities and not to live in illusions”. And we can continue to share the analogy with her thoughts that “those, who not only participate willy-nilly on whatever level and in whatever capacity in an organisation (e.g. an health care organisation) as it is but who think it is their duty to do whatever is ordered, are thereby implicitly denying the human faculty of judgement [...]. All governments, even the most autocratic ones, rest on *consent*, and the fallacy lies in the equation of consent with obedience. An adult consents where a child obeys ; if an adult is said to obey, he actually *supports* the organisation or the authority or the law that claims obedience [...]. Any organisation, any body politic (i.e. corps social) is constituted of rulers and ruled, and that the former give commands and the latter obey orders”. Max Weber once wrote that to save the chances for his orders to be executed, the man supposed to exercise authority in a rational system of legal domination will “normally” need and administrative structure : a bureaucracy (11,12). However, in a strictly bureaucratic organisation, with its fixed hierarchical order, it would make much more sense to look upon the functioning of the cogs and wheels in terms of overall support for a common enterprise than to look in our usual terms of obedience to superiors. Arendt called this the “*cog-theory*” (10) : “when we describe a system – how it works, the relations between the various branches, how the huge bureaucratic machineries function of which the channels of command are part and different forces are interconnected, to mention only outstanding characteristics – it is inevitable that we speak of all persons used by the system in terms of cogs and wheels that keep the administration running. Each cog, that is, each person must be expendable (disposable) without changing the system, an assumption underlying all bureaucracies, all civil services, and all functions properly speaking”. If we evaluate the system in its frame of reference, we can speak of good and bad systems. “Our criteria are the freedom, or the happiness or the degree of participation of the citizens, but the question of the personal responsibility of those who run the whole affair is a

marginal issue". However, as morality depends on freedom of choice, then in case there is freedom of choice for a person at the cog level, his personal responsibility is involved. And in case there is power and freedom of choice for a person at the leadership level, his personal and political responsibility are involved. Thus, physicians should not forget that "in a courtroom there is no system on trial, but a person, and if the defendant happens to be a functionary, he stands accused precisely because even a functionary is still a human being, and it is in this capacity that he stands trial". We know also that the small cogs, the first line soldiers (as the physicians are on the health care battlefield) can actually commit the most obvious crimes and would indeed become the scapegoat. Why? Because "in every bureaucratic system the shifting of responsibilities is a matter of daily routine, and if one wishes to define bureaucracy in terms of political sciences, that is, the rules of offices, as contrasted to the rule of men, of one man, or of the few, or of the many. *Bureaucracy unhappily is the rule of nobody* and for this very reason perhaps the least human and most cruel form of rulership. But in the courtroom, these definitions are of no avail. For to the answer: "Not I but the system did it in which I was a simple cog", the court immediately raises the next question: "And why, if you please, did you become a cog or continue to be a cog under such circumstances?". If the defendant wishes to shift responsibilities, he must again implicate other persons, he must name names, and these persons appear then as possible co-defendants because they also do not appear as the embodiment of bureaucracy. This shift of responsibilities is probably the most threatening aspect of the health care system evolution particularly for the medical profession. We must face an evidence; if we, as physicians, obey – without thinking – all the somewhat confused rules of the rapidly evolving health care system, we actually support its bureaucracy blindly. On the contrary, if we withdraw our tacit consent, if we refuse our support by shunning those places of "responsibility" where such support, under the name of blind obedience, is required, then in fact we disobey the rules of the system [...]. This is nothing new because "the potential in civil *disobedience* has been discovered during the XXth century, and it takes only a moment to imagine how effective a weapon this could be" (10). In certain circumstances, some degree of disobedience, which is akin to constructive activism, can be necessary to allow physicians to practise fairly their job while remaining the patient's advocate. Then, constructive activism is the legitimate expression of the professionalism of physicians assuming their personal and political responsibility, it is far from being radical corporatism.

Crossroads of personal and political responsibilities

Health care is a human good, not an economical commodity. The point, where some degree of disobe-

dience and of constructive activism is required from physicians, has now been reached if physicians are to continue imposing on them the obligation to do what ought to be done: to provide this human good and not to become the *supply side* of an economical commodity. In 2006, physicians have to face more and more ethical issues at the bedside despite the fact that the environment of privately or publicly managed care is said to be morally neutral. Generically, managed health care refers simply to any system that aims at constraints on the clinician's management of care to achieve some stated purpose. That purpose may take many forms: the quality of care provided to an individual patient, the personal well-being of the patient, the containment of costs, the welfare of society, or the making of profit. Some of these objectives are morally sound; some are morally reprehensible. Ultimately, the moral status of any system of health care will depend upon the purpose, the means employed to attain that purpose, and the priorities between and among purposes or means when they conflict with each other. Ethics of medicine is derived from the philosophy of medicine, which is derived from the practice of medicine, which is derived from the reality of medicine. In other words, ethical issues at the bedside are at the crossroads of personal and political responsibilities. In order to go safely through these crossroads, we need personal judgement while facing ethical conflicts and while choosing the best compromises between the caring dimensions of the patient-physician relationship. But as physicians are not practising in a desert, they must also be supported by the sensible and wise political judgement of people in charge of a democracy.

The socioeconomic aspect of the EBM criticism

Let us develop this criticism by focusing over an example about surgical practice.

From a clinician's point of view, laparoscopic cholecystectomy has rapidly appeared to be the best way to treat patients with gallstones. This technique has, however, also produced a shift in health care resources. In a 1994 study from Maryland (13), patients undergoing laparoscopic cholecystectomy tended to be younger, white, to present with less serious problems and to have private health insurance or belong to an HMO ($p < 0.001$). The very same kind of shift in health care resource allocation has been found in the countries of Western Europe since the beginning of the blitz of laparoscopic surgery in the early 1990s. This example is a clear illustration of the latent conflict that can arise between the macroeconomics of health care resource availability, with its related political willingness towards efficient and fair allocation, and the microeconomics of effective care delivered by first line practitioners fearing for their professional autonomy.

The same type of results have been demonstrated in Belgium by the National Survey on Cholecystectomy Related Bile Duct Injury (14,15). This type of study

clearly shows that the EBM tool has a rational political and economical impact that would be used more and more by health care payors if physicians do not wipe themselves their doorstep.

Innovation, patient vulnerability and Ethics

The problem is not only a semantic or a philosophical one where innovation in medicine and surgery is concerned. Innovation should also invoke morally troublesome issues for the medical or surgical innovator, even though a certain level of innovation is expected in our daily surgical practice when we encounter unanticipated findings: "We couldn't remove the obstructing tumour, but we were able to bypass it". Innovation is highly valued in our societies, but innovation in medicine or surgery can lead to unforeseen complications and raises three moral issues (7,16).

First, there is the profound trust that *vulnerable* patients feel toward their physician. Even when the physician innovates, the patient expects the physician to be his advocate for optimal care, not an advocate for innovative research or for some minimalist standard. The *risk* is that the physician will cease to be the *conservative guardian*, given to using traditional techniques that have been validated by years of experience. This trait is expressed daily in the operating room in many ritualised routines. Members of the operating room team constitute a moral community with strong implicit standards to protect the patient and the surgeon from danger, including dangerous innovations (8,16,17).

Secondly, there is the unbalancing effect of new procedures on traditional safeguards of medical and surgical competence. The term "*innovation*" has a seductive connotation of added value in our market society. There is even a class of patients who are psychologically disposed to seek innovative treatment because it is the *latest* and, by sometimes erroneous inference, the *best* that is available. In medical and surgical practice, however, the patient's preference is not the final word, even though patients behave themselves more and more like consumers. This is the reason why instead of using the word *innovation* we should use the term "*non-validated*" to describe the status of newly introduced procedures (8,16,17). The word non-validated accurately captures the sense of moral hazard that should be attached to the use of newly introduced procedures in vulnerable and trusting patients. "Non-validated" also implies that the expert medical and surgical community still has policies ensuring honesty and fidelity to trust, and that these apply to newly introduced procedures before they are widely accepted and validated.

Thirdly, there is an imperative need for a systematic approach to the evaluation of new surgical procedures and to the accreditation process of training. Under pressure from patients, equipment manufacturers, public media, and insurers – all of which have penetrated the sanctuary of the operating room, bypassing the strong

implicit standards of the moral community represented by the operating room team – surgeons may believe they are required to introduce non validated procedures they have learned in less than ideal forums, such as weekend courses or workshops sponsored by the industry. Often, accreditation of such training and the certification of the skills acquired are problematic. When innovative physicians return with uncertified skills to introduce non-validated treatments in trusting patients, we are denying the basic principles of medical ethics and we have a recipe for clinical disaster.

General conclusions

Clinically relevant attitudes and/or guidelines issued by a rational EBM approach are attitudes and guidelines that integrate *individual clinical expertise* with the best *available external clinical evidence* from systematic research and patient's values and expectations (9). These guidelines should aim to provide an unbiased summary of the evidences in order to respond to a clinical or health policy question, to identify gaps in the existing clinical research, and to improve the quality of new research (7,18).

Sir Miles Irving, director of the British NHS Health Technology Programme, proposed at the annual meeting of the European Society of Surgery in Berlin (7,18) in December 1999, the following list of priorities – the sequence of which is important to consider - that have to be met for a guideline to be considered as "*clinically relevant*": validity; reliability; charity and compassion; clinical applicability; patient and user involvement; linked to audit; reproducibility; clinical flexibility; scheduled review date; meticulous documentation, and cost effectiveness.

This list of priorities could be useful in transforming the actual reality of medical double standards. Furthermore, it is somewhat relevant – and reassuring – to note that *charity* and *compassion* are in third position and *cost effectiveness* in last position. In the world of managed care, physicians need to develop a health policy agenda that emphasises patient care issues (i.e. availability; freedom of choice, and the patient's best interests) above provider's or payer's interests. Nevertheless, they are also required to enhance their education programmes and the continuing objective assessment of the way medicine and surgery are performed and transformed. They should also assume an increased leadership role in developing critical evaluation of non-validated techniques by favouring the development of sound clinical trials and by considering EBM not as a weapon turned against, or targeted at, the medical profession, but as a valuable tool that may provide some answers to chronically unresolved questions which persist in the art of medicine and surgery (19).

EBM is not "cook book medicine", but can provide guidelines and check lists for optimal patient's care. For *evidence based medicine* to become also *consensus*

based medicine, several steps have to be followed : formulation of precise and answerable clinical questions ; searching the literature for current best evidence ; assessing the validity, impact, and applicability of the information obtained ; and sitting down and discussing in order to confirm that *evidence* based medicine is really *consensus* based medicine, which introduces more than a simple nuance between *rational* and *reasonable* medical practice. However, to follow this process in order to make choices more coherent will require not only energy and creativity but also time. And as time is money, the health authorities should finally consider the efficient funding of clinical research, which in return could prove to be effective investment in terms of health care for the population and sound efficient choices in term of resource allocation (3,4,7,8,17).

If *mystique* is the atmosphere of mystery and veneration investing some doctrines, arts, profession or people, it can also denote any professional skill or technique designed or able to mystify and impress the lay person. Hence the sequence of the priorities proposed by Miles Irving (18) could be helpful firstly to stop mystifying the lay patient, and secondly to reverse the current trivial socio-economic trends in the health care business in which the name of the game is sometimes to avoid caring for sick people by enrolling a disproportionate number of relatively healthy patients – “*creaming*” –, or by reducing the contingent of very sick and high risk patients – “*dumping*” (19). Above all, such a sequence or priorities could help keep alive the enlightening mystique of the art and profession of medicine and surgery : “*The secret of patient care is in caring for the patient*” (20).

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