books & ideas.net

The Human Element vs. the Standardization of Medical Care

Élie AZRIA

Originally conceived to help physicians make enlightened decisions, evidence-based medicine in North America and elsewhere has become a risk management method fostering the standardization of medical practice and the dehumanization of relations between doctors and patients.

In the wake of the development of epidemiology and clinical research, scientific rationality increasingly prevails in the practice of medicine, emancipating it not only from mystical and magical beliefs, from traditions and certain dogmas that appeared to be unassailable, but also from the vice grip of manufacturers of all manner of purportedly beneficial medications.[1] Clinical research has developed so much, both quantitatively and qualitatively, that clinicians now find it difficult to get their bearings amid the profusion of knowledge it has produced. This difficulty is due to the sustained pace of publication of scientific research, the tremendous variability thereof in terms of scientific relevance, and epidemiological methods and statistical analysis that have become increasingly complex and inaccessible to non-specialists. To help physicians cope with the difficulty of choosing the findings most relevant in treating a given patient, evidence-based medicine (EBM) grew up in the early 1990s around a group of epidemiologists at McMaster University in Ontario, a method that was to catch on in the medical profession and claim the status of a new standard of medical practice. Its authors and advocates defined it as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."[2]

EBM rates evidence based on the research methods employed,[3] the conditions under which the experimental design is carried out, and any biases detected. So EBM takes an analytical and critical approach to knowledge drawn from scientific publications and assigns to research results – and to the ensuing recommendations for the provision of care – evidentiary quality levels on which doctors can rely in making decisions. At the outset, it was supposed to be pedagogical. The idea was to train practitioners in selecting scientific knowledge and using it in clinical practice, particularly by training them to read the literature critically to ensure that doctors would have

[1] Cf. Marks, H., *La médecine des preuves, histoire et anthropologie des essais cliniques (1900-1990)*, Empêcheurs de penser en rond, p. 65.
[2] Cf. Sackett, D., *Evidence Based Medicine*, New York, Churchill Livingstone, 2000.
[3] The studies yielding the highest-quality evidence in this hierarchy are "double-blind randomized" trials, which are used in developing drugs and patient care systems as well as in assessing the effectiveness of a medical approach or treatment. The point of double-blind randomized trials is to minimize the influence that certain information (use of active ingredient or placebo, for example) might have on the measured variables if known to the patient (first "blind") or to the examining physician (second "blind").

some measure of critical autonomy in the face of a wealth of knowledge that was becoming more and more abundant, technical and difficult to use.

But as the EBM paradigm met with mounting success in North America, Europe and Asia, doctors were gradually steered towards an increasingly procedural approach to medicine, i.e. a practice of care increasingly circumscribed by protocols. They were complying with the express will of the supervisory authorities and public or private-sector insurers to rationalize medical practices by standardizing them. It now appears quite clear that the objectives were none other than to implement neoliberal-style health care management systems borrowed from the industrial sector and the theories of New Public Management (NPM).[4] To manage health care, like any industrial process, practices had to be standardized by establishing a procedural approach to care, which required a solid and convincing basis for the care givers to go by. In a procedural system based exclusively on confirmed scientific data that were far from covering the whole field of medical practices, the uncertainty attaching to the use of scientific knowledge in clinical practice had to be minimized, even systematically negated.

EBM to deny uncertainty

EBM, originally a mere meta-methodology that made allowances for the uncertainty of medical knowledge, has gradually moved away from its pedagogical objective in order to comply with this demand for the standardization of medical practices. It has prioritized efforts to draw up summaries of medical knowledge, then recommendations, reference material and protocols for the treatment of various diseases and conditions.[5] Forgetting its original mission, which was to train practitioners and guarantee them a certain critical autonomy in dealing with a profusion of scientific knowledge that was difficult to handle, EBM soon became the generic name for a system that produces and prescribes medical standards, thereby becoming an instrument of this drive to standardize care-giving practices.[6] But to endow this uncertain knowledge, which should have been tested and contextualized, with the force of law within a framework of more and more restrictive protocols was a way of laying the groundwork for the minimization, even the negation, of the uncertainty attaching to that knowledge, an uncertainty that is not disregarded in a rigorous scientific approach. Thus, EBM was diverted from its initial purpose and instrumentalized in a bid to standardize clinical practice and thus negate – or rather deny – the uncertainty attaching to knowledge.

However, despite the considerable advances in clinical research, the clinician remains, and cannot but remain, unsure about how to treat a given patient. This abiding uncertainty stems from the ways in which scientific knowledge is produced as well as disseminated and applied. Purely

---

[4] Cf. Bezes, P., "*New Public Management* made in France" in *L'hôpital en réanimation*, Éditions du Croquant, Paris, 2011. This book was reviewed by Aurélien Bordet (N.B. in French) in *La Vie des idées* (February 13, 2012). (http://www.laviedesidees.fr/L-hopital-mis-a-mal-par-le.html).

[5] This protocol-producing activity is so inflated that acts of care not governed by such a protocol have now become few and far between.

[6] Gordon Guyatt, one of the founders of EBM, is well aware of this development. His remarks are quoted by Daly J in *Evidence Based Medicine and the Search for a Science of Clinical Care*, 2005: University of California Press, p. 90-91: "When I started, I thought we were going to turn people into evidence based practitioners, that they were really going to understand the methodology, that they were really going to critique the literature and apply the results to clinical practice. I no longer believe that. What I believe now is that there will be a minority of people who will be evidence-based practitioners, and the other folk will be evidence users."

rational answers are far from being available all the time because, first of all, to this day the scientific approach only covers a small number of medical questions, some of which are not amenable to current research methods. Furthermore, this is because the reasoning underlying the clinical research approach, an intrinsically inductive reasoning, can only produce knowledge that is conjectural in essence, with truths that are merely probable, based on evidence of varying quality.[7] Consequently, data drawn from retrospective case studies cannot claim the same scientific validity as data from a study experimentally testing a randomized intervention. Statistics, which have become the principal tool of clinical research, make it possible to model uncertainty, but by no means to eliminate it. Lastly, if there are experimental designs in clinical research that make it theoretically possible to control fully for biases, in their application they are inevitably confronted with the contingent nature of a field in which uncertainty increases to the extent that the internal validity of the research is compromised by difficulties encountered in practice by the investigators. However rigorous researchers may be, we must recognize and accept the fact that man, the subject of this clinical research, cannot control his every parameter.

The matter becomes a bit more complicated once we begin to factor in conflicts of interest that may affect certain researchers. Commercial conflicts of interest often occur in medical research, a world characterized by widespread interference by the powerful pharmaceutical industry. But there are other conflicts, too. In an academic world dominated by bibliometric indices, scientific integrity, even the ethics of research and care, may go by the board in the rush to publish,[8] thereby vitiating the reliability of the findings and consequently the soundness of any medical decisions based on those findings. From the most minor and unwitting cutting of corners and scientific compromises to outright graft, a whole gamut of unprofessional behavior can significantly undermine the validity of scientific knowledge, as certain studies have shown.[9]

The application of this general knowledge in patient care ultimately gives rise to another form of uncertainty. When available, the knowledge gleaned from clinical research should help provide a foundation for doctors' decisions, but cannot be the only such foundation. Medical practice actually needs to bring two worlds together: one is scientific, the world of generalities and multiple cases, population studies, probabilities and other risk modeling. The other, limited to the individual patient, to the expression of his or her particularity and variability, is that of affects and the unquantifiable. Medicine involves constantly going back and forth between the uniqueness of the individual and the multiple nature of scientific knowledge.

---

[7] The problem of induction, a crucial problem in contemporary epistemology, was set forth by David Hume in *An Enquiry Concerning Human Understanding* (1748). To combat the skepticism that might be engendered by this exposure of a logical gap in the reasoning presiding over every approach to knowledge production outside the framework of formal science, a number of scientists and philosophers have strived to resolve this problem, including the neopositivists of the Vienna circle around Moritz Schlick, and Karl Popper, who was to come up with one of the most persuasive responses. Despite these philosophical exertions, the problem of induction also gave rise to a movement relativizing the specificity of what science can say about the world.

[8] As Jean-Michel Berthelot points out, "Recognition is without any doubt the main symbolic gratification in the field of science, and it would be naïve to think that researchers are indifferent to it. It is also the precondition for access to material and positional advantages that mark out a career and find expression in increased remuneration, powers and audience" (Berthelot, J.-M., *L'emprise du vrai*, PUF 2008, p. 100).

[9] Cf. Martinson, B.C., M.S. Anderson, and R. de Vries, "Scientists behaving badly," *Nature*, 2005, 435(7043), p. 737-8. Based on a study, the authors show that the pharmacological and medical research sector is particularly plagued by scientific fraud and criminal behavior, probably owing to the sizeable financial stakes involved.

Denying scientific uncertainty reflects a warped conception of knowledge. While it does make it possible by means of specious certainties to standardize practices and alleviate the anxiety afflicting clinicians in their everyday efforts, it turns them into agents no longer capable of viewing scientific research with the requisite critical detachment and compelled instead to submit to evidence-based recommendations. They become, in short, mere executors. Such a development cannot but sterilize creativity and hamstring the potential of clinical research. The upshot is to base care on a foundation that is less stable than it would seem, which ultimately poses a threat to the patients' best interests.

Dehumanizing care

The problem of the production of standardized knowledge is exacerbated by the problem of its application to care. The two are inextricably bound up together: denying the inherent uncertainty of knowledge already betokens a desire to eliminate the human dimension of care. The scientific method proceeds from objectification, i.e. an approach that effaces the observer and foregrounds the object of study instead. This approach concerns clinical research as well, in which the double blind principle is the most demonstrative illustration. Now, recognition of the multiple factors that inevitably limit the extent to which the observer can efface himself, a recognition that actually bolsters the validity of knowledge, ought to be an integral part of the scientific approach. However, whether owing to ignorance or to the above-mentioned conflicting interests, the lingering existence of this subjective element is very frequently minimized, even denied. While infringements of objectification procedures are indeed sources of bias and mar the internal validity of the knowledge produced, negating these biases has the effect of lending essentially fragile results a veneer of robustness they do not actually deserve. On the other hand, discussing and allowing for the biases that will necessarily limit the objectivity of an experiment amounts to recognizing the role man plays in the empirical approach. The negation thereof is not only testimony to a profound misapprehension of how science works, it also authorizes the widespread deployment of this standardization process, the effect of which is to reduce the patient to the standardized name of their illness or condition.

In focusing on the illness, defined according to highly precise nosographic criteria, at the expense of the individual patient, we forget all the contingency, complexity and singularity introduced by man in the way he experiences his illness and responds to his treatment, even in his preferences. The patient is thereby stripped of his humanity and viewed more as an epidemiological statistic than as an individual being cared for.

We should at this juncture point out the paradox of a progressive epistemological development that has led scientific knowledge to determine what sort of care to provide for the patient's greatest good, but which has given rise, conversely, to a dehumanization of the patient. This paradox stems from the scientific approach and from clinical epidemiology, which, in order to build up knowledge, has no choice but to base its findings on population studies through the study of sample populations. This approach is fundamental, but must not be exclusive, lest it confine care givers to a narrowly epidemiological view of the patient and lose in pertinence as a result.

The clinician's own humanity, which expresses itself in his judgment on each unique medical situation, remains the last bulwark against the aforesaid dehumanization of the patient and of the

care relationship. This bulwark is at risk of crumbling as well, under siege from the procedural view of care. The process of the standardization of medical practice is indeed based on the deep-seated notion that human beings are fallible, so the only way to make systems fail-safe is to get rid of the "human factor." While there is no denying the first part of this postulate (man is unquestionably fallible), the second part is more objectionable, elevating science and technology to the role of infallible guardians of truth. This notion, already very widespread in a number of industrial sectors, has blown up out of all proportion in the management of health care activity. It is a modern-day form of positivism that places unstinting trust in the products of science and its ability to produce truth, and once again denying the uncertainty attaching to the production of knowledge that is by nature conjectural, limited and provisional. In so doing, it views man almost exclusively through the prism of his fallibility, his irrational nature and his propensity for disturbing what are otherwise smoothly functioning systems. In this conception of man as a source of irrationality, contingency and, ultimately, risk, what other option is there but to circumscribe him, and even remove him? Removing the human element appears to be the means to secure the dependability that our administrators and supervisors measure by means of indicators. Thus, the principles of risk management that have been imported into medicine from the industrial and aeronautic sectors go hand in hand with the standardization of care and the systematic and methodical denigration of the human element present in each clinician. This denigration involves belittling the clinician's experience and judgment, and making arrangements to ensure that he is interchangeable. The risk managers seek to minimize the clinician's autonomy in order to maximize the system's failsafe reliability.[10]

The standardization of evidence-based care is a way of eliminating man from the decisionmaking process, an elimination regarded as a prerequisite for controlling risk and expenditure. Through the increasing predominance of protocols, recommendations for clinical practice, consensus conferences and other guides to best practice, the activity of clinicians is becoming all the more standardized and narrowly circumscribed to the point of significantly reducing their autonomy. Their judgment is completely devalued as a result of the mounting influence of these syntheses by knowledge experts, upon which practitioners have precious little opportunity to express a truly critical opinion. Their autonomy is all the more restricted insofar as the experts' ascendancy is compounded by that of the medical profession as a whole, which, despite its beneficial effects, also has the effect of devaluing the individual practitioner's judgment.

Ultimately, it is the clinician's decisionmaking capacity itself that is at risk. In the program whose contours are taking shape before our eyes, the practice of medicine will be confined to procedures established by experts and applied by practitioners who are reduced to being mere "intelligent gorillas," to use the term Frederick Winslow Taylor coined to describe factory workers circumscribed by his procedures. This approach prioritizing the management of "quality" and cost indicators on a collective scale entails sacrificing the idea of "customized care." Now, unlike traditional sacrifice, accepted in principle by a whole society that is convinced of its effectiveness and expected benefits, the sacrifice described here, in which the victim is not a substitute but an actual human being, is knowingly accepted only by its executors and justified by the adduced arguments of rationality, profitability and effectiveness. In the present case, however, this type of transaction is ethically unspeakable and cannot lay claim to any legitimacy

[10] Cf. Amalberti, R, *et al.,* "Five System Barriers to Achieving Ultrasafe Health Care*," Annals of Internal Medicine*, 2005, 142(9), p. 756-64.

whatsoever in a society that is supposed to place the human being at the very top of its hierarchy of values. To dodge the contradiction between this accepted rationalistic mindset and the unspeakable sacrifice it entails, the latter is concealed through a rhetorical manipulation of the term "quality." Behind this watchword "quality" and all the newspeak that goes with it, we see in fact a set of terms and indicators designed to quantify and assess health care, in other words to subject care to a mercantile and fail-safe rationale leading to convergent behaviors and the success of the undertaking to standardize health care.

An illustration of the standardization of medical practices

For over four decades now, obstetricians have been grappling with the question of the best method for the delivery of a fetus in case of breech presentation. In order to reduce neonatal risk, would it not be preferable to suggest to women whose fetus is in breech position at term to undergo a caesarian section before they go into labor?

Although prior to the year 2000 there was not a single study of the matter on which to base a standard of care, a publication in the renowned British journal *The Lancet* changed the situation.[11] The Canadian team conducting the study summed up their findings thus: "Perinatal mortality, neonatal mortality, or serious neonatal morbidity was significantly lower for the planned caesarean section group than for the planned vaginal birth group." Their conclusion was that every woman with a fetus in the breech presentation at term should be advised to undergo a caesarean section. Although this is a study whose experimental planning (randomized trial) meets the highest methodological standards, it remains extremely questionable owing to a number of biases.[12] Nonetheless, it led to the publication of recommendations systematically imposing a caesarian in several different countries. Some of the biases undermining the study's conclusions are significant. Not least among them is the fact that the study took into account neonatal mortality related not to the approach to delivery, but to congenital malformations, which were more numerous in the group of women assigned to planned vaginal birth. Also questionable is the training of the participating practitioners in breech presentation delivery, seeing as handling such deliveries was far from being routine in a large number of the participating medical centers and that 18.5% of the women who delivered vaginally were attended by doctors in training, and not experienced obstetricians. The latter was not only a breach of the protocol stipulating that the trials would be conducted only at centers where an experienced obstetrician could oversee these deliveries. It was also a bias inasmuch as this deviation from protocol is likely to have altered the results, and neonatal morbidity in the group of women assigned to vaginal birth could have been reduced by observing this important point of protocol.

No study is proof against bias, and we see here how negating the uncertainty linked to multiple biases in this trial led to the dissemination of a recommendation purportedly based on solid

[11] Cf. Hannah, M.E., *et al.*, "Planned Caesarean Section Versus Planned Vaginal Birth for Breech Presentation at Term: a Randomised Multicentre Trial. Term Breech Trial Collaborative Group," *The Lancet*, 2000, 356(9239), p. 1375-83.

[12] The limitations and bias in this trial have been pointed out by several authors, notably Goffinet *et al*. (*Breech presentation: Questions raised by the controlled trial by Hannah et al. on systematic use of cesarean section for breech presentations*. J Gynecol Obstet Biol Reprod, 2001. 30(2): p.187-90), Van Roosmalen *et al*. (*There is still room for disagreement about vaginal delivery of breech infant at term.* BJOG 2002;109:967-9), and Glezerman (*Five years to the term breech trial: the rise and fall of a randomized controlled trial.* Am J Obstet Gynecol 2006; 194:1039-42).

scientific facts, thereby making it possible to standardize obstetric practice in a large part of the Western world.[13]

While not a single scientific publication today can say a caesarian section is preferable to vaginal delivery, the know-how required for the practice of the latter is such that it has appeared necessary to care managers to endorse a systematic approach which any doctor is expected to be able to perform, namely a caesarian. In so doing, they have not only restricted the clinicians' individual autonomy, but also contributed to the disappearance, by breaking a chain of knowledge transmission, of an "artisanal" practice requiring practical skill above all. Far from being scientifically grounded, this choice underestimates clinicians' ability to identify women who might be well suited for vaginal delivery and wholly ignores the individual conditions and preferences of pregnant women.

Conclusion

While the criticism levelled here at efforts to standardize EBM-based care might seem aggressive, it is by no means our object to deny the considerable progress and value of an approach that draws on data from clinical research. On the contrary, medical practice must make full use thereof. In this regard, EBM as envisaged by its founders, i.e. an approach that involved giving clinicians the requisite tools to get their bearings amid the increasingly complex profusion of data from clinical research and to help them judiciously work the data into their daily practice, would have been invaluable. Unfortunately, however, in a context dominated by the ascendancy of what is known as "new public management," which seeks to standardize the practice of patient care in order to control costs and risks more effectively, the EBM system has been diverted from its pedagogical purpose, which was to train clinicians in the critical interpretation of these data. On the contrary, the whole EBM enterprise has become a means of generating standards and, as a result, the strong arm of the campaign to standardize health care.

Rationalization can be construed in various ways: as the transformation of action into action that is consistent with what has been rationally demonstrated, hence as an endeavor to shake off the influence of emotions. It can also be understood as a drive to maximize quantifiable interests. In proposing to place medicine on a solid rational foundation, these two components of rationality have been combined, and the former (the quest to eliminate emotional input) soon instrumentalized and subverted by the latter (the bid to maximize quantifiable interests). The rationalization of care thus morphs into a business whose profitability is gauged in terms of such criteria as economic cost, reliability and quality – the latter two having been transformed in the process, through the use of indicators, into quantifiable criteria just like cost. Where scientific arguments are advanced in a normative mode and formalized in increasingly coercive reference documents, the object is clearly to gear the practice of care towards satisfying these indicators.

[13] As shown by Rietberg *et al.* (*The Effect of the Term Breech Trial on Medical Intervention Behaviour and Neonatal Outcome in The Netherlands: an Analysis of 35,453 Term Breech Infants*, *Bjog*, 2005, 112(2), p.205-9), this trial had a major impact on obstetric practice in terms of increasing the use of caesarians for breech presentation. In addition to these results, which were published in a prestigious journal, its impact on medical practice has been further amplified by the recommendations published by certain learned societies, including the American Congress of Obstetricians and Gynecologists and the Society of Obstetricians and Gynecologists of Canada (SOGC).

As we have seen, transforming scientific arguments, which are always fragile and falsifiable, into standards involves a certain denial of the uncertainty attaching to clinical research data. Imposing more and more care protocols on clinicians, thereby restricting their critical capacity, has the effect of denigrating experience, clinical judgment and the expression of sensitivity on the grounds that these human abilities are not standardizable or universally identical. Consequently, they are regarded solely as potential flaws in the system, which is an untenable position if the individual patient is to remain the priority in providing care. This bid to eliminate the "human factor" by negating the clinician's intelligence, to reduce him to an agent whose conduct is dictated by protocols, might succeed in controlling indicators designed to assess risk or health care costs. But the individual will ultimately be the one who loses out in this epistemological development, which, by changing the nature of medical knowledge, has made the individual the instrument of this standardization. By seeking to drive out the skilled artisan that exists inside each clinician and retain only the evidence-based agent, we are radically changing the face of care. It is no longer a matter of the relationship between two individuals jointly seeking to find the medical option best suited to a situation that is always unique, but the relationship between an interchangeable clinician, transformed, to use Amartya Sen's expression, into a "rational idiot" uncritically applying set protocols, and a patient reduced to objective and similarly standardized clinical and paraclinical parameters, in sum to a dot on a bell curve.

The elimination of such artisanal skills as delivering breech babies follows this logic of rationalization and standardization. However, the elimination of *praxis*, the sole point of confrontation between theoretical models and the contingent nature of reality, is untenable in a discipline like medicine whose full scope cannot be covered by science alone. The two components of medicine are art and science, and they must strike a balance in a dialectical relationship. Preserving artisanal know-how and revalorizing clinical judgment and experience against the forces of standardization, whose methods bear an uncanny resemblance to those of industrial rationalization, means preserving an approach to care that prioritizes the individual, who tends to be forgotten in the new public management of care.

And yet there is no call for pessimism about these latter-day developments. Without by any means denying the confidence we may have in science and in the possibilities of clinical research, the object here is to reaffirm the confidence we may have in man as well. That medical rationality needs to acknowledge its own limitations should not cause any shame about what might be perceived as the failure of an aspiration. Through the power it has acquired, medical rationality has furnished all the evidence necessary for its legitimacy and cannot be fundamentally called into question by these objections to a rationalism that is repeating the mistakes of positivism. Admitting uncertainty should not be cause for shame or denial, but should be considered chiefly, with regard to medical knowledge and the practice of care, as an epistemological and ethical challenge.

Published in Books&Ideas, 5th June, 2014. Translated from the French by Eric Rosencrantz, with the support of the Florence Gould Foundation.

First published in French in La Vie des Idées, 26th June 2012.