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Evidence and the industrialization of medicine

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Summary

Medicine is changing rapidly. In part, this is due to the accumulation of discoveries in biomedical science. However, this is not sufficient to explain the changes clinicians see. Whereas once medical advance concerned discoveries external to clinical practice (such as the identification of a causative microorganism or gene), medical practice *itself* is now a subject of study. What clinicians know, how they acquire knowledge, and how knowledge is distributed are all subjects of scrutiny. In short, medicine is being industrialized: we can see the twin changes of specialization, and the desire to codify practice such that those with different educational backgrounds can undertake a clinical role. Key to such change is the role played by evidence. Whereas once natural science was seen to determine clinical practice, this view is now known to be mistaken. How we can formally combine evidence from different traditions is, despite the claims of the evidence-based medicine movement, as yet unresolved.

Introduction

It is a platitude to remark that medicine is living through an age of unparalleled scientific discovery. There are more researchers, more journals and more drugs than ever. In the 21st century, science and medicine are both big businesses. From the viewpoint of the individual clinician, the practice of medicine also seems to be changing rapidly and it would be natural to imagine that these changes in clinical practice are simply a result of progress in medical science and technology. If this viewpoint is correct, what one does in the clinic is different this year from last because of the accumulation of new scientific knowledge.

Many clinicians and other observers feel, however, that the above explanation is not the whole story. To give some examples: questions about how care is organized, whether doctors' tasks can be performed by other staff, and how to choose between patients for limited resources (rationing) all seem to be issues at the forefront of change in a way that they were not in the past. Whereas once the identification of a causative microorganism or gene led to a change in clinical practice, such changes concerned matters 'external' to doctors' own professional standing. To be sure, it was the medical profession that implemented advance, but these advances were themselves about the 'external' natural world – not about the physicians. Things look very different now for it seems that the practice of medicine itself – how physicians are trained, how they work and how well they work – commands widespread scrutiny. It seems that a background in natural science is no longer the passport it once was to lifelong professional independence. Worst of all, it sometimes appears that the organization of clinical care is more a matter of politics than medical expertise.

I will argue that these changes, real as they are, need to be viewed with more breadth than they often are, and in a historical context. The central issue I suggest is one of medical epistemology, the study of how we acquire, disseminate and distribute medical knowledge and expertise. Medicine, is primarily a knowledge-based activity and it, like so many other activities, is being industrialized.[1,2] Change in medicine is increasingly driven by the twin forces of specialization, and the desire to codify medical practice, i.e. to produce rules that can be followed by those from a range of educational and

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professional backgrounds.[2] The battle is over the intellectual heartlands of clinical practice and how the knowledge that underpins clinical practice is acquired, distributed and validated. Medical knowledge is no longer synonymous with training in anatomy, physiology or molecular genetics. I will use two historical examples to set the scene.

How do you choose an annuity?

The idea that age is not a key determinant of the price of an annuity would seem bizarre to the modern observer. We are used to the idea that age, alongside other demographic information such as gender, is a key predictor of most illnesses, and consequently, of life expectancy. It was not always so. Before John Graunt's publication of *Bills of Mortality* in 1662, the established way to price an annuity rested largely on intuition and what we would all recognize as clinical judgement.[3,4] The individual's demeanour would be observed, his accent and where he resided noted, the cut of his attire would provide information about his wealth, and so on. Local knowledge was paramount. The sale was concerned with an individual, not a population. Graunt's publication and subsequent life tables changed all of this, although the change was resisted for several centuries.[3] But just look at how an annuity can be purchased in the current day. Age and gender, with or without some other easily obtained variables, can be fed into an internet page and a purchase made in seconds. What was once an intuitive skill has been replaced by a simple codification, and the algorithms work better and are cheaper.

What determines the supply of health care?

For much of the 19th and 20th centuries, the answer to what determined health care appeared self-evident. Science provided an explanation for illness and sometimes the means to ameliorate disease. If the patient had disease X and presented to physician Y then the appropriate treatment Z would be delivered. This is what doctors knew: if the patient presented to physicians other than Y, then the therapeutic course would be the same.

If anybody ever felt this view was accurate, these beliefs were dashed by the publication in 1973 of John Wennberg's study of variation in medical practice in the USA.[5] Originally submitted to (and rejected by) the *New England Journal of Medicine*, Wennberg's paper was published in *Science*.[5] It has since been recognized as a classic, once again showing that the history of scientific advance is often the history of papers and ideas that were initially rejected.

Wennberg had been interested in the supply of particular types of health care. Historically, people would have said the supply of care (such as the number of operations) would reflect the burden of disease. What Wennberg found was different. He found that the rates of common elective surgical procedures varied in ways that were not explicable in terms of the distribution of disease. It appeared that physicians were not agreed on when, and how often, treatment Z should be provided for disease X.

Why should John Wennberg's work be considered so revolutionary? Simply because whereas once doctors had paraded their training in natural and clinical science as a justification of clinical behaviour, it was now clear that other factors were at work. Doctors were no longer external and independent to the problems of healthcare but, in fact, their actions, their very clinical behaviour, was now under inspection. This in turn led to a family of cognate questions. What evidence underpins clinical practice? How is this evidence gathered, and how well do doctors stick to this evidence? Given that there is variation in practice, how can standard operating protocols be put in place? In other words, how can the medical product be made both more efficient, uniform and provided at lowest unit cost?

How do we acquire the knowledge that underpins medical practice?

There are two traditions that have underpinned the acquisition of medical knowledge in modern times. The first and oldest, we can easily date from the mid-19th century.[6] It is the one that is so familiar to those who have passed through medical school, namely that of experimental physiology, a discipline that we can trace back to Claude Bernard and earlier. It is this tradition that is reflected today by the wealth of scientific work in genetics and cell biology. It is this approach that tells us that filaggrin is a key determinant of the skin-barrier function and that mutation of filaggrin leads to atopic dermatitis.

There are limitations to this approach, however. It lends itself poorly to scaling up to the level of the whole person or clinical encounter, let alone the population. We can rarely make quantitative predictions from the actions of a single molecule up to the scale required to look at health and health systems in populations. John Ziman recounts how John Tyndall, the British physicist, believed that it would be possible to predict *Hamlet* from a knowledge of the forces between the atoms in a mutton chop![7]

We now know however, that the world is not simply predictable from the micro to the macro. The issue of how to deliver ultraviolet (UV)B phototherapy provides a timely dermatological example.[8] The identification of the molecular mechanisms that underpin a cell's response to UVB and the resulting DNA damage has been one of the hottest areas in cell science for the past 25 years, but, despite this, we have no quantitative theory that comes anywhere near explaining how phototherapy works nor whether different wavebands of UVB will be more or less carcinogenic, nor whether giving phototherapy two or three times a week is preferable.[8]

The second tradition of knowledge acquisition complements the first. This is the tradition that traces its history back to R. A. Fisher (and beyond) and agricultural statistics, and that led subsequently to the development of the medical randomized controlled trial (RCT) by Austin Bradford Hill and others in the mid-20th century.[3,4,6] It is salutary to note how recent the development of statistical methods were to the development of much mainstream medical science.

These two approaches, those of experimental physiology and those of statistics, are both seen as indispensable today to produce the evidence that underpins clinical practice. However, as I will explain, they are neither sufficient nor is it clear how we integrate evidence from these different approaches.

The crucial role of evidence and the problem of how to summarize evidence

Having set the scene, I will now try and bring the disparate strands of my argument together. I have argued that medicine is being industrialized. A key feature of this is that the practice of medicine is becoming increasingly specialized, thus tasks can be specified and undertaken by those who, in comparison with historical norms, have less education and less training.[1,2] Specialization in this sense requires that medical practice is codified, and that actual practice is based on this codification. This implies that practice is increasingly uniform and that there is a clear audit chain from the acquisition of evidence through to clinical practice. It is for this reason that the role of evidence and how that evidence is produced, stored and validated has assumed such importance.

People often think that the need to assess treatments using RCTs and to synthesize evidence to produce guidelines is motivated by concerns over cost or therapeutic efficacy. This is indeed part of the reason, but the bigger picture is that evidence assumes such importance because it is the framework upon which care can be made more specialized and the behaviour of that system audited. Explicit evidence and documentation, rather than clinical intuition, is what links discovery through to delivery. This process raises a number of issues, into which clinicians, more than any other group, have insights. I discuss some of them, briefly, below.

At the beginning of the 20th century physicians accounted for about 1 : 3 of healthcare workers. By the early 1980s, the ratio had fallen to 1 : 16.[9] This trend will continue as the range of skills that are required in modern medicine increase, but a major driver will be the attempt to replace physicians with a lower cost, and in some respects, a more flexible labour force. The specialization of labour, and its reliance on 'tick-box' management is of course not without its downside, as anybody who tries to access help via semiautomated telephone helplines can attest. In many instances, it is not at all clear that the value of service is comparable with what a more flexible and knowledgeable human might provide. In the UK, for instance there appears an endless enthusiasm to replace specialists with generalists or nurses, but here there is a great irony. For much as the desire to produce evidence that underpins drug use is championed, there is scant evidence to monitor changes in practice that are arguably even more important. Once it is accepted, as physicians were historically slow to admit, that the organization of care and services is crucial, then it becomes cogent to argue that the organization of care now has to abide by the same standards of proof that are used to assess, for instance, a new treatment for psoriasis. However, observers of the scene will know that this is not the case, partly because the traditions of what constitutes 'proof' in biomedical science are different from those that have been dominant in management or economics.

Earlier, I outlined the two dominant traditions in medical science, those of experimental physiology, and those of statistical methods. How these two traditions are combined is problematic, more so when we realize that so much of the clinical encounter is hard to capture. In recent years what has been described as the 'evidence-based medicine' (EBM) movement has attempted to unify and systematize 'evidence' and claim that evidence can indeed be reduced to probability statements.[10] In any absolute sense, this attempt has failed. It has failed because evidence requires judgement, and we have no formal calculus for integrating different types of evidential material, and because we are not certain how to capture all of a clinical encounter.[11–15] On the other hand, the statistical method is extraordinary

easy to marry to the bureaucratic control of health, and from this perspective, clinical judgement may be seen as partisan and self-serving. Because formal studies are expensive, organizations that can control the budget can often influence how practice is undertaken. Whereas clinical experience requires little formal funding, RCT and evidence collation is expensive. Arguments such as 'there is no evidence to justify that a new intervention' can be used to slow down useful advance or, conversely, to put a brake on unwarranted optimism.

Conclusion

Medicine is becoming industrialized. Task specification and codification allow an ever greater division of labour. Explicit evidence is a key lynchpin of the framework that supports such specialization. The battle for what constitutes appropriate evidence to guide care and on which to audit care will be a dominant theme in clinical medicine for the next 25 years. The problem of how to formally integrate different modes of evidence remains unresolved, and clinicians have a key role in framing how such advance occurs.

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