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Commentary

Clinical Judgement - a Contemporary Narrative. The Lost Chord of Evidence-Based Medicine (EBM)

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The 1960s were notable for wide variations between doctors in how they managed common clinical problems, and for the absence of good research evidence to improve the position. Half a century ago, the slogan 'Evidence Based Medicine' (EBM) was coined to address these problems and associated with Archie Cochrane, the noted public health physician and epidemiologist.

Some 25 years later, Sackett [1] listed the three essential components of EBM as 'best available research', 'clinical judgement' and 'patient values', promoting the double blind randomised controlled trial (RCT) as the gold standard for defining 'best available evidence'. Sackett [2] emphasised the importance of blending judgement with evidence, because 'without clinical expertise, practice risks becoming tyrannised by evidence…which may be inapplicable or inappropriate for the individual patient'. This fits with Greenhalgh's [2] well-received and extensively referenced 2014 commentary 'Evidence based medicine: a movement in crisis?' which described how the progressive development of algorithmic rules has distorted the purpose of the original evidence based medicine brand. A more recent debate between Accad and Francis [3] revisited the question 'does EBM adversely affect clinical judgement'.

Given that EBM seems so obviously a 'good idea', what has gone wrong?

LESSONS FROM COVID 19

We are already spectators of the COVID-19 blame game as a party political exercise between governments and oppositions nationally and internationally. The recurring themes are about 'following the science/evidence'; what exactly was the evidence; what did the experts advise; if you didn't 'follow the science/evidence' - why not; and if you 'followed the science/evidence', why didn't you do it sooner?

Listening carefully to what the experts say in their interviews, it is generally that their principal task has been to collate and review the best available - and often rapidly changing - biomedical evidence relating to the Covid-19 virus. They pass their collective opinion (not necessarily or always unanimous) to government, but accept that how to blend their bioscience contribution with the complementary inputs from other disciplines (notably economic, and the social sciences) is a political issue for government to decide. And they say that finding the right answer will never be easy.

And so it is in Medicine. Greenhalgh's review captures many of the factors contributing to the disaffection of many working clinicians with the 'tyranny' of EBM. Most significantly, 'best available evidence' has come to be seen as only that derived from biomedically designed RCTs, where the population characteristics being randomised are those easily measured but which exclude many others of at least equal multi-disciplinary importance which are harder to measure and difficult to incorporate in clinical trials.

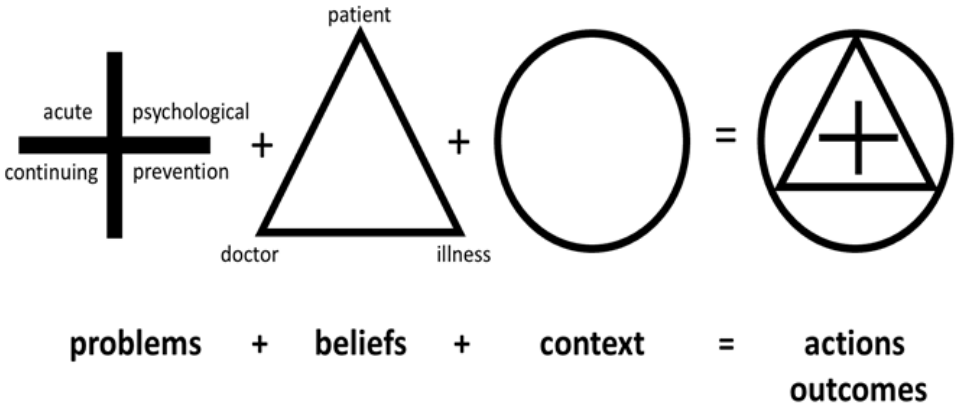
Of equal importance is the political reality of how what starts as an initially apparent 'good idea' evolves through an almost inevitable 'mission creep', first to the formulation of guidelines, then to targets, and on to contractual pressures and incentives. In the UK this has been particularly noticeable in how the general practice QOF (Quality and Outcomes Framework) has altered the dynamics of consultations, many patients now feeling that their meetings with their doctors are driven by QOF priorities rather than the real agendas they bring to their consultations. In addition, failure to comply with EBM 'rules' lays doctors open to disciplinary hearings and to litigation.

This chain of events is known to political commentators as 'authoritarian drift'. Amongst other things, it also leads to defensive medical practice, over-referral, over-investigation and over-prescribing. These realities are already apparent.

This essay attempts to look at how 'clinical judgement' and 'best available evidence' can be better aligned to reflect how clinicians actually work.

ONE RESEARCH BASE

I will develop my argument by reflecting on my own half-



century long research career [4]. In 1970, my first (and last!) RCT, carried out along with a colleague in a neighbouring inner-city Glasgow practice was published [5]. The RCT was of early antibiotic against placebo in winter respiratory illness in normally fit adult males. The research found no advantage to antibiotic takers. That research has had no discernible effect on clinical practice. The researches described below help to explain why.

Appendicitis and abdominal pain (1962-1970)

In the 1960s, more than half the appendices removed from young female patients with acute abdominal pain were normal. Surgeons varied materially in deciding whether to operate or not in borderline cases. Partly the variation was due to competing beliefs as to whether the risks of missing an actual appendicitis in someone who might subsequently die from a recurrent episode of actual appendicitis, were less or greater than the risk of death from removing a normal appendix from someone undergoing possibly avoidable surgery. The work towards providing an answer was complicated, but it appeared that he risks of death from either of these two misadventures was roughly the same, and that the liklihood of a surgeon experiencing either misadventure was less than once in a surgical lifetime. Two non-biomedical subsets of the data were perhaps of greater interest. First, the belief held by patients that 'appendicitis runs in families' was not sustainable, but it was the case that having your appendix out did run in families. Second, the relatives of medical and nursing families were more likely than others to have an operation after referral to hospital with possible appendicitis [6].

Antibiotics for general practice respiratory tract infections (1966 - c1970)

I have already referred to my first research project in this field. But there were more interesting results to come from further researches influenced by my own awareness of the non-biological factors that affected my own prescribing decisions.

Three studies fit in here. The first showed that in this area of general practice at least, instead of doctors following the normally accepted process of making a diagnosis and then deciding the treatment, doctors often decide on treatment first and afterwards attach a diagnosis to justify their action [7,8]. (In retrospect, I realise that the same can happen in the management of possible appendicitis by surgeons). In the second study, doctors were shown a series of inflamed throats. Alongside the pictures were a series of case histories, half the sample including contextual information (like being a Friday night, or the weekend before an interview). The contextual information markedly altered the prescribing decisions made [9]. The third study showed that mothers who regularly took drugs to relieve anxiety, had children who were twice as likely to have antibiotics for minor respiratory illness during their childhood years [10]. At such consultations was the mother or the child the patient?

Quality of care at general practice consultations (1970-present)

I was aware that in my own clinical work I worked differently when under stress. Although the commonest stressor was time pressure, other drivers included anxiety over problems with ill patients, and of course personal tensions in my own life. My research team carried out a study of the influences of time and stress on clinical decision-making at routine general practice consultations. They found that both factors (acting either together or separately) resulted in less psychological and social co-morbidity being identified, to less attention being given to the co-morbidity that was identified, and to a greater likelihood of a prescription being given [11,12].

Quite separately in the early 1990s, the development of the internal market in health care (including general practice fund-holding), and the incentivisation of various aspects of medical practice added new contextual influences to clinical practice. In our evaluation of the Scottish trial of fund-holding in general practice, we did find benefits to the care of patients with incentivised conditions (notably diabetes and hypertension; but also that there were disbenefits to many groups of patients with non-incentivised conditions of relatively high prevalence. These included chronic pain, digestive problems, and skin conditions, in all of which social and psychological co-morbidity was high [13]. A further cluster of researches centred round the determinants of 'patient enablement', an outcome measure developed to capture one of the key benefits from a good consultation with a general practitioner or indeed with any health professional. 'Enablement' captures patients' feeling that after their consultation they felt they understood their health problem better, and felt more able to cope with it. We found that the principal correlates with it were 'knowing the doctor well' (a proxy for continuity of care), and time spent at the consultation [14]. Interesting differences were found for ethnic minorities, and when ethnic minority patients consulted with a doctor in their own language, where greater enablement was generated in shorter time [15].

THE ACADEMIC TASK

The word 'academic' is often defined in a rather pejorative way as 'not of practical relevance; of only theoretical interest'. But in turn the definition of 'atheory' is given as 'a set of principles on which the practice of an activity is based'.

In 1970 , Thomas Kuhn, a scientific historian published a landmark text 'The Structure of Scientific Revolutions [16] arguing that a discipline develops when it discovers a new theory to address unanswered questions which unite its researchers, when existing theories have outlived their usefulness. Although Kuhn did not include any medical examples in his text, others used his thinking to argue that in medicine the bioscience model on its own needed to be replaced, or at least explicitly complemented, by a more holistic patient-centred vision.

EBM now needs to evolve into a less constricting model as suggested below.

MODELLING CLINICAL JUDGEMENT (FIGURE 1)

According to conventional wisdom and teaching, it would be reasonable to assume that the direct bridge between the left hand and right hand boxes would be 'best available evidence'. But from the researches I have described above, this 'best available evidence' has to be significantly richer than which can be gleaned from biomedical RCTs alone. Thus the two middle boxes contain the various issues covered by 'beliefs' and 'context', many of which have been touched on earlier in this essay. My model suggests that the sharing of 'beliefs' about the meaning of health and illness by doctors and patients (often mediated by strong doctor-patient interactions and fostered through good continuity of care [17]) will help prioritise the multi-faceted problems presented by patients at routine consultations. And in turn that awareness of the increasingly important issues of the 'context' in which care takes place will further influence how management decisions are taken and in turn the outcomes which follow. (It is of course arguable that the positioning of the two middle boxes might be exchanged without devaluing the overall thrust of the model).

This model is, I think, a credible representation of the concept of 'clinical judgement' proposed by the proponents of EBM but slowly eroded with the passage of time. Its merit lies in part in the range and balance of the issues it incorporates, and in part because it captures the realities of how the majority of clinicians actually work now and will want to work in the future.

Alvin Feinstein's seminal book entitled 'Clinical Judgement' was published in 1967 [18]. Shortly after he wrote memorably 'Until the methods of science are made satisfactory for all the important distinctions of human phenomena, our best approach to many problems in therapy will be to rely on the the judgements of thoughtful people who are familiar with the total realities of human ailments'[19]. Hopefully this Essay may have added something useful to this vision.

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