End the diagnostic culture of "rule-out"

We need to make the most of clinical context rather than order every investigation, writes **Saurabh Jha**

I remonstrated with Watson, the neurosurgeon, "The patient's skull was struck by a baseball bat. He has a perfectly legitimate reason for subarachnoid hemorrhage. He already had a CT [computed tomogram] of the head showing the bleed in good detail. Why another?"

"But you don't know that there is no intracranial aneurysm. You can't rule that out. He needs a CT angiogram of the brain immediately," protested Watson.

Hit by a hard object (cause) and blood in brain (effect) is deductive reasoning at its simplest. But Watson was correct: I could not rule out cerebral artery aneurysm without a CT angiogram. I could not, for that matter, rule out bleeding brain metastases from lung cancer. Perhaps the patient needed a CT of the chest, I suggested facetiously.

The diagnostic permutations in medicine are innumerable, and what prevents doctors from descending into parody is the application of conditional probability: Bayes' theorem. Without clinical context we stare into the abyss.

The likelihood that someone with cerebral aneurysm hit by a bat develops subarachnoid hemorrhage (near certainty) is not the same as the likelihood that someone who develops subarachnoid hemorrhage after high impact trauma has an aneurysm, hitherto undisclosed (very low). In fact, the likelihood of the latter is less than the likelihood of finding a cerebral artery aneurysm in a person picked randomly off the street.

No statute protects patients with cerebral aneurysms from being hit by a bat. It's the law of parsimony summed up by the popular adage: if you hear hoof beats in Texas think of horses not zebras. However improbable, it was not impossible. That was Watson's point. He was practicing a form of diagnostic medicine designed to catch zebras in Texas: "rule-out" medicine.

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Watson's rationale for fishing for rarities—"can't be ruled out"—is unfalsifiable. This phrase cannot be disproved. It smashes Bayes' theorem and Occam's razor to smithereens. It is kryptonite to clinical acumen.

Before I am asked to get off my high horse I should confess that I too use the phrase. My interpretations of medical imaging often contain such truisms as "small pulmonary clots can't be entirely ruled out" and "the possibility of infection can't be excluded with absolute certainty."

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Recently I reported on a CT of a college student tackled fiercely in soccer. He had flank ecchymosis, a couple of fractured ribs, and blood in the adrenal gland. I asked that he receive follow-up magnetic resonance imaging (MRI) to exclude the possibility of an underlying adrenal mass.

"Is being kicked in the flank not enough to explain adrenal hemorrhage?" the trauma surgeon asked rhetorically at the collapse of my critical faculties. "I've been burnt before," I sheepishly defended. And I had, or rather the patient had, but that was a different body part. With a safety culture it is easier to extrapolate, to see similarities between patients, than to differentiate. Discernment requires effort.

How did we arrive here? How did medicine change from confirmation to refutation, from "rule-in" to "rule-out"? Two common explanations for the high costs of healthcare—fee for service and defensive medicine—do not readily help. Watson had no monetary gain from the CT angiogram. Nor do I think Watson had a premonition of a subpoena for missing an aneurysm.

Watson ordered the study because he could; because CT is available. George Mallory quipped, when asked why he wanted to climb Everest: "Because it is there." Watson ordered the study because he feared being wrong.

Of course, if the CT was negative for aneurysm, which it was, Watson would be wrong. But there is wrong: falsely declaring disease in a healthy person—a false positive. And there is (really) wrong: falsely declaring health in a diseased person—a false negative.

Since the Institute of Medicine's report on medical errors, *To Err is Human*, many doctors have chosen being wrong over being really wrong. Between a false positive and false negative, I'll take the false positive. If I must err then I will err on the side of caution.

The choice has made diagnosis more sensitive: the chances of missing cancer in someone with cancer when cancer is suspected are exceedingly low. But you can't have your sensitivity and eat it, too. The trade off is specificity: there is a chance of declaring health in someone who actually is healthy.

Watson is a fine product of medical education. He is well read. He is thorough. He is non-judgmental. He presents long lists of possibilities. Nothing can be elementary for Watson. He knows too much; so much so that in every horse he sees an opportunity for a zebra. Zebras are intellectually exciting.

With this change in medical culture, the adage "common things are common" now disclaims "yes but rare things are also common." Students used to be praised for arriving at a paucity of diagnoses after targeted patient assessment; they are now lauded for thinking of the atypical instead of the obvious.

The dialectic between an imperfect science and our unyielding quest for accuracy has led to our implacable intolerance of uncertainty, which drives the use of diagnostic services. Conquering uncertainty is impossible. Rule-out begets more rule-outs, more tests, and more uncertainty. Chest radiography to rule out pneumonia leads to "pneumonia not excluded but questionable lung mass, CT recommended," leading to "no mass but questionable aortic dissection, CT angiogram recommended," leading to "no aortic tear but questionable adrenal cancer, MRI recommended."

But who pays for this treasure hunt? Shuttled around the hospital with lines and tubes attached, hauled from bed to CT scan to bed, with a large bore cannula so that iodinated contrast can be injected at 5.5 ml a second, indulging Watson's boundless intellectual curiosity is not a trivial task for his patients. And neither is it for the healthcare system that must heal both Watson and his patients.

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NO HOLDS BARRED **Margaret McCartney**

Withdraw Saatchi's quackery bill

"Innovation" is a lovely word, with shine and goodness at its heart. Health Secretary Jeremy Hunt has said that Maurice Saatchi's proposed Medical Innovation Bill[1] would encourage "a climate where clinical pioneers have the freedom to make breakthroughs in medicine." It could "lead to major breakthroughs, such as a cure for cancer," Hunt said, by removing "barriers that prevent innovation which can save and improve lives."[2]

This is misguided. Saatchi's concern is for people with late stage cancer who "receive only the standard procedure . . . the endless repetition of a failed experiment." The bill seeks to protect those doctors who make "responsible innovation" when most medical opinion would be unsupportive of their proposals.[3] In Saatchi's view, doctors who currently work outside standard procedure may be leaving themselves vulnerable to accusations of negligence.[4]

Clinical trials work beyond standard procedure. They help us decide which novel treatments work and which are simply dangerous. The number of patients with cancer taking part in a clinical trial has increased from one in 26 in 2002 to one in six in 2010.[5]

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Read Mike Rawlins's recent column, "The "Saatchi bill" will allow responsible innovation in treatment" (*BMJ* 2014;348:g2771)

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Bizarrely, the bill makes no note of this success, or the capacity to do better. Worse still, the bill expressly forbids the innovating doctor "to carry out treatment for the purposes of research." This means that the patient would lack the protection of ethical research—including a systematic review of use of the proposed intervention first and guarantees that results will be published. A lack of learning would leave patients open to having the same bad treatment repeatedly—multiplying the harm, quite legally.

The only difference between medicine and pseudomedical nonsense is the use of—and ability to learn from—fair tests of treatments. This bill, therefore, is an open door to quackery. There are many expensive clinics already peddling false hope in the form of unproved or disproved interventions for cancer and other serious illnesses. They would legally be allowed to continue or expand, protected by this bill, allowing evidence-free opinion to masquerade as "responsible innovation."

Much could be done to improve the status quo but it needs to be based on evidence. Evidence shows that people with cancer often lack information about clinical trials, for example.[6] And the bureaucracy and delays surrounding research ethics committees are well documented.[7]

Saatchi's bill dismisses the slow successes of evidence based medicine, instead offering a public relations quick fix that is heavy on emotion but light on potential harms. The intentions may be honourable—more honourable would be the bill's withdrawal.

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BMJ BLOG OF THE WEEK **Sean Roche**

Is excessive bureaucracy unethical?

In subjecting the bureaucratic machine underpinning the NHS to ethical scrutiny, I suggest that we adhere to a basic premise: that it is ethically incumbent on a public health service to maximise the health and wellbeing of the population, within the constraints of the finite resources at its disposal.

In my view we currently fall far short of this imperative. A major obstacle is what I would describe as a "fetishization" of data, and the subsequent procedures for collecting it. In my specialty, psychiatry, there has been an alarming escalation in demands for various kinds of data to be collected and entered by clinicians who could be more profitably occupied by actually seeing patients in a therapeutic context. One driving force behind data-mania derives from an overly zealous Department of Health and local commissioners who need hard statistical evidence that they are getting value for money. "Payment by results" has brought a gamut of new scores and ratings of patients in order to render the market transaction between purchaser and provider smooth and transparent. Now, I am fully supportive of the intelligent use of data in the optimization of quality care, but I believe we have now exceeded a tipping point beyond which data-mania becomes wasteful, counterproductive, and violates our basic premise. In a word, unethical.

It is now commonplace in psychiatry that a clinician will spend more time entering information after a consultation than they spend with the patient. Commissioners fail to grasp an essential paradox. In order to be assured of "value for money," they demand that ever more information be collected as "evidence" of an (effective) intervention. But in so doing, far fewer patients will be seen in a timely way. Commissioners end up shooting themselves in the foot. There's an inevitable trade-off between time devoted to collecting and entering data, and time spent in therapeutic activites.

There are other ways in which data-mania results in unethical behavior. In data-obsessed systems, patients are increasingly conceived as abstract data sets. In psychiatry they are numerically rated and assigned "clusters" that determine subsequent care pathways. Moreover, distressed and vulnerable patients can feel badgered by data-oriented clinical encounters: How many hours do you work? Give up smoking (however distressed you're feeling right now)? Fill out this PROMS form, satisfaction survey, consent to share information . . . Data-fetishism creates an alienating rift between patient and practitioner.

We need to jettison the layers of bureaucracy that only gratify market-oriented administration. Money is tight, patients are waiting, and we need to deploy resources smartly. It's our ethical duty.

Sean Roche is a consultant psychiatrist in North London, and was a visiting research fellow in philosophy at King's College London 2012-14.

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