

Editorial

To Do or Not To Do-Doctors' Dilemma; Plea for Proper Audit

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*"Of the terrible doubt of appearances,
Of the uncertainty after all-that we may be deluded..."*

Walt Whitman

SUMMARY

There is a surfeit of information in the medical field, nearly 7% new information per month, that could baffle any practising physician. However, the wisdom needed for patient care comes from empirical experience based not just on information but knowledge as well. We must ensure, therefore, that these three pillars of wisdom i.e: information, knowledge and empirical experience, are audited on an ongoing basis.

"Knowledge" said Karl Popper "advances NOT by repeating known facts, but by refuting false dogmas". One can not agree more. Modern medicine abounds in dogmas: many of them have not been scientifically audited. Science is change. Every single hypothesis is true unless refuted by newer knowledge. Knowledge today in the medical field is replaced by information, resulting in doctors relying only on information and not wisdom. The so-called evidence-based medicine really is evidence burdened.

Wisdom alone should, therefore, guide the profession in CARING for our patients. Wisdom comes out of empirical experience, based on information and knowledge. However, medical muddling seems to be a profitable business. New tests, new devices, and even new drugs pour into this arena on an unprecedented scale.

It is time to audit all the technologies used in patient care just as we have placebo-controlled trials for drugs before releasing them for human use. Even in the case of drugs, in some rare instances, the release of drugs for patient use before being audited by such trials had resulted in major damage resulting in their withdrawal from the market^[1]. It stands to reason that we should debate the issue of auditing untested technologies that get into the arena of patient care.

Ever since medicine was accepted as a science in the European Universities in the 12th century, medicine has been using the methods of natural sciences including the use of linear mathematics. This has resulted in "doctors predicting the unpredictable," as the dynamic human body only follows non-linear mathematics in time evolution^[2] though natural sciences have learned a lot from modern quantum physics, medicine did not follow suit, to understand human consciousness that critically guides human health and illnesses^[3]. All these factors have compounded the mistakes in applying technology to medicine without proper audits.

Starting with some of the audits just completed, we could move on to other areas. Many of the unmeasured physiologic effects of indwelling catheters come to mind first. The Swan-Ganz catheter was introduced without appropriate validating studies to compare with identical groups without the catheter. This catheter, by itself, could be an adverse factor for many critically ill patients^[4]. In an observational study, Connors and colleagues showed that in critically ill patients, after adjusting for selection bias, the catheter was associated with increased mortality and increased utilization of resources^[5]. The authors suggested a prospective randomized study. Extrapolating another study done in Worcester, Robin estimated that around 15,000 unnecessary deaths could have occurred in 1984 alone and his paper goes on to estimate a total of nearly 100,000 excess deaths in the USA since 1975 due to the catheter^[6]. Following those studies, there was a justifiable demand for a moratorium on the use of the catheter until further prospective controlled studies cleared the mist. Understandably, there were strong opinions expressed against the demand for a moratorium, but the opinions, unfortunately, ignored some of the very valid data in the field^[7].

Coronary artery surgery is the next popular surgical procedure crying for proper audit. In the

early 1970s, there was a demand for audit in this area, and indeed all new surgical procedures, by controlled studies before being routinely performed in practice^[8]. There was hardly any substantial change in this area even as recently as 1997^[9]. A well-planned, prospective second opinion study of the need for bypass grafting showed that there is a major overuse of this procedure, even in the best centres in the US^[10]. More recently, an audit showed ethically unacceptable results of overuse of both bypass and angioplasty in the immediate post myocardial infarction scenario^[11].

Writing a very balanced editorial on the same issue, Harlan Krumholz from Yale University laments, "In a fee-for-service system, cardiac procedures generated billions of dollars in revenues each year. A high volume of procedures brought prestige and financial rewards to hospitals, physicians, and the vendors of medical equipment. In this environment, the US health care system rapidly produced and expanded the capacity to perform cardiac procedures and training. This increased capacity may also have fuelled demand for procedures^[12]".

This menace is spreading to other countries, more so to the developing countries where auditing is non-existent. Earlier, there was a plea for cutting cardiac surgical centres in the UK by a thinking cardiac surgeon^[13]. Journal editors could do a lot to avoid cognitive errors in data presentation as shown by this review of 60,000 bypass grafts in the US. While the original study said that everyone that undergoes an early bypass graft has an average increase in life expectancy of 4.26 extra months^[14]; the truth of the matter when properly presented, was that 6% of patients gained extra life of 3.5 years from early surgery, 4% gained 1.5 years and the bulk of 84% had no change at all^[15].

This brings us to the crucial question: if these kinds of publications are done and researchers hired only to sell academic medicine in the market!^[16] To cap it, bypass surgery of the coronary arteries is associated with adverse effects on the brain. Stroke, that occurs from 1.5 to 5.2% of patients undergoing this procedure according to various prospective studies, post-operative delirium, short-term cognitive changes and, in many cases, long-term permanent cognitive changes, make it imperative that the operation is done only in rare cases for relief of intractable angina and/or for stabilizing ventricular function^[17]. Poor medical research might be due to the vested interests enticing researchers with gifts and other allurements^[18,19].

There is nothing much to write home about the outcomes of another related procedure: angioplasty. Whereas there are small studies

eulogizing its benefits, there are enough audit data that do not show the procedure in very good light^[20]. Renal angioplasty is no better than anti-hypertensive therapy, although sold as the best for the former.^[21]

Another area that has not been audited is the routine check up (screening) of apparently healthy individuals. While it is true that doctors and technology could do a lot for the hapless victims of illnesses, there is no solid proof that our interference at the so-called "early asymptomatic" stage of diseases could control them better or prevent further damage. The human body's wisdom tries to do the necessary changes when things go wrong anywhere in the body. Only when this body's defense fails does a patient get symptoms. That is where our intervention would help.

An audit of multi-factorial, long-term preventive strategies to prevent cardiovascular diseases showed that at the end of fifteen years of observation, there were significantly excess cardiac deaths in the intervened group as compared to the controls^[22]. Screening for congenital hypothyroidism, breast cancer, and Down's syndrome had shown false positives to have permanently damaged the health of the screenees. Sick absenteeism increased significantly after the work place hypertension screening was started. Similar results came from some of the cholesterol check up programmes. In addition, people who get negative results on screening are shown to ignore health precautions. In Australia, this has resulted in higher episodes of illness. More studies are needed before launching wholesale screening programmes^[23].

However, this practice is spreading like wildfire all over the world since it makes lot of business sense to tell the world that we could do a lot to all the well people, as we would then be targeting a huge population with this false claim!

The menace of technology is taking a heavy toll on the health budgets of poorer countries, since medical students are taught to be totally dependent on technology for diagnosis. A recent audit of the diagnostic methods did show that 80% of the final accurate diagnosis and 100% of the future management strategies could be deduced at the end of reading the referral letter and listening to the patient. It could only be improved 4% by all the examinations and 8% more after all the tests, including positron emission tomography, are done^[24].

Medical education seems to be run mainly with the money from drug companies and technology manufacturers^[25]. Research data are many times twisted out of shape to help sell drugs and

technology, making life miserable for patients and, possibly, also increasing mortality. Most studies are subject to interpretation bias as shown elegantly by the now infamous UKPDS data. This study does not show any benefit on macro-vascular end points in patients with type 2 diabetes treated with insulin and sulphonylureas. Nevertheless, many authors, editors and the wider doctors' community interpreted this very study as providing evidence of benefit of intensive blood glucose control^[26].

The story of H0T study for tighter control of blood pressure is another pathetic story in this regard. While the study was stopped prematurely as there were higher deaths in the tightly controlled group with more powerful modern drugs, the study results were sold as showing benefit to patients with these drugs. Although many patients dropped out of the study in the beginning, the study was eventually analyzed by using the intention-to-treat analysis. Fundamental objectives of the H0T study remain to be achieved^[27]. Treated hypertensives had impaired mortality compared to their normotensive cousins, which becomes apparent after a decade of follow up showing that all is not well with antihypertensive treatment the way it is done these days^[28]. None of these findings either reach the practising doctor or even the text books, but the twisted version reaches, through the glossy company literature, every practitioner long before the study gets published!

All this has created enough and more damage to the medical profession. There needs to be a fundamental change in medical education to make the new doctors think for themselves before accepting published data unquestioningly. We should provide students with all the facilities to learn for themselves rather than trying to teach them. Shocking revelation that in USA around 100,000 people die every year due to medical errors makes one think if we are on the right track or not. The numbers could be much higher in some of the developing countries^[29]. Medical education should not exist to provide doctors with an opportunity to earn a living, but it should exist only to improve the health of the public.

A "pill for every ill" is not always true. Medicine should be able to "cure rarely, comfort mostly, but console always." The human and humane doctor is a very vital tool in stimulating the body's immune system in every disease situation, for proper healing to take place. *Primum Non Nocere* (first do no harm) is an old but true dictum to follow. Let us not make our interventions worse than the patient's suffering.

The time for openness has come and openness would be more relevant in the new millennium. There are a lot of things that we should not be

doing in medicine. We better act quickly to demolish many of the myths before more damage is done and the credibility of the medical profession is tarnished. The fine art of medicine that is improving the quality of the patient's day is the highest of arts. Medicine is an art, based on sound scientific principles. The human body is very wise and has its own self-correcting mechanisms which doctors should not destroy in their hurry to get even with diseases. Physicians, heal thyself first.

*"Fear not! Life still
Leaves human effort scope.
But, since life teems with ill,
Nurse no extravagant hope".*

Mathew Arnold
Empedocles on Etna

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