
Commented Summary from Current Medical Literature

Me, Make a Mistake??

Summary: As the attitude to adverse events has changed from the defensive “blame and shame culture” to an open and transparent health care delivery system, it is timely to examine the nature of human errors and their impact on the quality of surgical health care.

The approach of the review is generic rather than specific, and the account is based on the published psychologic and medical literature on the subject.

Rather than detailing the various “surgical errors”, the concept of error categories within the surgical setting committed by surgeons as front-line operators are discussed. The important components of safe surgical practice identified include organizational structure with strategic control of health care delivery, teamwork and leadership, evidence-based practice, proficiency, continued professional development of all staff, availability of wireless health information technology, and well-embedded incident reporting and adverse events disclosure systems. In our quest for the safest possible surgical health care, there is a need for prospective observational multidisciplinary (surgeons and human factors specialists) studies as distinct from retrospective reports of adverse events. There is also need for research to establish the ideal system architecture for anonymous reporting of near miss and no harm events in surgical practice.

Source : Cuschieri A. Nature of human error. *Ann Surg.* 2006; **244**: 642 – 648.

Comment: The Institute of Medicine in America, a nongovernmental scientific organization that provides reliable health information for the public, announced some time ago that nearly 100,000 hospital deaths a year in the United States can be traced to errors.¹ The conclusion that “to err is human”, was meant neither to condone the situation nor to imply that avoiding medical errors are humanly impossible. The human element operates all the time and everywhere. We see it in ourselves when we indignantly protest against slender accusation or insinuation of sloppy professional behavior, poor judgment, inadequate knowledge and — God forbid — lack of intellectual integrity.

When death is taken as the end point, it becomes relatively easy to trace the role of errors in causing them. For nonlethal errors, the grist for malpractice lawyers, it is more difficult to establish when and how an error has been committed, or for that matter what constitutes an error. We all know, of course, that the incidence of nonlethal errors is far greater than lethal ones. In England “The National Patient Safety Agency estimates that 900,000 incidents harming or nearly harming patients occur each year amongst NHS hospital inpatients”.² Here again, the human factor can be incriminated in most instances. Given these grim statistics, what can be done about it?

First step is to talk and write about it. In fact, medical error has become a very much discussed topic. The November 2006 issue of *Annals of Surgery* devoted its first section to three papers on errors committed by surgeons.³ The first paper by Professor Alfred Cuschieri analyzes systematically and scientifically the “Nature of Human Error and its Implications for Surgical Practice”. The subject, however, is presented in too abstract and philosophical manner to be of much value for the average surgeon. Next, Dr. Lucian Leape (an esteemed classmate of mine of bygone days) focuses on “When Good Doctors Go Bad: A Systems Problem”, describing how doctors acquire disabilities that lead to professional blunders. Fortunately, not many surgeons become disabled to that extent. Lastly, Dr. Thomas Russell explores the role of surgical organizations in influencing “Safety and Quality Improvement in Surgical Practice”, which undoubtedly is very important, but not the final solution.

The real aim, of course, should be how to reduce medical errors, because total elimination seems to be a humanly impossible task. These errors range from patients falling out of bed because of poor nursing supervision, to having a normal kidney removed because of the rush to finish the transplant procedure.

As stated by James Reason⁴: “though we cannot change the human condition, we can change the conditions under which humans work”. Two very valuable and practical steps have been recommended. One is to have guidelines, protocols, and formal check lists, as experience in the aviation industry has demonstrated.⁵ Since there should really be no such thing as ‘routine’ in medicine or surgery, religiously following a check list is the easiest way to avoid omission errors.

Next is to insist on the reporting of all errors, even suspected ones. The Royal College of Surgeons of England requires all surgeons to report all adverse events, with the proviso that the system be anonymized and not apportion blame.⁶ There remains the very important topic of keeping up to date on evidence-based medicine. This is where continuing medical education (CME) programs come in. There may be no objective way of proving (or disproving) the value of CME on the practice of medicine and surgery. But surely, any surgeon caught performing an outdated operation, is subject to scrutiny as not having acted in the patient’s best interest, hence having possibly committed an error.

Are there any specifically cultural as opposed to general and universal human factors conducive to medical errors? Here I have in mind the settings in some developing countries where modern medicine, in all its ramifications and complexity, does not have a long tradition behind it. The problem is that accurate data on the frequency of medical errors are difficult to come by in such countries — in itself a culturally influenced attitude in terms of reluctance or inability to collect data. In the same way, one should mention unwillingness to acknowledge or divulge blunders of oneself or others. Authority continues to play a dominant role in many societies. Not wanting to accept that those in authority are just as prone to mistakes as underlings, continues to remain a cultural norm in many previously autocratic societies. Finally, a *laissez-faire* and tolerant attitude is commonly observed in surgical wards and operating rooms of developing countries, often ascribed to lack of instruments and facilities, setting the stage for serious errors. In short, work ethics are not the same in all countries.

The whole subject of medical-surgical errors, including necessary and useful remedial steps, takes on different dimensions in different countries. It seems that whatever solutions to medical errors can be conjured up, they must be adjusted not only to individuals and circumstance, but also to the particular locality.

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References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human. Building a Safer Health System*. Washington, DC. National Academy Press; 1999.
2. Jackson CR, Gibbin KP. 'Per ardua...' Training tomorrow's surgeons using inter alia lessons from aviation. *J R Soc Med*. 2006; **99**: 554 – 558.
3. Cuschieri A. Nature of human error. *Ann Surg*. 2006; **244**: 642 – 648.
4. Reason J. Human error: models and management. *BMJ*. 2000; **320**: 768 – 770.
5. Coxon JP, Pattison SH, Parks JW, Stevenson PK, Kirby RS. Reducing human error in urology: lessons from aviation. *BJU Int*. 2003; **91**: 1 – 3.
6. The Royal College of Surgeons of England. *Good Surgical Practice*. London: The Royal College of Surgeons of England; 2002.

A Placebo-Controlled Trial of Pioglitazone in Patients with Nonalcoholic Steatohepatitis

Summary: Nonalcoholic steatohepatitis (NASH) is a common liver disease, which is associated with insulin resistance. It can potentially progress to end-stage liver disease and cirrhosis. No pharmacological therapy has been universally accepted for this condition. Weight loss has always been recommended as a helpful treatment in obese patients who diagnosed as having NASH. Pioglitazone is a thiazolidinedione that improves insulin resistance and is used in type 2 diabetes mellitus. Belfort et al evaluated the effect of a hypocaloric diet and pioglitazone versus diet and placebo. They randomly assigned 55 patients with impaired glucose tolerance or type 2 diabetes mellitus in whom NASH was confirmed by liver biopsy to either treatment group. They treated the patients for six months and then repeated the liver biopsy. In the

pioglitazone group the rate of normalization of liver aminotransferase levels was significantly higher. They had also more decrease in hepatic fat content. The necroinflammatory score in the pioglitazone group was significantly more reduced compared with the placebo group, whereas changes in fibrosis scores were not significantly different. As expected, the pioglitazone group had better improvement in glucose tolerance and glycemic control. The authors concluded that pioglitazone was a promising agent in the treatment of NASH.

Source: Belfort R, Harrison SA, Brown K, Darland C, Finch J, Hardies J, et al. A placebo-controlled trial of pioglitazone in subjects with nonalcoholic steatohepatitis. *N Engl J Med.* 2006; **355**: 2297 – 2307.

Comment: NASH is rapidly becoming an important and frequent cause of significant liver morbidity, especially among obese and diabetic patients. Currently, weight loss and control of diabetes or hyperlipidemia (if present) are the mainstays of treatment. But no specific medical treatment has been yet identified for NASH.

The pathogenesis of NASH is believed to involve two hits; the deposition of fat, and the initiation of hepatic damage. Insulin resistance is believed to be involved in both hits. Oxidative stress is also involved in at least the second hit.¹

Since NASH is associated with insulin resistance, it is rational that insulin sensitizing drugs be effective in its treatment. Many clinical studies have evaluated various insulin sensitizers, alone or in combination. Metformin has been evaluated in a few studies and conflicting reports are available.^{2 - 4} Pioglitazone appears to be more promising and a few recent studies confirm its effectiveness.⁵⁻⁷ Those studies, such as the one reported by Belfort et al that confirm the effectiveness by histological evaluations are especially helpful.

Antioxidants have also been proven to be effective. The authors refer to our open-labeled study on probucol, a lipid-lowering antioxidant, in nonalcoholic steatohepatitis.⁸ But they fail to cite our other study, which is a randomized double-blind controlled trial⁹ and an abstract we recently presented in Digestive Disease Week 2006 on histological changes.¹⁰ In these studies, we showed that probucol was effective in normalizing liver enzyme levels and improving liver histology. Other studies have pointed to the effectiveness of other antioxidants such as vitamin E and betaine.¹ But there is not enough evidence yet to support the routine use of any of these medications.

High quality trials such as the one performed by Belfort et al are strongly in demand. It appears to be the time to design a large multicenter trial probably including antioxidants and insulin sensitizing agents in combination.

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References

1. Angulo P. Nonalcoholic fatty liver disease. *N Engl J Med.* 2002; **346**: 1221 – 1231.
2. Duseja A, Murlidharan R, Bhansali A, Sharma S, Das A, Das R, et al. Assessment of insulin resistance and effect of metformin in nonalcoholic steatohepatitis — a preliminary report. *Indian J Gastroenterol.* 2004; **23**: 12 – 15.
3. Nair S, Diehl AM, Wiseman M, Farr GH Jr, Perrillo RP. Metformin in the treatment of nonalcoholic steatohepatitis: a pilot open label trial. *Aliment Pharmacol Ther.* 2004; **20**: 23 – 28.
4. Schwimmer JB, Middleton MS, Deutsch R, Lavine JE. A phase 2 clinical trial of metformin as a treatment for nondiabetic paediatric nonalcoholic steatohepatitis. *Aliment Pharmacol Ther.* 2005; **21**: 871 – 879.
5. Lutchman G, Promrat K, Kleiner DE, Heller T, Ghany MG, Yanovski JA, et al. Changes in serum adipokine levels during pioglitazone treatment for nonalcoholic steatohepatitis: relationship to histological improvement. *Clin Gastroenterol Hepatol.* 2006; **4**: 1048 – 1052.
6. Promrat K, Lutchman G, Uwaifo GI, Freedman RJ, Soza A, Heller T, et al. A pilot study of pioglitazone treatment for nonalcoholic steatohepatitis. *Hepatology.* 2004; **39**: 188 – 196.
7. Sanyal AJ, Mofrad PS, Contos MJ, Sargeant C, Luketic VA, Sterling RK, et al. A pilot study of vitamin E versus vitamin E and pioglitazone for the treatment of nonalcoholic steatohepatitis. *Clin Gastroenterol Hepatol.* 2004; **2**: 1107 – 1115.

8. Merat S, Malekzadeh R, Sohrabi MR, Hormazdi M, Naserimoghadam S, Mikaeli J, et al. ProbucoI in the treatment of nonalcoholic steatohepatitis: an open-labeled study. *J Clin Gastroenterol*. 2003; **36**: 266 – 268.
9. Merat S, Malekzadeh R, Sohrabi MR, Sotoudeh M, Rakhshani N, Sohrabpour AA, et al. ProbucoI in the treatment of nonalcoholic steatohepatitis: a double-blind randomized controlled study. *J Hepatol*. 2003; **38**: 414 – 418.
10. Merat S, Aduli M, Kazemi R, Sotoudeh M, Malekzadeh R. Changes in liver histology after one year of treatment with probucoI in nonalcoholic steatohepatitis. *Gastroenterology*. 2006; **130**: A595.

1000 Years Ago

Definition of medicine by Ibn-Sina (Avicenna)

Ibn-Sina or Avicenna (370 – 428 A.H./980 – 1037 A.D.), the great influential Iranian physician, at the beginning of the “Canon of Medicine” pointed out that “medicine is a branch of knowledge which deals with the states of health and disease in the human body, with the purpose of employing suitable means for preserving or restoring health”.

(Quoted from: **Science and Civilization in Islam**, by S. H. Nasr, 2nd edition, P: 219, Islamic Texts Society, Cambridge, UK, 1987)