

The Medical Journal as Whistleblower

January 2013 marks a bold new era in medical journal publishing. The BMJ has launched a frontal attack on incomplete data reporting by pharmaceutical companies. It has decided not to publish the results of human clinical trials if sponsors fail to make all the relevant anonymous patient level data available on request. For the last 3 years the BMJ has been fighting tooth and nail with the pharma giant Roche. The bone of contention is data regarding Tamiflu. In 2009 the UK government commissioned the Cochrane respiratory group to update its systematic review of neuraminidase inhibitors. But despite various strong arm tactics, Roche did not hand over all the relevant clinical data. Apparently about 60% of Roche's data from phase III trials of oseltamivir has never been published. This is disturbing when one realizes that countries have spent billions of dollars stockpiling a drug for which no one except the manufacturer has seen the complete evidence base. Indeed the EMA's (European Medical Association) unprecedented infringement proceedings launched against Roche last month suggest that even the manufacturer has never fully evaluated evidence it has collected on the drug's adverse effects.

The last few years have seen welcome changes to improve transparency in medical trial reporting. The first step was by the International Committee of Medical Journal Editors when they made registration of all clinical trials post July 2005 a prerequisite for publication. Then an American law has made it mandatory to submit basic results of all US clinical trials from September 2007. And most recently GlaxoSmithKline has decided to make available to scientists the raw data of all trials carried out since 2007 of both approved and abandoned drugs. It is time that the shroud of secrecy that drug companies maintain about efficacy and safety data of drugs is stripped off and the naked truth is revealed (*BMJ* 2012;345:e7304, www.guardian.co.uk. 12 November 2012).

The World's First Hepatitis E Vaccine

The world's first Hepatitis E vaccine has been produced in China. It may well be a boon to stem the 20 million infections and 70,000 deaths attributed annually to Hepatitis E. The vaccine was born out of a unique marriage of academia and industry. More than ten years ago, researchers at Xiamen University in Fujian province developed a protein from a genetically modified strain of *E. coli* which induces a strong immune response against hepatitis E. But the necessary economic thrust to this research was provided by the Yangshengtang Group, a company with interests in food and health care; which invested 15 million renminbi (US\$1.8 million in 2000) to set up a joint biotech laboratory in partnership with the university. The lab is now the National Institute of Diagnostics and Vaccine Development in Infectious Diseases (NIDVD). The Institute aims to develop more vaccines for disease routinely neglected by western researchers (*Nature* 491, 21–22, 1 November 2012).

Burnout In Doctors

A national study in the US comparing rates of burnout in physicians versus general population has thrown up interesting results. Of 27,276 physicians invited to participate, 7288 (26.7%) completed the survey. When assessed using the Maslach Burnout Inventory, 45.8% of physicians reported at least 1 symptom of burnout. The Maslach Inventory addresses three general areas – *Emotional exhaustion* measures feelings of being emotionally overextended and exhausted by one's work, *Depersonalization* which measures an unfeeling and impersonal response toward recipients of one's service, care treatment, or instruction; and *Personal accomplishment* which measures feelings of competence and successful achievement in one's work. Highest rates were among physicians at the front line of care access (family medicine, general internal medicine, and emergency medicine). As compared to the general population, physicians were more likely to have symptoms of burnout (37.9% vs 27.8%) and to be dissatisfied with work-life balance (40.2% vs 23.2%) ($P < .001$) (*Arch Intern Med.* 2012;172:1377-85).

Dengue- the Diabolical

In 1970, less than 10 countries were endemic for Dengue. Today this number has shot up to 100. The global incidence of DHF and DSS has shown a rise by 30%. Why has Dengue become increasingly malevolent? The initial clinical observations suggested that certain viral strains were associated with more severe disease. Others observed an increase in disease severity in patients who had been infected by more than one dengue virus serotype; this became known as the immune enhancement phenomenon. The truth as always lies probably in between. Fresh introduction of genetic material into prevalent strains have made them more virulent and phylogenetic and epidemiological analyses suggest that the more virulent genotypes are now displacing the mild ones.

Dengue virus transmission does not occur in isolation, but is embedded within a complex fabric of human social contexts. Detailed studies by the National Institute of Virology shows that the Dengue Virus (DENV) serotypes have changed in India over time relating to mass movement of people between countries. The American genotype of the DENV 2 was imported 100 years ago due to high traffic between South America and India. DENV 1 virus serotypes were imported from Singapore and Africa in the 1960's. In the 1980's new genotypes were introduced from Sri Lanka which correlates with human movements during the Sri Lankan conflict. NIV has also initiated a study on development of anti-dengue drugs from natural medicinal plants available in the country. Work on the Dengue vaccine is also on and expected to bear fruit by 2015. (*The Times of India* 26 October 2012, *The Hindu* 11 November 2012).

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