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EDITORIAL

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Who defines Truth ?

The truth that is being explored in this editorial is the available data used in the clinical pathway of managing patients. It is this knowledge that we seek, gather, understand and then through a process of distillation apply to the individual patient. The term used for this process is called 'Evidence based medicine'(EBM).

Prof. David Sackett, recognized as the father of EBM considered three components in EBM: the patient's expectations and wishes, clinical expertise and the best research evidence available (1). The best available research evidence can be ranked on a descending scale starting with systematic reviews and meta-analyses, Randomized Control Trials (RCTs) down to animal research and In vitro research. This evidence is then reflected against the clinician's experience and delivered in accordance with the patient's expectations.

Throughout this process there is an assumption of integrity and transparency in the research and flow of information. Research is to do with finding answers. And since answers depend on the questions that are asked, it is assumed that relevant and valid questions will be asked i.e. *"The right question"* (2). The research should be done in order to find answers to these questions. A robust methodology should be employed throughout the research process. The research data should be available for scrutiny and ultimately the research should be published based on the robustness of the research methodology employed for the research and not the results of the research. It is critical to understand that research is a continuous process and the knowledge of a given area is continuously being refined. In order for this process to occur, publications and critiques need to be 'freely' available to the clinicians, and there is an underlying assumption that this, is indeed the case. And finally, all the necessary information will be provided to the patient to make a decision; in order to be able to give 'informed consent' to the management protocol that is being offered.

A very brief review of the Covid-19 pandemic is an extremely instructive exercise in demonstrating how much we have drifted away, from the ideal concept of research integrity and transparency when it comes to the day-to-day practice of Medicine.

We were aware towards the end of 2019, that an epidemic of 'Flu' had 'originated' in the Wuhan province of China. As we witnessed on the news what was essentially viewed as a major health concern of China, almost overnight, became a health concern of Europe and then the rest of the world. The World Health Organization (WHO) as expected, became a central authority to co-ordinate this pandemic that was rapidly spreading unchecked throughout the world. Continuous bulletins were released advising international travel restrictions and many governments went into lockdown.

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'Test, test, test' was the continuous refrain from the WHO (3). No successful treatment regimens seem to be available. Ivermectin which seemed to be gathering popularity was not encouraged due to 'a lack of EBM' as a number of studies had not been able to prove its efficacy. The world was in a desperate need for a solution. Towards the end of 2020 the possibility of a vaccine became a reality. All efforts were focused on producing a vaccine. The then US President, Donald Trump, referred to this process as 'Operation Warp speed'. And as later admitted by a senior Pfizer executive J. Small, research was conducted at the 'speed of science' to develop this vaccine (4).

The fundamental paper that the vaccination process was based on was published in the NEJM which showed a 95% efficacy of protection with comparable adverse effects between the vaccinated group and the placebo group (5). The original recommendation based on the paper was a first dose followed by a booster. However, as it became apparent that the potency of the vaccine was diminishing over time, further booster doses were recommended - even in cases where one had already contracted Covid-19.

Today, most of the world has got over the pandemic. Business has more or less returned back to normal, though there is still the spread of a much less virulent version of the Covid-19. The current recommendation of the WHO-as of August 2023- is still to continue with vaccination and booster doses of the Covid -19 vaccine (6).

However, it is now becoming apparent that the vaccine was not as safe as it was thought to be. Though the original paper reported the incidence of the adverse effects of the vaccine being comparable to that of the placebo group; since then studies have consistently demonstrated that there is a significant increase of serious adverse effects among the vaccinated. These serious adverse effects fall into four major groups : Cardiovascular disease, Neurologic disease, Thrombo-vascular events, and Immunologic abnormalities and all have resulted in an increase in morbidity and mortality among the vaccinated group (7, 8). This in turn led to re-examining the process behind the vaccine development and it seems that what we are aware is, just the tip of the iceberg. First, there was the whistle blower claiming that the original work with regard to the vaccine data was falsified, patients were not blinded, vaccination staff were poorly trained and that there was limited supervision of the trial. This report was published by the BMJ provided with internal company documents, photos, e-mails and audio recordings (9). The FDA's limited supervision of the trial has since then been documented by other independent workers as well (10). As time passed more and more questions were being asked about the 'entire production process of the Pfizer vaccine' and it is becoming obvious that there is no hard evidence that the vaccine had been properly tested before its release. There were multiple 'senate committee' hearings where these facts have been questioned from Pfizer officials, which are easily accessible on the 'YouTube'. I have provided just one reference where a senior Pfizer official, J. Small, admits that at the time of the vaccine release they had not tested to see that the vaccine prevents transmission (4). These events are a testimony to show how far we have strayed from the ideals of EBM.

During the pandemic, it seemed that even the very basic EBM was being ignored. Under the constant refrain of the WHO's 'Test, test, test' exhaustive PCR testing was carried out. We ourselves witnessed the disruption to our daily life, elective and casualty lists getting derailed by this process.This testing process lacked any scientific validity. A study carried out in Wuhan involving nearly10 million residents showed that there was no evidence of asymptomatic spread of Covid-19 and the value of this existing mode of testing was discussed in a BMJ editorial as well as the local newspapers in Sri Lanka (11-13).

There are also a number of significant issues relating to the practice of EBM that needs to be considered in this scenario. Covid-19 had been in the world for over one year (late 2019 to early 2021) before a vaccine made an appearance. The natural herd immunity was taking place and admission rates to hospitals had noticed to be declining before the arrival of the vaccine (14). Dr. Peter McCullough one of the foremost physicians /scientists who studied Covid-19 extensively advocated early treatment for the disease in order to minimize the morbidity and mortality (15, 16) and attested to these facts in giving evidence at the Texas Senate Human and Health Services Committee as early as March 2021 (14). Front Line Covid-19 Crit-

ical Care Alliance (FLCCC) published guide lines on prophylaxis and treatment of Covid-19 (17). This data should have been publicized through the media, when considering the desperate state that the world was in at that time, considering the amount of coverage that was given portraying the suffering of humanity and the production effort spent on the vaccine. None of this data was given any publicity by the main stream media.

One of the more disturbing aspects surrounding the EBM approach was the WHO and the other Medical authorities stand on controlling the treatment of Covid-19. Though there were trials that did not show the efficacy of Ivermectin in the treatment of Covid-19, there were also well conducted trials showing the vast benefit of Ivermectin on Covid-19 (18, 19). In fact, the control of Coivd-19 in the Northern states of India and across a number of other countries had been attributed to the use of Ivermectin (20). The FDA advised against the use of Ivermectin and carried a picture of a horse to push their message that this is a veterinary drug (21). The WHO 'ordered' that Ivermectin should not be used outside a trial. How is this acceptable? All of the research articles we read only present evidence. It is up to the individual clinicians to assimilate this evidence and then decide what he/she plans to do in consultation with the patient; who has also been made aware of this evidence.

Insisting on vaccination of those who had already got Coivd-19 was another area that lacked EBM, even according to the known empirical knowledge about infectious disease pathophysiology. There is now evidence, showing conclusively that the natural acquisition of Covid-19 provides a much better immunity than what the vaccine could ever provide; questioning, on a much serious level, the efficacy of the vaccine. In an elegant study that was carried out in Israel it has been shown that those who had natural immunity are 13 times less likely to get infected again than those who were vaccinated; those who acquired natural immunity were 27 times less likely to get symptomatic infection than those who were vaccinated and in the vaccinated group there were 8 hospitalizations due to infection whereas in the natural immunity group this number was zero (22).

Today the most serious aspect following the Covid-19 pandemic is the continuing increase in the 'excess mortality rate' (EMR). What was expected was, an EMR below the average (if not average) of Pre-Covid years, definitely in 2022 and may be in 2023 as well. The reason being, Covid-19 was no longer a threat, the vaccine had protected people and the vulnerable groups who would have had natural deaths in 2022 and 2023, had already succumbed to Covid-19 and therefore would not be on the mortality statistics for 2022 and 2023. During 2020 the EMR was high, as expected due to the Covid -19 pandemic. However, instead of decreasing in 2022 and 2033 the EMR has remained high. Data from 2022 shows that countries that had a higher vaccination percentage (of their population) had a correspondingly higher EMR with comparison to other countries that had a lower vaccination rate, with this trend continuing into 2023 (23). This EMR has been brought up for debate by Andrew Bridgen MP in the British parliament, where a significant number of issues surrounding the Covid-19 vaccination process was questioned (24).

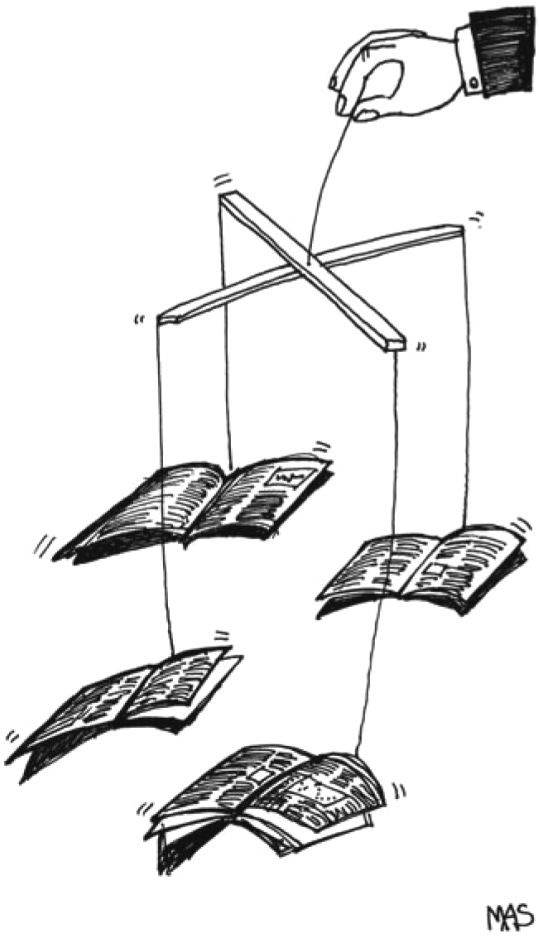
One needs to ask how was it that, what was thought to be initially a somewhat severe strain of a winter flu got depicted as a deadly respiratory disease? How was an entire world convinced to take a vaccine that was not effective-(did not prevent the acquisition of the virus, the manifestation of the disease or the spread to another person)- nor safe - (serious adverse effects beyond the Covid -19 infection itself)? Was it as a result of a McNamara fallacy* or was there something more sinister afoot? Is it because the narrative -truth (EBM)- is being controlled? In a very subtle way advice that was offered had instead become prescriptive. Physicians who did not comply were censured, and social media was controlled (and is still controlled) (25). Despite mounting evidence to the contrary, the vaccination process was made a mandatory process for functioning in society. The entire process on which EBM operates was disrupted at every single point.

One possible significant contribution to this process is the loss of independence of the health authorities. From the late 1970's following the embracement of neoliberal economic policies, which have now spread throughout the world; more and more of the funding of the health sector has passed towards the private sector from the state sector (26). This has resulted in a major percentage of the health and drug regulatory authori-

* McNamara fallacy , where analysis of a complex collection of data leads to a false conclusion.

ties being funded by the private sector. The US FDA, the UK MHRA and the Australia TGA have 65%, 86% and 96% respectively of their budget funded by the industry and the question has been asked : "From FDA to MHRA: are drug regulators for hire ?" (27).

The blowback of this on research is that, which research is being funded, is increasingly getting controlled by the industry -as it is the drug and health authorities that decide which research gets funded. The resulting increase in the number of publications that favoured 'Big Pharma' prompted, Richard Horton the editor of Lancet to write "Journals have devolved into information laundering operations for the pharmaceutical industry" almost 20 years ago (28). Richard Smith went on to discuss this issue as to how the pharmaceutical industry achieves its goals and as to why, peer review is not a solution for this problem (29). This fundamental tampering with the research ultimately feeds into reducing the integrity of EBM.



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(Illustration: Margaret Shear, Public Library of Science)

All of this needs to be taken in context of how the world works today. It is the same web of companies that fund the health authorities, that invest in the manufacture of drugs and vaccines and also control the media. For example, YouTube is owned by Google, whose parent company is Alphabet Inc. which is invested in Pfizer; which in turns funds the FDA (30, 31). We all experienced firsthand how the Covid pandemic changed the economies not just in our country, but throughout the world. It has been calculated that 573 people became billionaires during the Covid pandemic at a rate of one billionaire every thirty hours, while at a corresponding rate 263 million people would crash into extreme poverty at a million people every 33 hours (32). A few years back Dr. Sunil Wijayasinghe, a past president of the Sri Lanka Orthopaedic Association, in an after-dinner speech referred to the fact that 'Big Pharma' is influencing the normal values of a healthy HbA1c. The adoption of 7% as an A1c target led to a tenfold increase of the diabetic drug sales for $7.3 billion in 2000 to $74 billion in 2020 (33, 34)! It seems that science is indeed for sale (35).

The question is whose agenda is the WHO and the other regulatory organizations carrying out? The WHO is an unelected, diplomatically immune, tax-exempt group. Currently it is estimated that almost 84% of its funding is from private sources (36). The WHO is proposing a new Global Pandemic Treaty with amendments to the international health regulations (37) that if implemented will have the potential to override the democratic rights and sovereignty of individual countries i.e. They will be able to dictate when to consider a pandemic is in place, when and how long, countries are to be in lockdown etc… this has been brought up at the European parliament as well as the British parliament (38).

So, let me ask once again, who defines truth?

"Stability and growth in uncertain times" has been the theme of the Sri Lanka Orthopaedic Association (SLOA) for this year. And for any meaningful growth, a firm handle on truth is required, which in turn requires data. "Data! data! data!" he cried impatiently. "I can't make bricks without clay" as we will all recollect of the immortal character of Sherlock Holmes. Meaningful analysis of primary data is required to arrive at the 'truth'. It is our moral duty if not as men of science, then at least as the custodians of our patients, to stand on the

side of truth. Conventionally in our country the medical profession is considered to be the highest profession, where one could make the most meaningful impact on the society. 'රජකම නැත්නම් වෙදකම' (If one cannot be a king, then be a physician/surgeon). It is with this in mind, that I have dedicated this issue of the SLJOS-in my inaugural year as the Editor-in-Chief of this journal- to the study of data and research.

I wish to thank all who have contributed their time and expertise to this subject of data analysis and research. I wish to thank the Galle Medical Journal for giving me permission to reprint one of their leading articles that explains the McNamara fallacy- I have referred to- and questions the conventional approach to EBM, showing that EBM also needs to be questioned.

I thank Dr. Upali Banagala for his dedication to this journal throughout the last 15 years.

Finally, it gives me great pleasure to be able to inform the readership that Professor **Paul N Smith** AM BMBS FRACS HonDUniv FAOrthA , has joined our International Advisory Board. I would like to take this opportunity to formally thank him and wish him all the very best on behalf of the SLOA and the people of this country -the ultimate beneficiaries of our endeavours.

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Attadīpā Viharatha

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