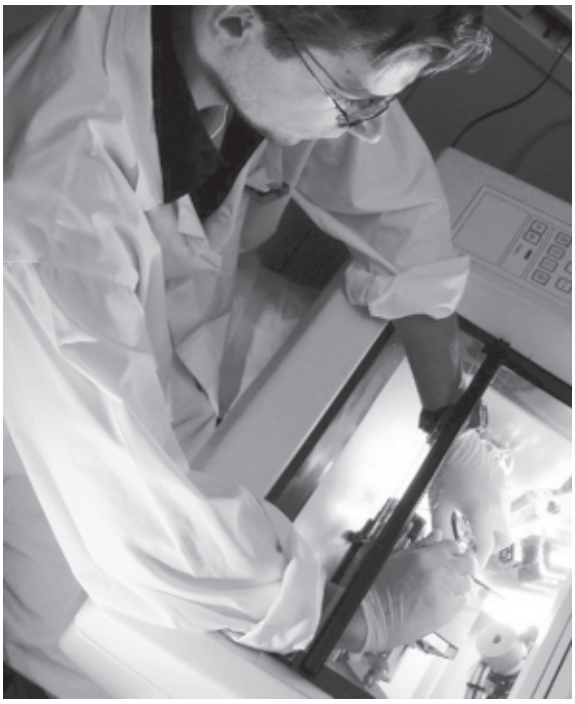
Quality Assurance and Medical Research

By Prof Woo Keng Thye



Many of us who have been involved in research over the past one to two decades will appreciate that support for researchers have improved by leaps and bounds. More than 20 years ago, the Ministry of Health (MOH) only disbursed $100,000 (with grants in the region of $2,000 to $3,000) a year through the Medical Clinical Research Committee (MCRC) which also issues Certificates for Clinical Trials under the Medicines Act. Today, the National Medical Research Council (NMRC) has a budget of $45 million a year. And yet, in today's context, $45 million a year does not seem quite enough.

"The mission of the NMRC is to engender the growth of research talent; to support high quality scientific and clinical research and to improve medical care and human health."

QUALITY ASSURANCE

In this commentary, I would like to stress on Quality of care in the conduct of research. "Quality of care" is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This is the definition of Quality from the Institute of Medicine (USA).

From the Australasian Colleges of Physicians and Paediatrics, one definition of Quality is that which gives complete patient satisfaction. Another is "the ability to achieve improved healthcare and its acceptability to patients and society."

The term Quality Assurance is not new to those involved in Clinical Trials. This is especially so with the introduction of the Good Clinical Practice Guidelines in Singapore in July 1998 by MOH under the Medicines Act. In today's context, we are talking about applying the same stringent measures not only for Clinical Trials through the Institutional Ethics Committee or the Institutional Review Board with strict monitoring and audit of the conduct of the research. This should apply not only to both Drug and non-Drug Clinical Trials, but also any research projects approved by the Ethics Committee. A strict Ethical Code should be observed in whatever manner of medical research, whether in the research laboratories or the experimental surgery laboratories, or whatever area of research we are in.

NMRC's definition of Quality Assurance would embrace these three areas, namely, high quality of research; conformity with ethical principles in the conduct of human, animal and basic research; and accountability in the use of public funds.

It has been held by some that Quality Assurance is an invention of the past few years. In fact, this is far from the truth. Quality Assurance has a long and significant heritage. In China, it has its origins, both for Medical Ethics as well as Quality Assurance in the person of Hua Tuo, a simple and humble Chinese physician, also known as the miracle healer who was also a pioneer in medical research, and who later became Chief of the Imperial Medical College set up by Prime Minister Cao Cao during the period of the Romance of the Three Kingdoms.

In 1747, James Lind, a Naval Surgeon from the Royal Navy, sought a cure for scurvy, then the scourge of sailors and explorers. He took 12 sailors with scurvy, divided them into pairs and gave each pair a purported remedy. Only the pair given lemon juice recovered within a week. You can see that clinical trials, even in those days, already had not only a scientific but also a Quality Assurance aspect. The Quality Aspect of clinical trials and research is of course enshrined in the Geneva Declaration which we all subscribe to. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration."

Exactly a century after Lind, Semmelweis in Vienna was wrestling with another problem – the horrendous death rate in women during childbirth due to childbirth fever. Speculating that there was a link between the autopsy room and the deaths, he demanded hand washing with carbolic soap and measured the results – there was a dramatic fall in deaths among his patients. At that time, he was ostracised by his colleagues and he left Vienna for Budapest, a broken man, and died insane.

The term Quality Assurance tends to produce negative impressions among doctors because in some institutions, it is foisted upon busy clinicians or performed in an amateurish fashion to satisfy bureaucracy. It is perceived as an administrative

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tool for detecting erring doctors, or a bureaucratic tool to justify resource limitations.

For me, Quality Assurance is neither an art nor a science. It is a philosophy – a way of life, and should form part of our work ethos.

INFORMED CONSENT

Medical progress is based on research which ultimately must rest in part on human experimentation involving human subjects. In the field of biomedical research, a fundamental distinction must be recognised between medical research, in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnosis or therapeutic value to the person subjected to the research. Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

I would now like to stress on the importance of informed consent in research. It is as important as taking consent for HIV testing but more complex. As medical researchers dealing with taking consent for patients' blood or other body fluids, tissues for any form of research including genetic studies, the emphasis should be on the doctor's total disclosure, including any procedures and / or related tests not documented in the research protocol (which should be rectified with new approval from the Ethics Committee if any additional procedures or tests are subsequently added). We must explain and discuss with the patient before we remove any blood, body fluids or tissues to ensure that the patient's refusal or consent is truly informed. I stress again that the emphasis should be on the doctor's disclosure rather than the patient's consent. The doctor must disclose whatever social risks or early benefits the tests results may bring if the sample is for genetic studies. In addition, the patient must be told how the data may be anonymised, or released to whom and for what purpose. If the test results are positive for a particular disease, the doctor must inform the patient and counsel him.

TOMORROW'S MEDICINE (2010)

We are already in the midst of an information technology (IT) revolution. Computer networking, automated health data capture, and intelligent information networks are already in place, but we still have to refine the process and have a long way to go. There are many opportunities for health-oriented telecommunication applications. The age of menu-driven or recipe medicine with computerised medical protocols for diagnosis and procedures is not too far off.

GENOMICS AND THE LIFE SCIENCES

Genomics begun in October 1990 as the U.S. Human Genome Project and the working draft was completed in June 2000. The application of genetic engineering technology will change our perspective of human biology. This will permit forecast of major diseases in individuals. The practice of medicine will shift from responding to illness after it reaches a certain threshold, to minimising unnecessary human morbidity.

Ongoing research in life sciences will usher in the age of gene therapy and other biotherapeutics.

CORE COMPETENCE AND RESEARCH CULTURE

Only when we have a thriving research culture, not only within our universities but also within our hospitals and national centres, can we change and enhance the landscape for medical research in Singapore. We have to engage in more meaningful and useful translational research. To this end, we must carefully shape the present clinician scientist scheme and nurture potential clinical scientists, in order to ensure a steady supply of clinical scientists who should act as mentors and role models for the younger clinical researchers.

We need to nurture and imbue in our young doctors the sense of fulfillment that can be derived from research. If we can fire the passion of our young medical minds, we will have the dynamo to propel the nation onwards to meet the challenges of the brave new world of the genomic era. Gene expression, polymorphism, SNP and haplotypes should form part of the new medical vocabulary.

Our medical graduates, schooled in a new language and adequately fortified with biovitamins of the new era will be able (to quote Albert Einstein) "to use their imagination to raise new questions, explore new possibilities and regard old problems from a new angle" – thus creating a new landscape for medical research which will enable the nation to meet the morning's challenges. ■