Challenges in Clinical Research in Malaysia

Z A M H Zabidi-Hussin, FRCPCH

Department of Paediatrics, School of Medical Sciences, Universiti Sains Malaysia, Kubang Kerian, Kelantan, 16150, Malaysia

INTRODUCTION

Although the percentage of Gross Domestic Product (GDP) spent on research and development in Malaysia is small compared to other developed nations, there has been a significant amount of resources dedicated to this endeavor. In the Eight Malaysian Plan, almost RM360 million was allocated to the Ministry of Science, Technology and Innovations for research purposes[1]. The Ministry of Education allocated RM100 million into the Fundamental Research Grant Scheme (FRGS) in 2002, a scheme designed to boost the knowledge on basic and fundamental sciences in Malaysia[2]. Similarly the Ministry of Health has allocated substantial amount of research grant in the Ninth Malaysian Plan through its various research divisions and centres. 2.4% of the total Ministry of Health development allocation is for Research and Development amounting to USD16.4 million[3].

It is expected that this trend of funding will continue for a long time to come. The Malaysian Government, in its Ninth Malaysian Plan has also clearly indicated that the main emphasis will be to invest in long term human development in the field of science and technology, boosting biotechnology and medical sciences. The Government has the desire to link all these to a credible biotechnology and medical service hub thus promoting the medical tourism industry.

Universities have also responded positively to the Government's recent initiative of creating Research-Intensive Universities. Multiple new Research Centres have been created along with the appointments of Research Deans from among the senior Professors. Some have even gone to the extent of undertaking out-of-space research experiments to gain an edge into medical research. New research alliances have been created and multiple research clusters formed[4].

The Potentials of Clinical Research in Malaysia

Malaysia has a gold mine of clinical cases, most of which have not been adequately mined through systematic research and publications. These clinical cases are reflections of the burden of disease faced by the health system in the country. Research funding priorities have in fact been formulated based on these disease patterns[5].

Some of the clinical cases seen in our hospitals are no longer seen in the more developed world, giving us the wonderful opportunity to utilize the latest methods in biotechnology, molecular genetics and neuroimaging to study and publish them internationally. These include diseases such as Rheumatic Fever, Systemic Lupus Erythromatosus (SLE), malignancies and tuberculosis. In the field of Child Health as an example, the prevalence of malnutrition among the paediatric population and the paradox of obesity that a developing nation is faced with, gives another chance for a complete collaborative study in the subject matter as has been found in a study linking malnutrition and the Geoinformation System (GIS)[6].

The heterogeneous population in Malaysia with its good expertise and infrastructure would also make creative clinical trials attractive especially in the field of pharmacogenomics. The widespread use of English in the medical training and interaction again provides wonderful opportunities for any clinical research to be linked to international bodies, thus making the capacity of our clinical researchers visible in the international arena.

Challenges in Undertaking Clinical Studies in Malaysia

a) Research in Government Hospitals

Although most of the state service-oriented hospitals have the necessary number of clinicians to provide medical care at the specialist level, their commitment to research activities are often limited by the tremendous clinical service burden including supervision of junior doctors. Furthermore out of more than 7000 medical and surgical specialists available in the country, more than 50% of them are working in busy private sector settings and are certainly not ready to undertake research activities. The profile of clinical cases seen in specialist private medical centres may also not be of the type suitable for research purposes.

Three major teaching hospitals namely, Hospital Universiti Sains Malaysia (HUSM), Hospital Universiti Kebangsaan Malaysia (HUKM) and University Malaya Medical Centre (UMMC) are staffed by academic clinicians whose job descriptions include research and publication. Academic clinicians belonging to the other 15 medical schools nationwide however, do not have access to their own university hospitals but have to rely on state government hospitals, for teaching. The constraints facing these hospitals make research activities limited. The ever increasing number of medical students in most medical faculties put additional teaching strain on these academicians, seriously limiting their research output. Although one is familiar with the intense requirements of international academic reputation, the basic teaching and learning work load faced by the limited number of clinicians in an academic department makes the 'publish or perish 'culture conveniently ignored, much to the dismay of Government ministers. A fully –developed academic department in an advanced country with 2-3 times the number of academicians we have would certainly be in a

Corresponding Author: Zabidi Azhar Mohd. Hussin, Department of Paediatrics, School of Medical Sciences, Universiti Sains Malaysia, Kubang Kerian, Kelantan, 16150, Malaysia Email: zabidi@Kb.usm.my

better position to undertake 'edge- of- technology' clinical research compared to counterparts here struggling with a full day clinic with 100 patients and a large group of medical students!

If ever the 'publish or perish 'culture is forced to be embraced under the above constraints, one is mindful that it would be done at the expense of teaching and clinical role modeling of medical students and trainees. These essential academic activities, I fear would be delegated to the vulnerable junior and inexperienced doctors[7].

A re-look at our clinical research agenda may therefore be necessary in order for our clinicians to remain competitive.

i) Establishing research and publication secretariat at major state and university hospitals.
Through this initiative, the infrastructure and strategic research planning could be done in a well coordinated manner. Researchers have often been blamed for undertaking 'exotic' researches which are not necessarily relevant to real patients' needs. Having such secretariat and leadership would certainly bring into resonant national research requirements. Frequent meetings between the various Research Secretariats would also enable sharing of information and avoiding research duplicates, so necessary for effective research grant disbursement.

This secretariat should be lead by a senior clinician and pay special emphasis in assisting clinicians to publish, rather than simply be research-grants administrators, or 'moral judges' beyond the scope of internationally-published Research and Ethical Guidelines. The secretariat needs to maintain a good database system to capture real-time clinical data while at the same time have ready access to a trained medical writer and medical statistician.

'Research-leave', 'sabbatical leave' or 'writing leave' may be considered as part and parcel of perks affordable to all clinicians rather than exclusively applied to university-based academic clinicians.

ii) Students as clinical researchers
The potential of undergraduate medical students in undertaking important clinical researches cannot be undermined, provided sufficient supervision is given. Universiti Sains Malaysia (USM), Universiti Putra Malaysia (UPM), and The International Medical University (IMU) are among those which make it compulsory for students to go through research methodology and statistics course and submit clinical projects as part of the requirements during their 5-year undergraduate training. This is done through various initiatives such as the Community and Family Case Studies (CFCS), Elective Bursaries funded by National Medical Foundations, Biomedical Sciences requirements and the Clinical Elective programmes. Indeed some of these clinical studies have received national awards and have even published in international high impact journals[8].

The future role and importance of medical students in clinical research can further be enhanced by having programmes such as the MBBS-PhD combination. Such an extended basic medical programme which is aimed to produce clinician-scientist has started in Australia and Singapore[9].

iii) Postgraduate medical researchers
The clinical research scenario in Malaysia has been changed dramatically over the years through the establishment in 1990s of the Masters of Medicine and Masters of Surgery programmes placing clinical research as their key requirements. This 4-year period of training undertaken in USM, UKM ,UM, and UNIMAS has managed to produce more than 3000 qualified medical specialists who had, not only undergone clinical training but had also submitted research dissertations examined by local and external examiners.

Research topics are identified during the second year of training. Researches are then undertaken after a series of research methodology and medical statistics course held throughput their period of postgraduate training. This approach in postgraduate medical education has been responsible for the large number of research presentations by our local postgraduates in national or international specialty meetings. Some have also been published in high impact international journals[8].

It is rather unfortunate that many such research efforts have culminated in the production of neatly-bound dissertations and not moved beyond medical school libraries, upon graduation of these specialists. The time available for them to pursue publication of their work becomes seriously impaired as they move on to take up busy service jobs throughout the country.

Incorporating the research element into the clinical postgraduate training is becoming a trend elsewhere in the world. Changes have taken place in the United Kingdom, USA and Australia specialist training programme which makes it necessary for some form of clinical research to be undertaken during the training of a resident specialist[10].

The clinical research approach in our postgraduate training in Malaysia may be enhanced further by having a combined MMed-PhD, through an extended period of training.

iii) Foreign students, Post docs
As Malaysia embarks upon making this country a hub for education, we see an increasing number of foreign medical doctors coming into the country for their postgraduate medical training at various levels. In USM, we witness a 10-fold increase in the number of postgraduates pursuing their clinical MMed over a 5-year period (2000-2006)[11]. Many of these highly talented doctors from overseas who would have otherwise gone to other countries are now involved in clinical research in Malaysia.

Researches involving foreign students would certainly be beneficial if combined data could be obtained from their respective countries, making cross continental comparison in clinical data possible. The ease of international travel, simplicity and safety of transport of medical specimen would pose no major barrier for this to happen, provided that the ethical issues have been subjected to rigorous scrutiny from the respective Institutional Review Boards, Ethics Committees and the Malaysian Medical Council. Involvement of international students and post docs would serve to benefit the scientific community, while at the same time give an-added value to our own students by enhancing their international exposure.

CONCLUSION

Among the major challenges in clinical research is to ensure adequate research collaboration between researchers and institutions. It would be a great loss of resources if research ideas and funding are unnecessarily duplicated between institutions. High level collaboration between Ministries of Higher Education, Health, Science, Technology and Innovations, and Non-Governmental Organizations is therefore needed to ensure that all pertinent research issues are dealt with across the various ministries. The collaboration may even extend to having common research-priority long term plans, allocation of funding and at a lower level, perhaps common Research and Ethics Board that will serve the need of all in a facilitative manner. By that approach the true meaning of working 'together' would be realised as opposed to the notion of working 'to gather' one's own fame and glory in pursuit of research excellence!

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