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Investigator Initiated Trials

Clinical trials can be industry sponsored (very common) or investigator initiated. Before we go into the details, let's have a look at the meanings of sponsor and sponsor-investigator as explained by the International Conference on Harmonization (ICH) Harmonized Tripartite Guideline for Good Clinical Practice (GCP) 1996.

The sponsor is an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. (ICH GCP 1.53)

The sponsor-investigator is an individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g. it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator. (ICH GCP 1.54)

Investigator initiated trial versus industry sponsored trials

Hence investigator initiated trials are clinical trials initiated and conducted by the clinician who has to bear the obligations of not only the investigator but also the sponsor. Doing a clinical trial is already a challenge in itself but more so when embarking on an investigator initiated one.

Understandably pharmaceutical companies have their own objectives in conducting trials and that is mainly to test drugs they developed for safety and efficacy and ultimately getting it registered or approved. Those companies also conduct post marketing studies to promote the use of certain drugs or to discover rare adverse events. Many clinicians are willing to and have been participating in industry sponsored trials mainly because of the opportunity to participate in research thereby gaining some professional satisfaction, getting updated in the developments of their related fields, networking/establishing contacts with other clinical investigators and other incidental benefits that come along with the research.

Why then do clinicians want to initiate their own trials?

The reasons for clinicians wanting to initiate their own trials are numerous and include some of the following.

- ◆ Concerns about the efficacy and safety of generic: this usually happens when there is a clinical suspicion of lack of anticipated therapeutic response. A therapeutic equivalence trial is an important option towards gathering the required scientific evidence.

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From The Editorial Desk....

A research-based fact is like an uncut diamond, valuable but of little use if not applied. For health research to flourish within the Ministry for Health, we need to encourage managers, clinicians and researchers to share expertise, resources, facilities, ideas, and to work in an integrated and coordinated manner. There is a need to continuously exploit the large pool of untapped research findings not only to facilitate drug discovery and development but towards improving the quality of health services. To this end, we need to intensify efforts to cultivate and facilitate the research culture amongst health care professionals and managers so that research will form part of their general work ethics.

With today's emphasis on E-economy, an important element towards facilitating this research culture is to provide up to date information for example, on research methodology and on work done by other research centers. The feature article in this issue discusses the important aspects that need to be considered either in undertaking clinical trials or in outsourcing for one. We would also like to bring to your attention about the formation of the Ministry's Herbal Medicine Research Centre (HMRC) located within the vicinity of the IMR. In view of the rapid growing market of the herbal medicine industry, the formation of HMRC is timely.

Our personality profile section focuses on the thoughts and aspirations of the man behind the reigns of the Clinical Research Centre, the youngest research institution within the MOH. Last but not least in our international column, we want to share with you some "non-technical" but nevertheless important research work with regards to doctors' behaviours and penchant.

News From NIH Component Institutes

INSTITUTE OF HEALTH MANAGEMENT

1. Rapid Response Mechanism

The Ministry of Health is committed to providing quality health care in a safe environment. In line with this, the Institute of Health Management is in the process of developing a "Rapid Response Mechanism. Through the latter, all departments within the Ministry of Health shall identify and investigate potential and real risk situations their clients may be or have been exposed to, and where necessary to take immediate corrective action as required. Every client's needs shall be addressed and responded to rapidly and all complaints shall be managed immediately at the place of the incident. In addition, all incidents (for which a set of definitions has been outlined) must be analyzed and the situation monitored with strategies developed to prevent recurrence.



Under the WHO Programme budget for Malaysia for the year 2002-2003, IHM has received a consultant for two projects proposed by this institute :

2. Health Management Strengthening Project with WHO

1. Development of a module and an action plan for Action Research

2. Consultancy on Health Management Strengthening

A WHO consultant from Australia, Associate Professor Dr. Ronald Van Konkelenberg, has been identified for both these projects. For Action Research, this project will be undertaken in two phases; preparation of the draft module in the first phase and organizing a workshop on Action Research using this draft module in phase 2.

For the project on Health Management Strengthening, a review is currently being undertaken on the Institute of Health Management's existing manpower capacity and capability to train and develop the managerial skills of the health managers in the public health sectors. Upon its completion, recommendations will be forwarded to the Ministry.

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Dato Dr. Zaki Morad bin Mohamad Zaher Director of the Network of Clinical Research Centres

Head of Department of Nephrology Hospital Kuala Lumpur

Dato' Dr. Zaki Morad bin Mohamad Zaher is the Director for the Network of Clinical Research Centre, Ministry of Health Malaysia. He is also the Head of the Nephrology Department at Hospital Kuala Lumpur and is often seen hurrying around the hospital attending to his clinical duties. He is known to his colleagues and staff to be a very approachable, disciplined and soft spoken person. Despite his busy schedule, he's always around to listen to his staff and offer them solutions to their various problems. He also manages the many responsibilities that are before him in a very structured and timely manner.

Dato' Dr. Zaki Morad heralds from Alor Star, Kedah. He received his primary schooling from Sultan Abdul Halim School Alor Star and completed his secondary education at the Sultan Abdul Hamid College Alor Star. At school, besides concentrating on his education, he also had a keen interest in outdoor activities. His favorite games were football, sepak takraw and badminton. He still believes that a healthy lifestyle is very important in this day and age. These days golf has become his game of choice, though he has very little spare time to spend at the golf course. He is also an avid reader and favor books in the spy and biography genre. He particularly likes novels written by John Le Carr and is of the opinion that spy novels written during the 'Cold War' era were more interesting. He also likes reading biographies of international figures of repute such as the biographies of YAB Dato Seri Dr. Mahathir Mohamad, Nelson Mandela, Mahatma Gandhi and Lee Kuan Yew. He also likes to keep up to date with international relations and international politics.

Dato' Dr. Zaki Morad graduated from University Malaya in 1975. Following this he was posted to Hospital Kuala Lumpur where he had honed his interest in Medicine and particularly in Nephrology. He then went on to successfully complete the MRCP (Edinburgh) Examination in 1980. Following which he underwent 2 years of Nephrology specialization at the Royal Hallamshire Hospital, Sheffield and Guy's Hospital, London. Upon his return from the UK, he continued to work in the Nephrology Department of Hospital Kuala Lumpur. And in 1987 he was promoted as the Head of the Nephrology, the post he holds today.

In the field on Nephrology, Dato' Dr. Zaki Morad has a very keen interest in Kidney Transplantation and Dialysis treatment. When he had initially worked in the Nephrology Department from 1984 - 1987 there were only 8 Hemodialysis Centers in the Ministry of Health (MOH). Now there are more than 60

MOH Hemodialysis centers in the MOH. He has helped in training and imparting his knowledge to most of the current Nephrologists in this country. He attained an interest in research while working under the guidance of Yg Bhg Tan Sri Dato' Dr Abu Bakar bin Suleiman.

Dato' Dr. Zaki Morad became the Director of the Network of Clinical Research Centers MOH in 1999. He has presided over the expansion and believes that the rapid progress made by CRC was possible only through good team work and collaboration. He states that CRC goal is to promote research among clinicians.

According to him,



traditionally clinicians have been very service-oriented and committed most of their time into their respective clinical specialties. In these times when there is such a great need for scientific evidence related to healthcare, Dato' Dr. Zaki Morad believes that clinicians should conduct research along with their respective clinical practices. This is where CRC aims to offer their services in facilitating the clinicians to conduct their research.

He feels that within a short time since its inception CRC has been able to establish itself as an Academic Research Organization and has successfully attracted good staff to work in CRC. Furthermore CRC has been able to conduct GCP Compliant Clinical Trials and to produce publications in international peer reviewed journal. CRC has also managed to put in place all the components of research in an organized manner. He attributes this to the good and able officers working in CRC now.

Through his active involvement in nephrology, research, professional organizations and various NGOs, Dato' Dr. Zaki Morad has compiled an impressive list of achievements nationally and internationally. He has been a Malaysian Medical Council (MMC) member for the past 12 years, and is currently the President of the Malaysian Society of

Transplantation. He is also the Past President of the Malaysian Society of Transplantation and he presently serves as Vice Chairman of the National Kidney Foundation. On the Academic scene, he is an honorary lecturer to International Medical University (IMU) and is also a member of the Academy of Medicine of Malaysia. He has been an examiner for the local Masters in Medicine program as well as the MRCP (UK) exams. On the International Scene, he is the secretary general of the Asian Pacific Society of Nephrology, the incoming President of the Asian Society of Transplantation and a committee member of then Commission of Global Advancement of Nephrology of International Society of Nephrology. His expertise in the field of Nephrology has been recognized internationally as he is on the Curriculum Development Committee of the International Society of Nephrology which serves to come up with a standard curriculum for nephrology trainees all over the world. He is also a member of the Scientific Program Committee for the next International Nephrology Society Meeting in Singapore in 2005.

He advises budding researchers and clinicians to look into their respective specialties and to find new areas where good research can be conducted. Overseas research findings may not be suitable for our local settings as the patient populations are different. He also felt that research is a team oriented process which should be well planned and organized. He understands and is aware that clinicians have multiple roles to fulfill and one such role is to provide service to their patients. However practicing clinicians should recognize that it is not good enough just to provide service, they should also be actively involved in research. A change of mindset is needed urgently within the clinicians in this country as doing research will enhance their clinical competence.

As we came to an end to this very lively and candid interview I requested Dato' Dr. Zaki Morad for an opinion of his view on the future of CRC. Promptly without hesitation, he said "CRC should encourage more clinicians to participate in research and to increase the research base of the organization by collaborating with the many varied clinical specialties within Ministry of Health Malaysia. CRC should build its strength on its core competencies. CRC should be flexible and team oriented in increasing the research competencies of the organization". And with that, I thanked him for his time and left this esteemed clinical researcher to his work.

Contributed by:
Dr. Sanjay Rampal

CLINICAL RESEARCH CENTRE, HOSPITAL KUALA LUMPUR

1. Clinical Economic Workshop

A workshop on Clinical Economics with the theme "What Every Clinician Needs to know" was successfully organized on the 5th – 7th February. This was a collaborative effort between the CRC, the Medical Development Division of the Ministry of Health and the Kuala Lumpur Society of Clinical Biostatistics. The workshop was formally officiated by the Director General of Health Malaysia, Y. Bhg. Tan Sri Datu Dr. Mohd Taha Mohd Arif.

2. Membership to INCLEN

As of Feb 2003 CRC has been accepted as a member of INCLEN (International Clinical Epidemiology Network). INCLEN is a network of physicians, statisticians and social scientists throughout the world that work together and are dedicated to improving the health of the people by promoting clinical practice based on the best evidence of effectiveness and the efficient use of resources. CRC is actively involved with INCLEN Trust and functions as an INCLEN CEU (Clinical Epidemiology Unit). Currently, the CRC is in the midst of conducting the EQUAL Research Project - a multi-country research project by the Group of INCLEN-SEA (International Clinical Epidemiology Network – Southeast Asia).

3. National Cancer Registry

The National Cancer Registry Advisory Committee had appointed the CRC to provide the functional capacity for the registration of cancer patients. CRC has established a Cancer Registry Unit for this and it maintains the registry



national databases. The Cancer Registry Unit has been functional since 1/4/2002. The National Cancer Registry (NCR) is a service supported by the Ministry of Health (MOH) to collect information about cancers in Malaysia, which will enable us to know the incidence of cancer, and to evaluate its risk factors

and treatment in the country. This information is useful in assisting the MOH, Non-Governmental Organizations, private healthcare providers and industry in program planning and evaluation, leading to cancer prevention and control.

The launching of the National Cancer Registry 1st Report will take place on the 4th July 2003. For more information please go to the NCR website at <http://www.crc.gov.my/ncr/>

4. National Cataract Surgery Registry Unit

The National Cataract Surgery Registry Advisory Committee had delegated the CRC to provide the functional capacity for the registration of cataract surgery patients. For this purpose, the CRC has established a Cataract Surgery Registry Unit.

The "Preliminary Report of National Cataract Surgery Registry January - March 2002" was presented to all the Heads of Ophthalmology Departments, source data producers and managers of intraocular lens companies on the 18th February 2003.

The full report can be accessed at the NCSR website (<http://www.crc.gov.my/ncsr/>)

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INSTITUTE OF MEDICAL RESEARCH

1. Commercialisation of the production of indigenous microbial control agent, Bacillus thuringiensis serotype H-14

Since 1988, IMR had been successful in isolating large number of indigenous bacteria that exhibited very high larvicidal activities against mosquitoes. Most of these bacteria are those of the Malaysian strains of Bacillus thuringiensis serotype H-14. These strains had been shown to be highly and selectively effective against mosquito species, both in the field and laboratory, but yet are completely harmless to all other non-target organisms such as fish, tadpole, man and other warm-blooded animals.

Because of the high activity of these strains, studies were undertaken to examine the possibility of local mass production of these agents. The first fermentation studies using shake-flask method were conducted in this Institute in 1990-1992 using locally-available wastes for the small scale production. Subsequently, in 1996 in collaboration with a local biotechnology company (INBIOTECH CO.) and Russian scientists, 3 local isolates of Bti were successfully produced in 100-liter bioreactor.

These products were highly effective against all mosquito larvae. Since 1997, the production of Malaysian isolates of Bti has reached the industrial scale and resulted in the production of a Bti product known as MOSBAC. The latter's bioefficiency against Aedes aegypti (a standard test mosquito) is about 0.5 mL/L or 5x10⁻⁴ mL/L, i.e. highly toxic to mosquito larvae. This formulation can be easily mixed with water and used for spraying. It is completely safe to all

non-target organisms and as such can be used in environmental sensitive places such as zoo, recreation parks, household containers etc. in addition to other mosquito breeding sites.

2. Development of a comprehensive test kit for the rapid detection of insecticide resistance-

Today resistance detection is dependent on the use of WHO test kits which provide insecticides for the direct testing of insects. Although useful and effective, WHO tests possess inherent weaknesses such as the requirement of large number of test insects, shelf life of test insecticide,

3. Commercial production of Bacillus sphaericus-

Bacillus sphaericus is another potent microbial control agent of mosquito larvae especially effective against Culex and Anopheles. Several promising isolates were successfully obtained from soil samples collected in P. Malaysia. Like B. thuringiensis, this agent is completely innocuous to all non-target organisms. However, unlike B. thuringiensis, it is difficult to grow in large scale fermentation due to its specific requirements. The successful development of a bioprocess for the large scale production of Bs has enabled its commercial production as a biolarvicide especially tailored for the control of Culex and Anopheles vectors. The product known as

MOSPHERIX is now ready for commercialisation.

4. Commercial development of an household insecticidal emulsion paint

This product, known as Painticide is now commercialised by a local company in collaboration with IMR. It is an emulsion paint formulation impregnated with a pyrethroid (deltamethrin) that allows the slow release of the insecticide to the wall

surface, thus allowing a long residual effect of more than 2 years. A synergist is added to prevent the development of resistance in the insects. The paint is used primarily in areas where conventional methods of insecticide application cannot be applied or where long term control of insects is needed. The paint formulation is known to be effective against all insects especially cockroaches, mosquitoes and flies.



high cost etc which have prevented their widespread use. IMR has developed a comprehensive kit for the rapid detection of non-specific esterases, oxidases and insensitive acetylcholinesterase, the detoxification enzymes responsible for resistance to insecticides.

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We boil at different degrees.
— Ralph Waldo Emerson

*It is not because things are difficult
that we do not dare;
it is because we do not dare
that things are difficult.* — Seneca

*Laughter is the shortest distance
between two people.*
— Borge, Victor

*All that we are is the result of what we have
thought.* — Buddha



— Eve —
*"God," said Adam, "Why did you make
Eve so beautiful?"
"So you would love her."*

*"But why did you make her so dumb?"
"So she would love you."*

*I have not failed 10,000 times, I
have successfully found 10,000
ways that do not work.*
— Thomas Edison

*When making your choice in life,
do not neglect to live.*
— Johnson, Samuel

NIH Component: Institute of Public Health

i) World Health Survey 2002

This collaborative research between the Ministry of Health and the World Health Organization is in the phase of data collection. Training of data collectors and field supervisors for Peninsula Malaysia was conducted from the 17th February till 3rd March 2003. The same training was conducted concurrently for Sabah and Sarawak from 5th till 15th of March. A total of 32 field supervisors and 128 data collectors were trained.

A pilot survey was conducted following the training session. The period for this nationwide data collection exercise is

expected to be completed by end of April 2003. Concurrent data entry is also being undertaken during this phase of data collection. Data entry and data cleaning is anticipated to be completed by mid May 2003.

ii) Malaysia Food Consumption Survey 2002

The Malaysian Food Consumption Survey 2002 is a collaborative research project being conducted by the Institute of Public Health and the Division of Public Health of the Ministry of Health. Its objective is to determine the food consumption and

physical activity of Malaysian adults. Covering both urban and rural areas of the whole country, the sampling frame used was obtained from the Department of Statistics' National Household Sampling Frame for the year 2002. About 1125 enumeration blocks were selected and an estimated 9000 individuals had been recruited for the survey.

Training for data collectors had been carried out in August 2002 and the survey has now completed the data collection phase. Data cleaning and data entry is currently being undertaken with analysis anticipated to be completed by end of 2003.

NIH Component: Clinical Research Centre

i) MMF in Lupus Nephritis Trial

An open labelled, multicentre, randomised phase II trial to determine the activity of mycophenolate mofetil (CellCept®) for the treatment of severe lupus nephritis

ii) DECIDE Trial

A Multi-centre, Open label, Randomized Controlled Efficacy study of Direct stenting compared to Conventional stenting in Diabetic patients undergoing Elective angioplasty for Coronary Artery Disease (DECIDE Trial)

iii) CAPD2 Trial

A Randomized, Multicentre, open label trial to establish the equivalence between

Staysafe® /ANDY-Disc® (FMC) and Ultrabag® (Baxter) in patients on CAPD

iv) Evidence for Quality in Asia and Australia (EQUAL) Project

A study of the development, dissemination, implementation and impact of Evidence Based tools for Tuberculosis and Hypertension Management.

v) Refractive Error in Children in the district of Gombak

An inter country study of the prevalence and associated factors of myopia and other visual impairments

vi) Economic Evaluation of the Ministry of Health Nephrology Services: Cost effectiveness of Centre Haemodialysis and Continuous Ambulatory Peritoneal Dialysis in the Ministry of Health hospitals

This is a multi-centre observational study designed to determine the cost efficiency and cost-effectiveness of the Haemodialysis (HD) and Continuous Ambulatory Peritoneal Dialysis (CAPD) services of the MOH dialysis program.

Cost-efficiency will be measured by cost per unit output; outputs being number of HD treatment procedures or number of CAPD patient-months. Cost-effectiveness will be measured by the Cost per life-year saved on HD or CAPD.

NIH Component: Institute for Medical Research

Harmonising Environment and Health Policy and Practice

A recent overview of the challenges to the general area of environmental management faced by Malaysia, has pointed out a number of major concerns facing all levels of government. The issues include indoor contamination, waste management, food and water safety and many others. These public health issues relate to the general issues raised in environmental management, and the interconnection is widely recognized through the 'window' of environmental health. It is therefore

appropriate to consider a management approach which will embrace the two and will also provide potential at the local level to improve efficiency in the use of resources. It is envisaged that this will bring about more effective outcomes of policy by harmonising health and environment fields where practicable.

The target site for the research project is MPPJ (Municipal Council of Petaling Jaya). The MPPJ has a well established framework for community participation in the implementation of the Local Agenda

21 Programme - a framework for local governments worldwide to engage in implementing sustainable development. This has resulted in the identification of a number of high priority areas (such as community noise and food safety) for which action plans are in place. This research is a collaborative effort between EHRC, WHO Collaborating Centre for Environmental Health (University of Western Sydney), LESTARI, IKU and MPPJ.

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If you are not living on the edge, you take up too much room. — Native American

*Principal Investigator:
Institute of Public Health*

QUALITY OF LIFE OF MALAYSIAN POPULATION: NORMS FOR THE SF-36

Population norms for Health Related Quality of Life using SF-36 have been obtained. A national sample was canvassed using a self-administered SF-36 questionnaire. Both Bahasa Malaysia and the English version were utilized. Response rate was 30.6%, with 3072 usable data. Male to female ratio was found to be 1.04 and the mean age was 39.8 years. The quality of life of the Malaysian population was noted to be affected by age and sex. Older population and women had reported to be experiencing poorer quality of life. The population norms for Malaysia differed from those of US, Canada and Australia.

*Principal Investigator:
Institute of Public Health*

A STUDY ON PRIVATE PRACTICE AMONG DOCTORS IN PUBLIC INSTITUTIONS

A combination of qualitative methods was used for this study. The study had reported that all public medical academic institutions with the exceptions of International Islamic University of Malaysia have some form of arrangements that allow their medical professionals to be involved in private practice. It was reported that limited private practice among the health professionals within the academic institutions have been legalized. These arrangements were classified as private wings within the respective institutions. Hospital Universiti Kebangsaan Malaysia and the University Malaya Medical Centre have established private wings whilst Hospital Universiti Sains Malaysia has only recently started theirs in 2002. Various stakeholders gave mixed reactions to the issue related to public doctors participating in private practice. The study concluded that private

practice appeared to be an attractive short-term solution to arrest the brain drain. Nevertheless, more in depth study needs to be undertaken as to its feasibility and implications in the long run.

*Principal Investigator:
Institute of Public Health*

PARTICULATE MATTER (PM₁₀) ON LUNG FUNCTION OF CHILDREN IN SUNGAI SIPUT, PERAK

The result of indoor PM₁₀ showed that the mean was 76.66 µg/m³. The study showed that there was a significant difference of mean of FVC % predicted ($p < 0.010$) between the exposed and comparative children. The study also indicated that there was a significant difference of mean of FEV₁ % predicted ($p < 0.010$). The exposed boys had lower FVC % predicted which was 68.05 compared to comparative boys 89.78. The same result was found for FEV₁ % predicted which was 73.71 compared to comparative boys 86.97. The study also showed that the FVC % predicted and FEV₁ % predicted was lower among girls who had had been exposed compared to comparative group. The exposed children had a prevalence of abnormal FVC % predicted of 82.4 which was higher than the comparative (5.4). The prevalence of abnormal FEV₁ % predicted was higher among the exposed (56.9) compared to the comparative (5.4). The study indicated that there was a negative linear relationship of FVC % predicted between the exposed and comparative children ($r = -0.478$, $p < 0.01$). The respiratory symptoms were measured by phlegm and cough. There was a significant association of phlegm and exposure of children ($\chi^2 = 15.286$, $p < 0.01$). The study also showed that there was a significant association of cough and exposure of children ($\chi^2 = 15.399$, $p < 0.01$). There was a negative linear relationship of FVC % predicted ($r = -0.529$, $p < 0.01$) and FEV₁ % predicted ($r = -0.525$, $p < 0.01$) with respiratory score. The study also

indicated that there was a negative linear relationship between symptom score with respiratory score ($r = -0.425$, $p < 0.01$). The conclusion of this study showed that PM₁₀ is adverse effect with children's lung function.

*Principal Investigator:
Institute of Health Management*

INCULCATING POSITIVE WORK VALUES AMONG DOCTORS IN PUBLIC SERVICES IN MALAYSIA

Corporate culture can simply be defined as "The way we do things around here". It comprised of assumptions, values, norms and tangible signs. Ministry of Health has started its culture building in 1991. Prior to this, they have been two studies to evaluate its implementation. There were two types of respondents and a self-administered was sent to all head of departments and all U3 medical officers in public services in Malaysia. About 50% (n=126) of head of departments and only 18% (n=1321) of medical officers responded. The study shows that at least 83% of head of departments perceived that the three core value of corporate culture has been implemented in their departments. However for rites and rituals, less than half of them have implemented it. Singing of corporate song is done more in hospital as compare to health. As for medical officer, only 28% of them have received training on corporate culture. Among those who have received training, only a quarter could understand the meaning of corporate culture. Doctors were also asked to give opinion on how to generate a caring doctor. About one-third suggests reducing the workload of doctors. Apart from increasing manpower, workload can also be reduced by reengineering the system and upgrading the doctors' competency.

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We can easily forgive a child who is afraid of the dark; the real tragedy of life is when adults are afraid of the light. — Plato.

Being a Doctor Means Having to Say You're Sorry
Laurie Barclay, MD

Feb. 25, 2003 — Neither doctors nor patients get the proper emotional support after being involved in a medical error, according to the results of a focus group analysis reported in the Feb. 26 issue of The Journal of the American Medical Association. The investigators suggest that doctors should make more of an effort to apologize to their patients, in addition to providing them with appropriate information regarding the nature and cause of the error.

"Health care institutions nationwide are developing ambitious programs to prevent medical errors," write Thomas G. Gallagher, MD, from the University Of Washington School Of Medicine in Seattle, and colleagues. "Yet, despite our best efforts, medical errors will inevitably occur."

Factors preventing full disclosure of medical errors to patients by physicians may include fear of a malpractice suit, concern about professional reputation, and feeling awkward or uncomfortable.

Of 13 focus groups held between April and June 2002, six involved only patients, four groups involved only physicians, and three groups included both patients and physicians. Of the 52 patients, 71% were female and 88% were white; average age was 60 years. Of the 46 academic and community physicians, 83% were male and 78% were white, and they had been in practice for an average of 16 years.

After reviewing transcripts of focus group discussions concerning a hypothetical medical error, the authors discovered that both patients and physicians had unmet needs regarding communication about errors. Patients wanted information about all harmful errors, including what happened, why it happened, how to improve the outcome, and how to prevent recurrences. Physicians agreed that harmful errors should be disclosed but were guarded in what they told patients about errors.

Although patients wanted an apology and other emotional support from physicians following errors, physicians were concerned that an apology might create legal liability. Physicians were also distraught over errors but did not know where to seek emotional support.

"The current response to medical errors may meet neither patients' desire for information about errors nor the needs of patients and physicians for emotional support following an error," the authors write. "Physicians should strive to meet patients' desire for an apology and for information on the nature, cause, and prevention of errors. Institutions should also address the emotional needs of practitioners who are involved in medical errors."

JAMA. 2003;289:1001-1007
<http://www.medscape.com/viewarticle/449917>

Work Hours More Important Than Money in Speciality Selection
When choosing a specialty, new physicians are more likely to base their decision on the amount of vacation time and schedule regularity than on income, new study findings show.

The results of the study suggest that efforts to increase the number of primary care physicians should consider other factors such as work schedule and vacation time, the researchers say.

"There seems to be general agreement that the US health care system has too few primary care physicians and too many specialists," lead author James Thornton, from Eastern Michigan University in Ypsilanti, told Reuters Health.

"Some have cited this as a factor contributing to high and rising medical care spending, as well as compromising the overall quality of care," he added. But, if the objective of health care policy is to increase the number of primary care physicians and decrease the number of

specialists, Thornton points out that information is needed to help understand the factors that influence specialty choice.

Together with co-author Fred Esposto, Thornton evaluated the factors that influence specialty selection for medical residents by analyzing national data published by the American Medical Association. The findings are reported in the January issue of Health Economics.

The findings indicate "that new physicians are more likely to choose specialties for which they expect to make higher future earnings, everything else [being] the same," Thornton noted.

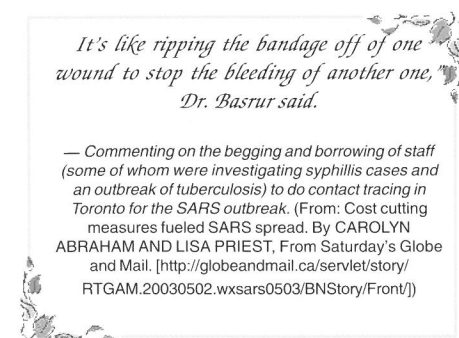
However, earnings were not the most important factor that guided specialty choice, he added. "Annual vacation time, weekly hours worked, and regularity of work schedule have a bigger effect on specialty choice than income."

"New physicians are very attracted to specialties for which they expect to have more annual vacation time, a regular work schedule, and, for primary care specialties, fewer hours worked in a typical week," Thornton said.

If the goal is to persuade more doctors to become primary care physicians, the findings suggest that work hour incentives rather than income benefits are more likely to achieve this objective, he noted.

Thornton believes that offering work hour incentives is feasible in the current medical care system where an increasing number of physicians are no longer self-employed, but are instead affiliated with large medical organizations.

Health Econ 2003;12:61-73.
http://www.medscape.com/viewarticle/449528_print



I) SMALL RESEARCH GRANTS (< RM 10,000 EACH)

PROJECT CODE
SRG-2002-3
PROJECT LEADER
En. Ravindran Thayan
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
To investigate the existence of tick-borne encephalitis (TBE) in Malaysia by a retrospective sero-prevalence study.
YEAR START 2002
YEAR END 2002

PROJECT CODE
SRG-2002-4
PROJECT LEADER
Dr Poh Eu Ping
DEPARTMENT
Department of Ophthalmology, Hospital Selayang
PROJECT TITLE
The Association between Helicobacter pylori infection and glaucoma.
YEAR START 2002
YEAR END 2003

PROJECT CODE
06-05-01-0002-EA001
PROJECT LEADER
Dato' Dr. Zaki Morad
DEPARTMENT
Hospital Kuala Lumpur
PROJECT TITLE
An open labels multicenter, randomized phase II trial to determined the activity of mycophenolate mofetil (CellCept) for the treatment of severe lupus nephritis
YEAR START 2002
YEAR END 2003

PROJECT CODE
06-05-01-0006-EA001
PROJECT LEADER
Dr. Gan Seng Chiew
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Evaluation of a low cost in-house serum lipoprotein (a) ELISA test kit for the rapid assessment of coronary heart disease
YEAR START 2002
YEAR END 2003

PROJECT CODE
06-05-01-0007-EA001
PROJECT LEADER
Dr. Mariana Hj Ahamad
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Preparation and standardization of extracts of local species of cockroaches for diagnosis of allergies
YEAR START 2002
YEAR END 2003

PROJECT CODE
06-05-01-0011-EA001
PROJECT LEADER
Nazni bt Hj Wasi Ahmad
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Development of comprehensive rapid tests for the screening of chemicals insecticide resistance in medically important insects

II) MAJOR RESEARCH GRANTS (> RM 10,000 EACH)

PROJECT CODE
MRG-2002-11
PROJECT LEADER
Dr. Lim Teck Onn
DEPARTMENT
Clinical Research Centre, Hospital Kuala Lumpur
PROJECT TITLE
Health Outcome Study on Neonatal Intensive Care
YEAR START 2003
YEAR END 2003

PROJECT CODE
MRG-2002-13
PROJECT LEADER
Dr. Goh Pik Pin
DEPARTMENT
Ophthalmology Department, Hospital Selayang
PROJECT TITLE
Refractive error study in children in Gombak District, Malaysia.
YEAR START 2003
YEAR END 2003

PROJECT CODE
MRG-2002-17
PROJECT LEADER
Dr Ho Tze Ming

YEAR START 2003
YEAR END 2003

PROJECT CODE
06-05-01-0012-EA001
PROJECT LEADER
Dr. Lee Han Lim
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Maggots therapy for wounds treatment
YEAR START 2003
YEAR END 2004

PROJECT CODE
06-05-01-0015-EA001
PROJECT LEADER
Dr. Noor Rain Abdullah
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Mechanism of action, in vitro and ex vivo Bioassay study of Medicinal Plants; Goniothalamus scortheicinii (Selada putih), Aralidium pinnatifidum (Hempedu buaya) Mitragyna speciosa and Mitragynine for anti malaria properties to malaria parasite, P. falciparum
YEAR START 2003
YEAR END 2004

PROJECT CODE
06-05-01-6134 PR0019/04-04
PROJECT LEADER
Dr. Nor Shahidah Khairullah
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Characterization of virological markers associated with hepatocellular carcinoma (HCC) in patients chronically infected with hepatitis B virus (HBV) and/or hepatitis C virus (HCV)
YEAR START 2002
YEAR END Not available

PROJECT CODE
06-05-01-0016 PR0047/19-01
PROJECT LEADER
Dr. Rohani Md Yasin

DEPARTMENT
Secretariat Standing Committee for Medical Research, c/o Institute for Medical Research
PROJECT TITLE
The application of Technology Foresight in the setting of health research priorities for the long term
YEAR START 2003
YEAR END 2003

PROJECT CODE
MRG-2003-3
PROJECT LEADER
Dr. Tan Seok Siam
DEPARTMENT
Unit Hepatologi, Jabatan Perubatan, Hospital Selayang
PROJECT TITLE
The Malaysian Liver Diseases Registry
YEAR START 2003
YEAR END 2004

PROJECT CODE
MRG-2003-5
PROJECT LEADER
Dr. Maimunah A Hamid
DEPARTMENT
Institute for Health Systems Research, c/o Institut Kesihatan Umum, Jalan Bangsar, 50590 Kuala Lumpur
PROJECT TITLE
Pilot Study for Health Research System Analysis
YEAR START 2003
YEAR END 2003

IRPA Approved For Year 2002

DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Epidemiology of antibiotic resistance in Malaysia
YEAR START 2002
YEAR END 2005

PROJECT CODE
06-05-01-0016 PR0047/19-18
PROJECT LEADER
Dr. Revathy Nallusamy
DEPARTMENT
Penang Hospital
PROJECT TITLE
Patients and parents perceptions on the use of antibiotics for common infections viz. upper respiratory infections and gastroenteritis
YEAR START 2003
YEAR END 2003

PROJECT CODE
06-05-01-0016 PR0047/19-05
PROJECT LEADER
Dr. Norazah Ahmad
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Studies on the molecular mechanisms of resistance of local isolates of methicillin-resistant Staphylococcus aureus to major classes of antibiotics and the clonality of MRSA
YEAR START 2003
YEAR END 2005

PROJECT CODE
06-05-01-0016 PR0047/19-02
PROJECT LEADER
Dr. Muhammad Amir Kamaruddin
DEPARTMENT
Institute for Medical Research
PROJECT TITLE
Household survey of antibiotic resistant enteric pathogen in Selangor and Wilayah Persekutuan
YEAR START 2003
YEAR END 2003

JANUARY**Applikasi Software SPSS**

Date : 27/03/03-30/03/03
 Coordinator : Zainuddin
 E-mail : ali@iku.gov.my
 Organisation : IPH

MARCH**Multinomial Logistics Regression Analysis Using SPSS**

Date : 6/03/03
 Coordinator : Pn Siti Haslinda Mohd Din
 E-mail : haslinda@iku.gov.my
 Organisation : IPH

Penggunaan Perpustakaan Virtual

Date : Not Available
 Coordinator : Pn Zarinah Kulam Hassan
 E-mail : zarinah@iku.gov.my
 Organisation : IPH

Hospital Management Strengthening

Date : 5/03/03-8/03/03
 Coordinator : Dr Roslan Johari
 E-mail : roslanj@moh.gov.my
 Organisation : IHM

Stress Management

Date : 11/03/03-13/03/03
 Coordinator : Puan Rohana Mahmud
 E-mail : ruhana@moh.gov.my
 Organisation : IHM

Workshop on the Development of a National System for Dissemination of Information On Environmental Hazards

Date : 19/03/03
 Coordinator : Dr Stephen Ambu
 E-mail : s-ambu@imr.gov.my
 Organisation : IMR

Systematic Review

Date : 24/03/03-25/03/03
 Coordinator : Dr Noorizah Mokhtar
 E-mail : noorizah@moh.gov.my
 Organisation : IHM

Industrial Training for Undergraduate from UPM, UKM, USM

Date : March to May
 Coordinator : Dr Tony Ng Kok Wai
 E-mail : Not Available
 Organisation : IMR

Workshop on Rodent Control

Date : 10/03/03-12/03/03
 Coordinator : Dr Stephen Ambu
 E-mail : s-ambu@imr.gov.my
 Organisation : IMR

Workshop on the Development of a National System for Dissemination of Information on Environment Hazards

Date : 19/03/03
 Coordinator : Dr Stephen Ambu
 E-mail : s-ambu@imr.gov.my
 Organisation : IMR

Kesihatan dan Kaunseling Remaja

Date : 24/03/03-28/03/03
 Coordinator : Dr Rafiza Shaharudin
 E-mail : zaza@iku.gov.my
 Organisation : IPH

APRIL**Patient Centered Services for Patient Satisfaction**

Date : 14/04/03-17/04/03
 Coordinator : Dr. Roslan Johari
 E-mail : roslanj@moh.gov.my
 Organisation : IHM

Kursus Perisian ACCESS

Date : 7/04/03-11/04/03
 Coordinator : En Zainuddin
 E-mail : Not Available
 Organisation : IMR

Komunikasi Pemakanan

Date : 8/04/03-11/04/03
 Coordinator : Puan Fatimah Salim
 E-mail : Fatimahs@iku.gov.my
 Organisation : IPH

Good Clinibal Practise Workshop

Date : 22/04/03-24/04/03
 Coordinator : Not available
 E-mail : Not available
 Organisation : IHM

Environmental Standard Operating Procedures (ESOP)

Date : 12/04/03
 Coordinator : Puan Usha Devi
 E-mail : Not Available
 Organisation : IMR

Team-based Problem Solving for Health Managers

Date : 22/04/03-25/04/03
 Coordinator : Dr. Roslan Johari
 E-mail : roslanj@moh.gov.my
 Organisation : IHM

Quality Control Circle

Date : 28/04/03-30/04/03
 Coordinator : Dr. Roslan Johari
 E-mail : roslanj@moh.gov.my
 Organisation : IHM

MAY**Occupational Health Training – Notification & Surveillance of Occupational Diseases (Medical Assistance)**

Date : 4/5/03-9/5/03
 Coordinator : En. Abdul Mujid Abdullah
 E-mail : mujid@iku.gov.my
 Organisation : IPH

Rawatan Susulan Pesakit Mental di Klinik Kesihatan

Date : 5/03/03-9/03/03
 Coordinator : Dr Jasvinder Kaur
 E-mail : jasvinder@iku.gov.my
 Organisation : IPH

Kursus Perisian EXEL

Date : 5/05/03-6/05/03
 Coordinator : En Zainuddin
 E-mail : Not Available
 Organisation : IMR

Good Laboratory Practice (GLP)

Date : 10/05/03
 Coordinator : Pn Usha Devi
 E-mail : Not Available
 Organisation : IMR

SEAMEO-TROPMED Post Graduate Diploma in Applied Parasitology & Entomology (DAP&E)

Date : May till October
 Coordinator : Dr Lokman Hakim
 E-mail : lokman@imr.gov.my
 Organisation : IHM

JUNE**BFHI – Assessors' Training**

Date : 2/06/03-4/06/03
 Coordinator : Puan Fatimah Salim
 E-mail : Fatimahs@iku.gov.my
 Organisation : IPH

Intranet Application and Their Usage(1)

Date/Month : Not available
 Coordinator : En Chang Poh Teik
 E-mail : cpt@iku.gov.my
 Organisation : IPH

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HERBAL MEDICINE RESEARCH CENTRE**BACKGROUND**

The Herbal Medicine Research Centre (HMRC) was established following the reorganisation of the Institute for Medical Research (IMR) in 2001. This reflects the new direction and commitment of the Ministry of Health, Malaysia in herbal medicine research.

It is timely that we explore Malaysia's rich natural resources in a more coordinated way. Research will provide invaluable information to support the rapid growing herbal medicine industry.

Research on herbal products should be carried out comprehensively and in compliance to international standards to provide scientific evidence for the safe and effective use of such products. The evaluation of safety and efficacy of herbal medicine products is part of the on-going research and development (R&D) activities on herbal and natural products of the country.

Funds for research are limited; therefore they should be disbursed according to research priorities, based on projected outcomes in terms of commercial potential of the products. The products must carry a guarantee of quality, based on evidence from clinical trials to validate the usefulness of those products. Scientific information derived from research is crucial in placing herbal medicine products in a proper perspective, so that they can be used confidently not only by traditional and complementary medicine practitioners, but also by allopathic medicine practitioners. This is in line with a recent call for a paradigm shift towards Integrated Medicine, which is also the mission of the National Policy on Traditional and Complementary Medicine (T/CM).

Since its establishment, the HMRC has been given the responsibility of coordinating various research activities including the gathering of information in related fields to serve both local and international needs.

UNITS

In order to achieve its objectives, the HMRC is organised into four units: the

Phytochemistry Unit, Bioassay Unit, Toxicology & Pharmacology Unit and Information Unit. Each of these units is responsible for specific activities.

The HMRC is also working in collaboration with other established organisations locally and abroad, and it envisages to become a centre of excellence in the field of herbal medicine research in the region and globally.

Phytochemistry Unit

The Phytochemistry Unit functions as a laboratory for herbal/plant collection and processing, sample preparation and chromatographic analysis of isolated extracts, fractions and compounds. The collection of samples such as raw plant materials and extracts from other research institutions is received by the Unit before being distributed to other laboratories within IMR for bioassays and toxicity tests. The Unit works closely with other Units within HMRC and IMR to coordinate plant collection, identification and phytochemical analysis. The Unit is also capable of carrying out standardization of extracts and herbal products.

Under the MIT-Malaysia Biotechnology Partnership Programme (MMBPP), an invention disclosure titled 'New cytotoxic agent isolated from *Centella asiatica* (Pegaga)' was filed by our researcher at the Massachusetts Institute Technology, USA. *Centella asiatica* (L) urban (Umbelliferae) has been reported to be used for wound healing and activating CNS; and to possess tonic effect similar to Ginseng, as well as anti-leprosy, anti-cancer and anti-bacterial properties. This invention is in regard to the isolation of 2 new compounds in Malaysian *Centella asiatica* that were found to have cytotoxic properties to human fibroblast cell system comparable to that of asiatic acid isolated earlier from the same plant.

Bioassay Unit

Activities of the Unit, involve carrying out various biological testing in vitro and in vivo, using standardized assay procedures to determine the biological properties and medicinal potentials of medicinal plants either as extracts or

pure chemical constituents. Medicinal plants are screened for anti-malarial properties and for anti-proliferative activity as potential anti-cancer agents. The cytotoxicity of plant extracts towards normal cell lines is also investigated. The Unit conducts research on development of medicinal plant products (extracts / compounds / derivatives) as anti-malarials. In vitro toxicity screening of herbal products is conducted for customers and manufacturers of herbal products. Plant materials are obtained from research collaborators such as Forest Research Institute Malaysia (FRIM), Universiti Pertanian Malaysia, Universiti Malaya and Universiti Sains Malaysia, Penang.

Possible mechanism of action and pharmacokinetics investigations are conducted on extracts found to possess anti-plasmodial activity from in vitro studies. In vivo studies of these extracts are also performed using the mouse model and rodent malaria, *P. berghei* ANKA strain. Until now about 224 plants have been screened for anti-plasmodial properties; 27% of those plants were demonstrated to be potential anti-plasmodials. Currently comprehensive studies are being conducted on 3 plants, i.e. *Goniothalamus scortheicinii*, *Eurycoma longifolia* and *Morinda* species.

For screening anti-proliferative activity towards determination as potential anti-cancer agents, extracts received from research collaborators have been tested using the MTT assay towards four cancer cell lines (from different origin). The extracts that demonstrated potential anti-proliferative properties are then given to other researchers for further investigation. The Bioassay Unit is also involved in research on anti-angiogenic and anti-myeloma properties of medicinal plants.

Toxicology and Pharmacology Unit

The Unit conducts in vivo general toxicology studies for Misai Kucing and Kacip Fatimah research projects listed below. The assays conducted including Acute Limit Toxicology Tests, Subacute Toxicology Tests and Chronic Toxicology

Tests. In vitro toxicology and molecular toxicology studies such as mutagenicity and genotoxicity are performed on different herbal extracts.

The Unit is responsible for some routine diagnostics that include the following:

1. Screening and confirmation of drugs of abuse; namely, morphine, cannabis and amphetamine type stimulants.
2. Analyzing various heavy metals in biological fluids from all government hospitals and private laboratories in Malaysia.
3. Organise and co-ordinate the National Drug Quality Control Programme (NDQCP).
4. Participating in External Quality Assessment Scheme for Trace Elements.

Research is another activity of the Unit. Current projects that the Unit is involved in are listed below:

1. Development & Clinical Trial Studies of Hemptu Bumi (*Andrographis paniculata*) as Commercial Preparation for the Prevention of Diabetes. (Dr Zakiah Ismail)
2. Toxicity Study of *Orthosiphon stamineus* (Misai Kucing) in Sprague-Dawley Rats. (Dr Zakiah Ismail)
3. Toxicology Studies of Standardized Kacip Fatimah (*Labisia pumila* var. *alata*, var. *pumila*) Preparation. (Dr Noral'ashikin Yahya)

Information Unit

The Unit acts as a repository that gathers and disseminates information related to herbal medicine and related areas. Some achievements of the Unit in the year 2002 include the following:

1. Compendium of Medicinal Plants Used in Malaysia

The 'Compendium of Medicinal Plants Used in Malaysia' was launched by the Most Honourable Dato' Sri Abdullah Ahmad Badawi, Deputy Prime Minister of Malaysia during the "The 4th International Traditional / Complementary Medicine Conference and Exhibition (INTRACOM 2002)" on 14 October 2002

The Compendium is a comprehensive documentation of traditional knowledge on medicinal plants of Malaysia referenced from numerous sources of classic and modern traditional medicine literatures that reflects the richness and diversity of ethnicity, cultural and religious beliefs in Malaysia. It is an important reference that contains ethnomedicinal information that can be used as a basis for further research by healthcare providers, scientists, consumers, students and others. This structured repository of medicinal plants also contributes towards the conservation of our local plants.

The Compendium, in Volume 1 & 2, contains description of 2002 domestic and cultivated plants that have been traditionally used as medicine in Malaysia. The scientific names of the plants have been arranged in alphabetical order. For each plant, there is information on its family, synonym, local name(s), habitat, the parts of the plant that are used and the traditional medicinal uses. The book also features 500 coloured photographs of various plants and a glossary of medical terms. The main reference is "A Dictionary of the Economic Products of the Malay Peninsular" (Volumes I and II) by Burkill I. H. (1935) (re-edited by H. M. Burkill in 1965). The price of the Compendium is at RM 400 per set.

THE GLOBAL INFORMATION HUB ON INTEGRATED MEDICINE

Malaysia was entrusted to implement this project after much deliberation during the 13th Commonwealth Health Minister's Meeting on 26-28 November 2001 and the Pre World Health Assembly meeting on 12 May 2002. The Global Information Hub for Integrated Medicine reflects the growing interest on traditional and complementary medicine and the concerted efforts to work towards integrated medicine. It was also agreed that Malaysia acts as the main sponsor of the project with participation of partners from other countries.

The project received the Malaysian Cabinet approval on August 2002. The objective of the project is to establish in

Malaysia, an information hub on integrated medicine for the world utilising strategic partnerships with other nations, international organizations and Not-for-profit Organisations (NGOs). This global electronic information resource will cover policy, practice, research, trade, education, safety, conservation, databases and intellectual property rights pertaining to traditional and complementary medicine (T/CM). The Hub of this nature, in partnership with other countries, international organizations and NGOs will spur T/CM practices and industries to greater heights, ultimately helping to integrate T/CM into main stream healthcare systems.

The Beta group was formed in June 2002 under the chairmanship of Dato' Dr. Mohd Ismail Merican, the Deputy Director-General of Health (Research and Technical Support). Other members are from the Ministry of Health (2 representatives from Institute for Medical Research and 1 representative from the Family Health Development Division), Malaysia Herbal Corporation (MHC, 2 representatives), Multimedia Development Corporation (MDC, 2 representatives) and a representative from the Prime Minister's Department. A few more members were appointed later i.e. one representative each from Medical-on-line and Universiti Sains Malaysia, and 2 representatives from the National Committee for Research and Development in Herbal Medicine. The full membership list of the Beta Group is listed in Appendix A.

The secretariat for this committee will be based in IMR and the members are representatives from IMR, MHC and MDC. Two technical committees (Information Technology and Content) will assist the Beta Group.

HMRC WEB PAGE

The web page houses information on HMRC's background, objectives and activities. It also features several policies relating to the traditional and complementary medicine, a photo gallery and linkages. The web page can be accessed through <http://imr.gov.my/ind2.htm>

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The objectives of the project are:

1. To establish strategies within MPPJ to harmonize health and environmental policy and practice at the local level under the framework of Agenda 21
2. To develop a Model of Best Practice using the MPPJ as a case study for future application in Malaysia. The current activities are:

1. Conducting a survey of available data resources and environmental health

indicators both internationally, nationally and locally of relevance to MPPJ.

2. Developing a database of the above to assist MPPJ in their use of the DPSEFA framework of environmental health management selected issues
3. Conducting field studies to develop mechanism for collection of selected local indicators where appropriate
4. Identifying and to develop the use of GIS and related approaches to assist in use of information

To date, Step 1 – 3 has been completed

using the allocated fund under the project code SRG-2002-1. The EHRC in collaboration with WHO Collaborating Centre for Environmental Health (University of Western Sydney) is now working with MPPJ to develop the use of GIS on the selected environmental indicator, community noise.

(Environmental Health Research Centre, Institute for Medical Research; Institute of Public Health; Municipal Council of Petaling Jaya; LESTARI, University Kebangsaan Malaysia)

Continued from pg 10

JUNE

Intranet Application and Their Usage(2)

Date/Month : Not available
Coordinator : En Chang Poh Teik
E-mail : cpt@iku.gov.my
Organisation : IPH

Kursus MS Word

Date : 3/06/03-4/06/03
Coordinator : Pn Zaleha
E-mail : Not Available
Organisation : IMR

Kursus Mikroskopi Malaria & Filaria

Date : 2/06/03-5/06/03
Coordinator : Dr Lokman Hakim
E-mail : lokman@imr.gov.my
Organisation : IMR

EH Forum: Environmental Health Indicator

Date : 5/06/03
Coordinator : Puan Asmaliza
E-mail : Not Available
Organisation : IMR

Personal Protective Equipment (PPE)

Date : 6/06/03
Coordinator : Dr Maizura
E-mail : Not Available
Organisation : IMR

Breastfeeding Counselling

Date : 16/06/03-23/06/03
Coordinator : Puan Rahmah Ahmad
E-mail : rahmah@iku.gov.my
Organisation : IPH

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Principal Investigator:
Institute of Health Management

PROBLEMS FACED BY HEALTH SUPERVISORS IN THE DISTRICT

Supervisors play a vital role in ensuring that frontline workers performed their tasks in accordance to the Ministry of Health objectives. Self-administered questionnaires were sent by mail to all the district health supervisors in Malaysia. Only 69 Senior Health Inspectors (54%), 128 Health Sisters (66%) and 58 Senior Medical Assistant (50%) responded. The majority of them were happy with their job although more than 62% of them perceived that they were overworked. Further, only less than 30% were always under stress at work. The main problem identified by Health Sisters was poor attitude amongst staff. For the Senior Health Inspectors and Senior Medical

Assistant, their main problem was heavy workload. Attitudinal problem amongst nurses should be given high priority as they deal with the public daily. Training and counseling should be the main strategy.

Principal Investigator:
Institute of Medical Research

DETECTION OF THE AF4-MLL TRANSLOCATION I.E. T (4; 11) (Q21; Q23), BY RT-PCR, IN MULTI-ETHNIC MALAYSIAN PAEDIATRIC PATIENTS WITH ACUTE LEUKEMIA.

The clinical characteristics of t (4; 11) positive leukemia are young age at presentation (<1 year), hyperleukocytosis, hepatosplenomegaly, relatively high CNS involvement, over-representation of females and a poor response to

treatment. The aim of this project was to establish an RT-PCR assay for the detection of the t (4; 11) translocation. The optimum conditions for this assay were determined by using published nested primers and a t (4; 11) positive case, P89, identified by cytogenetics. cDNA from this patient was available from a previous study of the TEL-AML1 translocation. Once the optimum conditions had been established, we tested several cases from the TEL-AML1 study which conformed to the characteristics of t (4; 11) positive cases. Two cases yielded fusion transcripts of different sizes. Sequencing revealed that in P76 the fusion transcript consisted of exon 11 of the MLL gene joined to the AF4 gene, and in P120, the fusion transcript of exon 10 of the MLL gene joined to the AF4 gene.

INSTITUTE OF PUBLIC HEALTH

1. World Health Survey 2002 Operations Room

An operation's centre has been built for the ongoing World Health Survey spearheaded by the Institute in collaboration with the World Health Organization. Costing approximately RM70,000, this cabin has been furnished with computers for data entry, white boards, telephone lines and a fax machine. This operation's centre is manned between 7.30am till 10.30pm daily for the whole duration of the survey.

3. Healthy Kitchen

A model kitchen has been built in preparation for training of health staff



5. Training for New Intake of Health Education Officers

Twenty new Health Education Officers (HEOs) reported for training in the Institute on the 5 November 2002. The training comprises of lectures, tutorials and practical attachments at the end of which they will be awarded a Masters in Health Sciences (Health Education) on successful completion. To date the group has already completed 1 semester.



in the implementation of the "Dapur Sihat Masyarakat" activity in the health clinics. Built at a cost of approximately RM40,000, this kitchen will function as a "cooking laboratory" for all the in-service training programmes relating to food and nutrition. This facility is located at the trainee Health Inspector's accommodation block.



2. Upgrading of Facilities

The Institute has spent approximately RM200,000 upgrading the canteen, library and lecture halls. Work started at the end of 2002 and completed in early March this year. It is hoped that the upgrading of facilities will enhance the working as well as the learning environment for the Institute.

4. Herbal Garden

The Institute has started a "herbal" garden located at the open area opposite the staff quarters. The aim of the herbal garden is to educate the staff and students on the various types of herbal plants available. A soft launch of the garden was officiated by the Institute's Director in early April this year.

6. The Sixth National Institutes of Health Scientific Conference

The Institute has been given the honour to organize the 6th NIH Scientific Conference to be held in the later part of this year. The place, venue, exact date and scientific programme for this conference will be made known through posters and flyers.

Experience is what you get when you do not get what you want. — Anonymous

*"The greatest difficulties lie where we are not looking for them."
— Johann Wolfgang von Goethe*

Contd from page 1

- ◆ Evaluation of a new product (drug or device) that has come into the formulary or is under consideration for approval.
- ◆ "Off label" prescriptions: often the approved medications are studied for an indication that is not in the approved labeling. The drug company does not want to sponsor such studies for various reasons; economics being the main reason.
- ◆ Pharmaceutical companies have specific designs or formats for their trials and recruited investigators have to conduct the trials as per specifications. Rarely are they allowed to modify the study design or management and because of that investigators may need to compromise on certain important issues.
- ◆ Personal motivation: an investigator initiated trial is not only challenging, it has plenty of risks. The benefits are great and lead to greater personal satisfaction for the investigator.
- ◆ Personal motivation: an investigator initiated trial is not only challenging, it has plenty of risks. The benefits are great and lead to greater personal satisfaction for the investigator.

Conducting a trial is not something to be taken lightly. It is a daunting task for many. More importantly it involves the use of human subjects and it is our duty to see that such trials are conducted ethically and the data obtained are of good quality.

Malaysia adopted the ICH GCP in 1999 and since then all trials in this country must comply with these standards.

GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and the clinical trial data are credible. (ICH Harmonized Tripartite Guideline for Good Clinical Practice 1996)

An individual clinician cannot be expected to have all the resources nor the skills to initiate and conduct such GCP compliant trials. The Clinical Research Centre (CRC) has been operational since the year 2000 and was established to provide a comprehensive range of services to support the conduct of clinical trials.

Some key services needed to support conduct of a trial are:

Project Management

It is the art of directing and coordinating human and material resources throughout the life of a project by using modern management techniques to achieve pre-determined objective of scope, cost, time and quality in order to meet or exceed stakeholder expectations.

Protocol development

Developing a document that describes the objective(s), design, methodology, statistical considerations, and the organization of a trial.

IRB/IEC submission

Submission of documents required for scientific and ethics evaluation to the Institutional Review Board (IRB) or Independent Ethics Committee (IEC). The IRB/IEC is an independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

(ICH GCP 1.31)

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*The reason why worry kills more people than work is that more people worry than work.
— Frost, Robert*

There is nothing either good or bad but thinking makes it so. — Shakespeare, William

Trial initiation – Investigator’s meeting/Site initiation

Study Initiation Investigator’s Meeting is a meeting to:

- ☞ Ensure that the investigators and study coordinators are acquainted with the study procedures, verification procedures, audits and inspection procedures.
- ☞ Provide the Investigator/site staff with general instruction to ensure that he/she understands and accepts the obligation incurred in undertaking the study.
- ☞ Ensure that the study is planned, set up, conducted, documented and reported according to the protocol, related standard operating procedures (SOPs), ICH-GCP and applicable regulatory requirements.

Study Initiation Site Visit is conducted to:

- ☞ Ensure that the site is ready to enroll the first patient.
- ☞ Verify site has current protocol, standard operating procedures, other essential documents and the study supplies to conduct the trial properly.

Central randomization service

Every high quality trial in Malaysia requires access to a central randomization service. This is a computerized system that is set up to perform the randomization centrally to avoid the randomization being subverted.

Trial Monitoring

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported in accordance with the protocol, SOP, GCP and the applicable regulatory requirements

Site management

Coordinating research activities at the sites and working effectively with sites.

Study documentation

Definition: All records in any form (including, but not limited to, written, electronic, magnetic and optical records, scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and / or a trial, and the actions taken.

Safety surveillance

This is a surveillance procedure put in place to track and evaluate the risk of undesirable effects resulting from the use of test drugs. For this CRC is using Clintrace which is a comprehensive database application for reporting and tracking clinical adverse events.

Biostatistics

Services provided to help researchers in their research and include study design and sample size planning, and statistical analysis.

Medical writing

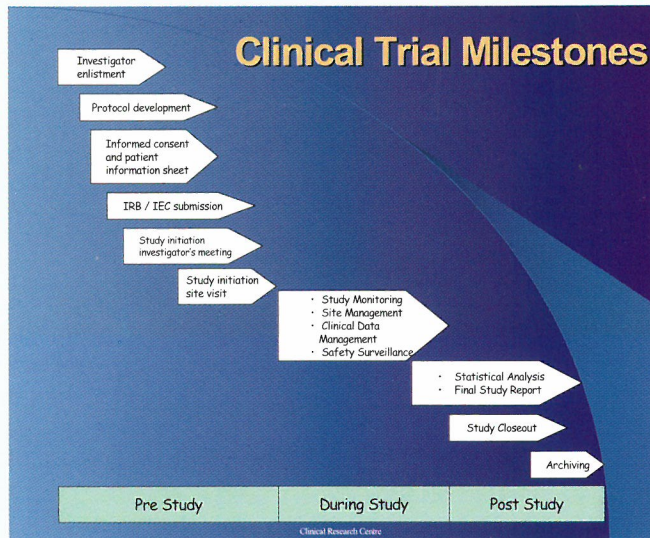
Preparation of related scientific reports and papers for publication.

Trial closeout and archive

On completion of a trial, a study closeout is done and this is a fairly complex procedure requiring proper planning.

Archiving is the storing of all documentation which provides evidence that a clinical study has been conducted in accordance with the principles of GCP.

As a responsible doctor and employee of the Ministry of Health you really need to give some thought to these issues before embarking on an investigator initiated trial or participating in any trial. We would certainly advise you to seek a credible research organization to support you in this ambitious endeavour. They need to protect your interest, Ministry of Health’s interest, and your patients’ interest as trial subjects.



Clinical Data Management (CDM)

It is a very general term that covers the procedures for collection of data at clinical sites and the quality control of these data both at site and after they have been submitted to a central coordinating centre.

Case Report Form (CRF) Development

Definition of CRF: A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

CRFs are designed to facilitate data analysis; all essential data is recorded patient by patient and visit by visit.

Data on CRFs are the basis for the trial report and also for any publication, as well as preparation of part of the data for regulatory approval of a new drug.

*Contributed by:
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