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# CRO Experience in Malaysia

**N Naeem**

Country Head of Clinical Operations, Quintiles Malaysia

## **SUMMARY**

The pharmaceutical market in Malaysia is one of the fastest growing in Asia Pacific with the CAGR of 10.5%. According to www.clintrials.gov, clinical studies in Asia increased 67% during the past two years, with high growth rates in China, Korea, Thailand and Singapore. However the growth rate of clinical studies in Malaysia has lagged behind these countries. Given its strong government support and commitment to developing Malaysia as a clinical research hub, as well as its good regulatory infrastructure, qualified professionals and large multi-ethnic population, Malaysia is becoming a destination of choice for conducting clinical trials. These factors have led a number of multi-national Clinical Research Organisations (CROs) to establish or grow their presence in Malaysia in recent years – which will ultimately result in an increased level of clinical trial activity and overall growth. For CROs to truly flourish in Malaysia, increase in both the interest level of investigators to conduct clinical trials in Malaysia as well as growth in the number of investigative sites is required. To reach its full potential in the clinical research industry, an ongoing commitment from and collaboration with the government is essential to ensure that Malaysia can become a strong player in the clinical research arena.

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# Use of Patient Registry Data

**P P Goh**

Acting Director, Clinical Research Centre, Ministry of Health, Malaysia

## **SUMMARY**

The four important performance measures that a responsible healthcare manager needs to assess are the 4Es - EFFECTIVENESS, EFFICIENCY, EQUITY, and ESTEEMING. Effectiveness is best served by sustaining a quality and safe service. Efficiency is valued by the minimum time, money and effort spent in delivering that service. Equity is fairness in the distribution of access to the service and distribution of burden of financing. Esteeming is how responsive the service to legitimate expectations of the clients or patients. Most of these are readily available in the Patient Registries, which is a collective system of data collection and analysis in different disciplines, coordinated by the Clinical Research Centre, one of the six National Institutes of Health of Malaysia. To date there are a total of 30 patient registries. A question for effectiveness in nephrology could be, is the dialysis service that we give effective? One measure is long term survival outcomes. Data from the National Renal Registry found that Haemodialysis (HD) was more effective, where patients on HD had longer survival probability compared to those on Continuous Ambulatory Peritoneal Dialysis. Efficiency gain was illustrated using data from the same registry. By increasing the service volume it was proven that the unit cost of HD dropped tremendously. Equity, measured in the same registry, revealed a healthy growth of dialysis provision in Malaysia which was parallel to the growth of GDP, meaning as our country becomes richer, access for our patients has also improved. Besides the 4Es for center level performance, individual performance can also be monitored via patient registries using add-on tools. One such tool is the Cumulative Sum (CUSUM). For example, a consultant Ophthalmologist, using his/her registry may now monitor the competency of their trainees in doing cataract surgery to track complications such as posterior capsular rupture or vision outcome. Data from the National Eye Database (NED) are linked directly to the tool and each time data on the procedure is entered, the CUSUM website is able to upload data real-time for assessment by the trainee and her supervising consultant. The consultant may use the chart to objectively ascertain the minimum time and number of cases needed for each trainee to establish competency in the procedure. Another important use of registry data is for Key Performance Indicators (KPI) monitoring. The NED and the Malaysian National Neonatal Registry (MNNR) track the rate of adverse events such as rate of cataract surgery complication and survival of low birth weight babies as KPI for their disciplines. Since registry source data producers are from all MOH hospitals, KPI give a mean of bench marking where centre performance can be compared. Besides quality assurance and patient safety analysis, patient registry also provides a ready pool, real life data which facilitate clinical audit and thus assist clinicians in making evidence based policy for the improvement of healthcare service. Patient registries, a bottom ups initiative from many dedicated clinical groups, working together with CRC, provide a powerful tool to track and trend clinical disease and practices. Data from patient registry has certainly made useful contributions in patient care; a role that responsible health managers must uphold.

# Site Management and Investigator Relationships: US and European Perspectives from a Global CRO

**A R Chasse**

Head Global Prime Sites & Senior Director Site Management, Quintiles Inc, USA

## **SUMMARY**

At the end of the first decade of the 21st century, the pharmaceutical industry has never faced more pressure to optimize its research and development model. Costs of development are rising, demands for greater amounts of safety and efficacy data are growing, patent expiries are approaching, and pricing pressure from payors is increasing – all while patients worldwide are in need of new treatments for a large variety of diseases. Recent mergers have enhanced pipeline diversity for individual pharma companies, but that alone will not sustain a broken R&D model. To ensure the needs of all stakeholders are met, pharma and CROs are increasingly combining their experience and innovation to develop strategies for greater efficiency and higher quality. That type of strategic collaboration has been far less common between pharma/CROs and research sites. The most important element of successful study completion is the ability of clinical investigators to oversee efficient administrative processes, recruit patients safely and ethically while meeting timelines, and generate high quality data that facilitate rigorous statistical analysis. This symposium will describe industry's efforts to develop closer working relationships with sites and investigators in the United States and Europe. Mr. Chasse will discuss industry's motivation for partnering with sites, early efforts and lessons learned, and how once-tactical relationships have evolved into true strategic partnerships. Attendees will also gain insight into the future of industry/site relationships and why it is critical to accelerate these efforts in East Asia.

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# Cognitive Testing for Risk Behaviour in Youth

**M R Norazilah**

Institute of Health Behavioural Research, National Institutes of Health, Malaysia

## **SUMMARY**

This is a qualitative research using in-depth face to face interview, aims to test respondents' cognitive burden towards the newly created National Youth Health Behavioural Research instruments. This is a crucial test to improve the quality of the instrument before using it for the actual study in 2010. From this method, cognitive testing covers four processes: the ability to recall previous information, ability to evaluate as well as respond to all of the faulty research questions to respondents. Respondents for this research comprised of 24 students from Forms One, Two and Four of two secondary schools. The sampling method used was stratified random sampling, which met the required criteria. The process of data collection was in-depth cognitive interview and audio recording. The data were analysed descriptively. Research findings indicated that 12 (36%) out of 33 questions need to be improved. The weakness was due to respondents' lack of understanding on certain terms and phrases used, the sentences were too long, questions were too technical, and the inability of the respondents to recall activities that happened more than seven days earlier. As for the knowledge component, two items out of 32 were not understood by the respondents because of its technicality. As for the attitude section, two out of 40 questions were not understood. In conclusion, the overall quality of instrument being used for the national youth behaviour risk factor surveillance system research was acceptable as only the practices component caused difficulty to respondents. However, certain questions that were not understood by respondents need to be improved in order to improve the quality of the instrument.

# High Risk Behaviours Among National Service Trainees

**H I Zawaha, U Edawaty, C R Sulaiman, N Nik Rubiah, M S Noridah, N Ahmad Shahrul, H N Siti Sa'adiyah, I Zainon**

Senior Health Education Officer, Institute for Health Behavioural Research, National Institutes of Health, Ministry of Health, Malaysia

## SUMMARY

The National Service Training Programme, or Program Latihan Khidmat Negara (PLKN), is Malaysia's national service program. The three month program, which started in December 2003, began as way to encourage friendship between youths of certain ages from different races and ethnic groups and address concerns that the country's various races were becoming increasingly isolated from one another. The implementation of PLKN was in line with adolescence's critical role in the country's effort to achieve the status of a fully developed country by the year 2020. This study was conducted from December 2008 till July 2009 involving nine National Service Training Camps in Selangor. A total of 6025 trainees participated in the study using a cross sectional study design using self administered questionnaires. The main objective of this study is to determine level of practices on health risk behaviour identified; Drug abuses, alcohol consumption and sexual activities among National Service trainees. This study showed that 25.1% of the trainees ever consumed alcohol, 22.9% ever smoked cigarette, 1.6% of the trainees are drug abusers and 10% among trainees ever engaged in sex. Among those who ever engaged in sex, 89.6% of the trainees had sex since secondary school and 7% at upper secondary school. 89% of the total respondents admitted reading or watching pornographic materials. Finding of the study supports the National Study on Reproductive Health of Adolescents conducted by the National Population and Family Development Board in 1994 which found that substance abuse in various forms like smoking, glue-sniffing and ingesting cough medicines were reported by respondents as common and over two-thirds of youth aged 13 to 19 years have had at least some exposure to pornographic materials. This study clearly showed our youths are exposed to various types of high risk behaviours and there is a need for a comprehensive and coordinated prevention program to address adolescents at all levels. This requires the use of various channels of communication and smart partnership between Ministry of Health (MOH), Ministry of Education (MOE), and Non government organisations.

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## Issues and Challenges facing the Commercialization of New Medicines

**A S Paau**

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## SUMMARY

Modern sciences, especially with the advances in the multidisciplinary pharmaceutical sciences in the last 50 years, have contributed greatly to human healthcare by increasing our understanding of the disease processes and by helping us conquer numerous major and grave diseases in human. More human lives have been saved in the last few decades than in any era in human history. The commercialization of new medicines, however, is now at a cross road facing new issues and challenges. In addition to the traditional regulatory hurdles that ensure efficacy and safety, new issues such as conflict of interest, ethnic diversity, gender difference, patient stratification and privacy influenced by the advances in molecular genetic methodologies and information technologies, socioeconomic barrier to essential medicine access, desire for personal legacy, increasing specialization, and the perspective-driven concept of pharmacoeconomics all add to the challenges of the commercialization of new medicines. The commercialization of new medicines is a costly and time-consuming process that is highly influenced not only by the government through its approval and labeling processes and its reimbursement/formulary approval schemes, but also by the insurance industry, the healthcare providers (private physicians, HMOs and hospitals – public and private) and the pharmaceutical industry itself. The patients are increasingly confused by the existing and the new medicines and are more and more consumerism oriented as they are increasingly influenced by advertisement to cultivate desire rather than of needs. Such consumerism-driven use of medicine over-shadows the introduction of new medicines that are driven by good sciences.

# Good Laboratory Practice (GLP) Compliance Monitoring Programme in Malaysia

**A Hasenah**

Head, Good Laboratory Practice Compliance Unit, National Pharmaceutical Control Bureau (NPCB), Ministry of Health, Malaysia

## **SUMMARY**

The Malaysian Government through a Cabinet decision in February 2008 had agreed to appoint NPCB as Malaysian Compliance Monitoring Authority (CMA) for monitoring compliance to OECD Principles of Good Laboratory Practice (GLP) to the non-clinical safety testing of test items contained in pharmaceutical products, cosmetic products, veterinary drugs and food additives. The Drug Control Authority in the 214th meeting in March 2009 had enforced this decision in accordance to Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 (Amendment) 2006, followed by the Directive issued by Senior Director of Pharmaceutical Services in June 2009. Department of Standards Malaysia (STANDARDS MALAYSIA), Ministry of Science, Technology and Innovation, Malaysia which is the other Compliance Monitoring Authority is responsible for chemicals such as pesticides, feed additives, industrial chemicals and non-pharmaceutical biotechnology products. Ministry of Health Malaysia is the coordinator for Good Laboratory Practice (GLP) Compliance Monitoring Programme (CMP) in Malaysia and adopting the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Good Laboratory Practice is a voluntary scheme. There are two mechanisms by which a Test Facility can enter into the program. Test Facility can submit an application to NPCB; or through request of inspection received from national or international authority. In both cases, the Test Facility shall be entered into NPCB compliance monitoring program only after the Test Facility has received GLP compliance certificate. The procedure for application and Application Form can be obtained and downloaded from NPCB GLP Compliance Programme webpage. NPCB GLP Compliance Programme includes Pre-Inspection, Inspection, Surveillance Inspection and Extra Ordinary Inspections. NPCB keeps register and monitor Test Facility within two years since the last inspection, in accordance with the Master Register of Compliance Programme. Pre-inspection is carried out for the first time to familiarise and to verify that the Test Facility has the resources to undertake GLP studies in respect of management structure, physical layout of buildings and range of studies. The inspection is a full inspection that involves both Test Facility Inspection and Study Audit (completed and on-going studies). Surveillance inspection is conducted within two years after the last inspection. Extra ordinary inspection is carried out in situations such as upon request of national or international authority, verification on the implementation of the corrective actions, extension of scope, significant changes in the test facility or when the CMA feel necessary. An inspection report is prepared after the inspection and/or study audit. Test Facility in compliance will be issued a certificate with statement of GLP compliance to show the Test Facility has been inspected and found to be operating in compliance with Principles of GLP.

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# Institute for Medical Research: Towards Good Laboratory Practice Compliance

**I Zakiah**

Head, Herbal Medicine Research Centre, Institute for Medical Research, Kuala Lumpur, Malaysia

## **SUMMARY**

Herbal medicine research initiative at IMR was established with the objective to provide scientific information of such product especially in the area of efficacy and safety. This information is important in leading to decision making for allowing product registration and clinical trials. The pre-clinical toxicology conducted need to follow international standard in ensuring that data generated, accepted by the professional especially the regulator of the respective country. Adding to existing IMR quality standard activity, Good Laboratory Practice become necessary and was initiated few years ago. Meeting the ten important elements, were a real challenge as it involved different discipline and profession to understand and implement all the aspect including the planning, conducting, recording, reporting and archiving pre-clinical toxicology study. Malaysia has recently registered as Mutual Acceptance Data (MAD) country with the OECD and this has add into more pressure for such achievement since the period of three years is set for completion of the whole exercise and this become critical for both the compliance monitoring authority and the laboratory. With all the support and continuous effort, we hope to see IMR obtain the GLP compliance for the scope of toxicology testing of pharmaceutical products in the near future.

# Animal Use in Laboratory Experiments: Ethical Issues

**J S Dhaliwal**

Allergy and Immunology Research Centre, Institute for Medical Research, Kuala Lumpur, Malaysia

## SUMMARY

Legislation to prevent animal abuse came into force in England in the 1870's. These laws were the precursors of laws, regulations and codes of practice governing the use and treatment of animals that have now been introduced worldwide. There are organisations that have adopted the position that all animal use, for whatever purpose, should be prohibited. This is untenable because animal use is integral in human society. By their nature, moral arguments are not empirical, and cannot be resolved. Religion based moral arguments do not preclude the use of animals by humans but mandate that suffering is minimised. In most societies, the final stand on this issue reflects a compromise. Our aim has been to find a balance between the legitimate interests of society and our conscience and this requires us to be humane, to minimise pain and suffering and to eliminate needless loss of life. The use of animals in research has contributed much to Man's total sum of knowledge. Their use has helped in understanding disease processes, the development of immunisation, drugs and treatments. However justifiable this may be, it should not prevent us from constantly seeking ways to minimise the use of animals. The Animal Care and Use Committee of the Ministry of Health (MOH) which was set up in the 1980's uses replacement, reduction and refinement as its guiding principle. This means that the absolute minimum number of animals is used in experiments, that they do not suffer and that they are treated humanely. Replacement is the substitution of animals with *in vitro* reagents. Reduction is using the minimum number of animals in experiments. Refinement is constantly assessing experimental endpoints, discomfort, and pain. The code that governs the use of animals in MOH facilities is encapsulated in the 'Principles and Guide to Ethical Use of Laboratory Animals' published by the MOH in 2000. The approval process is part of a review process that examines the scientific merit, the appropriateness and numbers of the animals to be used, and the justification and the competence of the investigators. Ongoing projects using animals are also monitored to ensure that the work carried out is within the ambit of the approval. The Malaysian Code of Practice for the care and use of animals for scientific purposes is undergoing review. This Code will set a national standard for institutional animal care and use committees.

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## Latest Development on H1N1 Vaccines

**N Petrovsky**

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## SUMMARY

The recent swine flu (H1N1/2009) pandemic which fortunately turned out to be less serious than originally foreseen has provided a perfect opportunity for governments to perform a real life assessment of global pandemic policies and preparedness and for vaccine developers and manufacturers to review their production strategies. Importantly, the swine flu pandemic helped identify which vaccine technologies could deliver and which could not. Recombinant hemagglutinin (rHA) vaccine approaches overcome inefficiencies and slowness of egg-based influenza vaccine manufacture and when combined with novel adjuvants offer many potential benefits for pandemic vaccines. During the swine flu pandemic in 2009 we conducted in Adelaide, Australia in 281 adults aged 18-70 years. A randomised and blinded human trial of rHA 2009 H1N1 vaccine (Panblok®) at doses ranging from 3-45ug with or without a polysaccharide adjuvant (Advax™). Endpoints were safety as assessed by solicited and unsolicited adverse events and seroprotection, seroconversion and geometric mean titre increase by hemagglutination inhibition (HAI) assay. The highest seroconversion rates were seen in the younger 18-49 year old group receiving the highest 45 ug dose of adjuvanted vaccine. These subjects had post-vaccine HAI responses that were similar in levels to those after clinical infection. The addition of Advax™ adjuvant had a major boosting effect on seroprotection and seroconversion with rates being approximately doubled. The vaccine was well tolerated with no vaccine-related serious adverse effects. This recombinant adjuvanted vaccine that represents state of the art influenza vaccine technology was the first vaccine in the world to reach the clinic, little more than 4 weeks after WHO declared a swine flu pandemic. Countries that do not currently have a domestic vaccine manufacturing capability, must seriously consider their best options for secure future pandemic vaccine supply. One option would be to invest in building a highly competitive domestic and export vaccine infrastructure, leapfrogging over existing foreign vaccine manufacturers by deliberately adopting next generation vaccine technologies rather than just replicating the outdated vaccine manufacturing practices of existing manufacturers. If the swine flu pandemic showed one thing it is that the world in general remains ill-prepared for a truly devastating influenza pandemic such as the 1918 Spanish flu. Whilst H5N1 avian influenza has gone out the press and the public's view, it continues to cause deaths in Asia, and remains an ever present pandemic threat should it mutate in appropriate directions. It would be a shame if the public health lessons that can be learnt from the handling of the swine flu pandemic were lost because of general relief that it turned out to be less serious than expected, at least so far.

# Making Healthy Food Accessible to Patients at Klinik Kesihatan Ulu Tiram

**M Sariah**

Family Health Specialist, Health Clinic Ulu Tiram, Malaysia

## **SUMMARY**

This study, performed using action research approach, is to make healthy food accessible for patients and staff at Klinik Kesihatan Ulu Tiram. It is also conducted to provide knowledge on healthy food and food safety and to improve patients' satisfaction when food is easily accessible especially for diabetic patients who have to fast prior to blood taking. Data and information were gathered through discussion, personal observation of participants, interviews, survey, focus group discussion and opinion during meetings. The food provider was chosen through open advertisement and training for her was conducted by our district dietician. Initial survey showed that 96% of patient and staff agreed that healthy food should be made accessible at the clinic compound. After the third month, majority of patients were satisfied with the availability of food, amount, price and location of the food corner but found that the information on healthy food and food safety was still lacking. The final survey is ongoing. This project, using action research approach, has succeeded in making healthy food accessible and improving patients' satisfaction at Klinik Kesihatan Ulu Tiram.

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## Can I Get My Denture Fast?

**A R Jamaliah, A Noridah, H Joriah**

Senior Dental Officer, Dental Clinic Johor Bharu, Ministry of Health, Malaysia

## **SUMMARY**

Denture making is one of the main outpatient services provided by dental clinic. However, due to various factors e.g. shortage in the number of dental technologist, the waiting time for denture making has extended beyond 12 months. Our Key Performance Indicator (KPI) stated the waiting time for denture making is three months. The aim of this study is to reduce waiting time for denture making and to identify steps that could be taken to improve internal and external stakeholders satisfactions.

The specific objectives are

1. To reduce waiting time for denture.
2. To reduce number of patients in Waiting List.
3. To improve quality of life of patients.
4. To improve staff knowledge, attitude and practice.

The project was started in June 2008 until February 2009 using all the steps involved in Action Research. Waiting time for denture making meant time interval between the date the name of patient is registered in the Waiting List (WL) Appointment Book and the actual appointment date given. The concept of Action Research was used in this study. Data was collected from the Waiting List Book in Klinik Pergigian Mahmoodiah (KPL), Johor Bahru. The data was used and analysed. The number of patients in the Waiting List Book was monitored monthly and suggestions for improving the waiting time for denture were made. The concept of action research was used in this project. In this process, research, action and evaluation was conducted in series of cycles. In the process, actions produced change and new understanding to problems. Various methods were used in the process and these include brainstorming, surveys, meetings, and focus group discussion. Participation of all stakeholders was our priority. Waiting Time for denture was reduced after the project was implemented. This project has led to abolishment of single waiting list book. In April 2008, there were 733 patients, in the Waiting List. They have waited for 25 months for the denture appointment and have registered since March 2006. Since the project started, the number of patients given appointment has increased as tabulated above compared to the project. The highest number of patients called was 57 in July 2008. In November 2008, there was no patient called because of shortage of officer at that time. This shortage was overcome in December. By January 2009, the waiting time has been reduced to 19 months. By the end of project, we manage to reduce the number of patients in the waiting list from 733 to 548 patients. We have achieved our objective of reducing waiting time for denture. We manage to reduce the waiting time from 25 months to 19 months. However, it is still far from our KPI of 3 months. We will recommend to the management to continue this project until we achieve favourable result. This project had led to some effective changes. We have abolished single Waiting List Book and cases are distributed into four Waiting List Books (one for each surgery) since May 2009. With this change more commitment is expected from the Dental Officers.



# Regulation of Biologics: An Overview

**A Arpah**

Head Biotechnology Section, Centre for Product Registration, National Pharmaceutical Control Bureau

## SUMMARY

Development of biological medicines has been extremely rapid in recent years and the potential of such products for improving health care on a global scale is immense. Vaccines innovation is accelerating, made possible through advances in molecular biology and novel technologies meaning biologicals are increasingly sophisticated and complex. Regulation aims at assuring quality, safety and efficacy of products in order to promote and protect public health. The assessment, control, and surveillance of biological medicines are major challenges for National Regulatory Authority confronted by a steadily increasing number of novel products, complex quality concerns, and new technical issues. A paradigm is occurring where biologicals such as vaccines that will be used globally are increasingly being manufactured and first licensed in countries with the highest disease burdens. This is placing extra responsibilities on regulators in such countries, often in the context of limited regulatory resources. With the emerging global market the volume of biological products crossing national borders continues to rise, it has become critical that regulatory knowledge and experience is shared, and approaches to regulatory control harmonised to the greatest extent possible. Importantly, collaboration and partnership between public health authorities, regulators and industry be established early in the product development. Understandably, there is pressure from patients to make biological medicines more widely available and cheaper. It is challenging to establish a well-defined regulatory structure that can simultaneously foster 'generic' development and preserve incentive for innovators to create novel biotherapeutics.

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## Immediate Notification of Critical Laboratory Values - How Critical Are We?

**M Lily, S Sararaks, T Y Tengku Norita, M D Noor Aishah, L L Low, K C Keah, M H Ainul Nadziha, A Roslinah, Y Mohd Sadek, M Habibah Bee, A Manual, H Irdayu, A H Maimunah**

Consultant Pathologist/Quality Manager, Department of Pathology, Hospital Kuala Lumpur, Malaysia

## SUMMARY

The concept of critical values, defined as an imminent life threatening laboratory result requiring immediate physician notification, has been widely adopted as a standard of good laboratory practice worldwide and mandated by accreditation bodies. There is increased attention to the issues of effective communication among caregivers, especially for laboratory critical value reporting. However, what is the practice in Malaysia? This presentation shares results of a study on improving notification in Malaysia, and lessons for improvement. The first phase was a cross sectional mailed survey to assess current practices in all 126 MOH hospitals, while in the second phase, the aim was to develop a list of laboratory tests with critical values and procedure for notification. Literature review and workshops with laboratory, clinicians and nursing personnel resulted in a preliminary consensus. To obtain opinion from a wider range of specialists, the Delphi survey was used. The third phase involved an interventional trial to assess the effectiveness of an intervention package to improve notification. The initial survey showed that the importance of critical value reporting was poorly recognised in MOH hospital laboratories. A QuickGuide (version 1) that incorporated the revised values and procedures was developed to enable hospital laboratories to implement critical value reporting. The procedure incorporated covered many of the recommendations advocated in Safe Practice Recommendations from the Massachusetts Coalition for Prevention of Medical Errors. In addition, notification of critical results improved significantly with the intervention package for certain types of hospitals. Lessons learnt for communicating critical laboratory values are discussed. Critical laboratory value reporting is still poorly recognized in MOH hospital laboratories. The QuickGuide version 1 could be used by hospital laboratories for implementing critical value notification, and the intervention package could be implemented to improve notification. Healthcare providers and practitioners all have a role to play in improving notification.

# Handoff Communication – Let's do it Right

**K K Carol Lim, S K Chan, E L Chew, A F Anita Lim, S Sararaks, H Ainul, A Roslinah, L S Tan, L L Low, A B Azman, A H Maimunah**

Maternal Fetal Medicine Specialist, Consultant Obstetrician & Gynaecologist, Ministry of Health, Malaysia

## SUMMARY

Handoff communication refers to the transfer of professional responsibility and accountability for some or all aspects of care for a patient, or a group of patients, to another person or professional group on temporary or permanent basis. This is also termed "handover", "clinical handover", or "passover". Discharge communication involves the transfer of information and materials from health care providers to patients/carers at the point of discharge. The information may include admission details, follow-up care plan, medication advice, etc. Materials commonly provided include appointment cards, discharge summaries, health education leaflets, referral letters and investigation request forms if required. The follow up care of patients discharged from hospitals are shared among patients and their carers (government and private sectors) whose access to adequate discharge information is of paramount importance. Cross-sectional studies were done to assess handoff communication (HOC) processes among doctors, and discharge communication in MOH hospitals. The latter involved interviewing patients regarding level of knowledge while the former was a self-administered questionnaire on reported practices. The systematic review was conducted to identify and assess best practices reported internationally that could be adopted/adapted for local use. Most common methods for handoff process: by phone (post-call 54.5%; pre-call 56.0%) and briefing sessions (post-call 52.0%; pre-call 51.7%), and two thirds had a structured time for HOC (post-call 68.6%; pre-call 67.6%). Less than one quarter had a standard practice/procedure for handing over (post-call 25.1%; pre-call 14.6%) while less than 10% had a standard checklist/form for handing over. Discharge communication study found 60.6% (CI 14.6, 100.0) of hospital inpatients received discharge summaries. Only 62.7% (CI 43.6, 81.7) knew the names of their medication, 46.1% (CI 34.3, 57.9) knew the side effects of their medication, 28.4% (CI 18.8, 38.1) knew the emergency number to call after discharge and 47.0% (CI 22.4, 71.7) was given appointment cards. From the systematic review, initial search of 333 potentially relevant studies were retrieved, of which only 18 met our inclusion criteria. From the 18 studies, only three looked at primary discharge communication outcomes, eight looked at secondary outcomes and seven looked at both outcomes. Intervention strategies were multipronged. Those which significantly improved discharge communication were use of standardised/structured verbal and written information leaflet, use of discharge coordinator/ physician and/or nurse to explain, incorporation of an assessment and feedback on comprehension tool, professional instruction, educational materials, telephone instructions, home visits, post-discharge communication with patients and discharge summary. This study demonstrated that health care providers, both public and private, need to develop and implement an effective, standard approach for handoff and discharge communication in hospitals. The MOH should place priority for effective discharge communication to be considered as means towards patient safety. Effective handoff communication ensures smooth transition of patient from one health care setting to another to ensure continuity of care.

# WHO Vaccines Prequalification

**N Dellepiane**

Scientist Quality, Safety and Standards, Department of Immunization, Vaccines and Biologicals, WHO

## **SUMMARY**

The World Health Organization has established a vaccines prequalification procedure since 1987. This presentation will briefly describe its purpose, principles and steps together with its added value and implications. The Vaccines prequalification programme is a service provided by WHO to the United Nations purchasing agencies with regards to assuring the quality, safety and efficacy of the vaccines for purchase. Currently, a total of 124 countries are served by UN procurement agencies, 90 through UNICEF Supply Division, and 34 through the PAHO RF. This accounts for approximately 64% of the total population receiving vaccines of assured quality. Because of the importance of oversight of the manufacturer's NRA for prequalification of a product, a new policy endorsed by an expert committee in 2004 requires a mandatory assessment of NRAs in all the countries for which prequalified vaccines are listed and in countries where manufacturers intend to apply to WHO for vaccine prequalification. The prequalification procedure relies on functional National Regulatory Authorities in producing countries and evaluates only vaccines that have been granted a marketing authorization (or a surrogate to a MA, i.e. scientific opinion by EMA). If the conditions above are met, WHO reviews the manufacturer's product summary file, which describes the product, the production process, the facilities, the quality system, and clinical data generated to demonstrate its safety and utility for the intended purpose in the target group. The written standards developed by the ECBS are one of the bases for developing specifications for the procurement tender document. WHO provides independent testing to confirm consistency of final product characteristics and to ensure that the product meets the specifications in the relevant tender, and organizes a site visit to the manufacturing facilities to assess compliance with GMP and to verify the information in the file. Agreements are reached with the manufacturer and the NRA on continuing responsibilities, reporting requirements, and shipping and packaging specifications. Once prequalification status has been conferred, the continuing oversight of the prequalified vaccine falls under the responsibility of the relevant NRA. When the vaccine is reassessed, a process that happens at prescribed intervals to maintain prequalification status, by a WHO team of experts, generally NRA representatives participate as observers during the site visit. The information gathered during the reassessment both from review of an updated product summary file and at the time of the site visit serves as feedback on the NRA performance with regard to the oversight of the specific product and leverages further improvement. The added value of the prequalification evaluation is that in addition to the assessment performed by the NRA in country of manufacture, it focuses on the specific aspects that are relevant to the UN target population, such as immunisation schedules compatible with those in developing countries, non-interference with vaccines co-administered following these schedules, clinical data relevant to the target population, product characteristics suitable for use in developing countries such as presentation in vials rather than in pre-filled syringes, stability profile suitable for tropical countries with weak cold chain systems, etc. Such vaccines are therefore evaluated first by the NRA in country of origin and secondly by WHO to ensure that the WHO recommendations and the UN specifications which reflect the needs of the national immunisation programmes are met. In the past, most prequalified vaccines were produced in industrialised countries. An outcome of the prequalification process is that it sets up an independent and unbiased method to evaluate vaccines proposed for purchase no matter where they are produced, thus allowing emerging suppliers to compete on the international market. The result of this is that the number and percentage of vaccines, both traditional and new, coming from emerging suppliers, whose prices may be lower, and who may be able to supply basic vaccines in larger proportion of vaccines of assured quality by region quantities, have increased, contributing to the security of vaccine supply worldwide.

# Validation of GMP Facilities

**A G M Hector**

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## SUMMARY

It is widely known that emerging new technologies and the necessity to fight existing and newly discovered illnesses have kept the pharmaceutical industry growing progressively. In the last decade, governments and private investors have realised the relevance and strength of this sector not only from the human point of view but also for its profitability. That is why a considerable number of facilities are being built all over the globe. The guidelines of the regulatory authorities (FDA, EMEA, NPCB, etc) for the production of drugs to be used in humans under cGMP conditions (Current Good Manufacturing Practices) have become more and more stringent over the years. These guidelines undergo revisions and harmonisation periodically. Therefore, it is of vital importance to have a regulatory compliant design and qualification scheme when dealing with the development of a new facility for pharmaceutical manufacturing. Even though the International Society for Pharmaceutical Engineering (ISPE) provides some guidelines and advice on how the validation of a newly built facility and its equipment should be performed, there is no documentation that supplies validation engineers with a step by step standard procedure. Hence, users often put a lot of resources towards validation. These validation exercises tend to be redundant and often excessive. Although there is a lack of detailed methods for qualification exercises, there are some common steps that can be taken to ensure cGMP compliance of a facility. These steps include: Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT), Commissioning, Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). The above mentioned steps come together to shape the acceptance chain. Throughout all these phases, the facility and the equipment will be challenged with different tests that will ensure that they were constructed properly and perform according to the user requirement specifications (URS). It will also ensure that they give consistency to the process they were designed for and can therefore be declared in conformance with the URS. This presentation will focus on the long road and many challenges that manufacturers of pharmaceuticals have to overcome. The challenges range from the design issues of the custom facility to guaranteeing full functionality without stepping out of the regulatory spectrum. Other important topics related to compliance will also be addressed such as, who will perform the qualification, and how it should be done if you want it to be successful and acceptable for the current requirements in the industry. The similarities and differences between the various acceptance chain stages will be discussed. A perspective will be given on what things should and should not be done during validation. The documentation needs for each stage will also be presented. This will cover the organisation of the documentation and the sign-off process. Finally, calibration of critical instruments will be discussed, which is an important part of supporting the facility and equipment validation.

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# The Growing Role of Asian Contract Development and Manufacturing Organisation for Biologics

**K Mohd Nazlee**

Chief Executive Officer, Inno Biologics Sdn Bhd

## SUMMARY

On a global scenario, the drug's development process is becoming increasingly complex, time consuming with rapid escalating costs. Improvement and paradigm shift in R&D strategy are both necessary to boost productivity. Historically, the R&D services most commonly outsourced are the clinical trial project and data management involving large patient populations. In recent years, the portfolio of services offered by CMOs (Contract Manufacturing Organisation) has widened dramatically which includes early stage of drug discovery and development processes. As the number of new drugs approved is declining and mounting pressure to replace potential revenues lost to patent expiration, pharmaceutical companies are rapidly transitioning their portfolios to large, biological molecules. As this occurs, R&D outsourcing is an opportunity for pharma companies to ensure speeding up drug development and growing revenues. The use of external outsourcing has become an important strategic issue for both pharma and biotechnology companies. A CMO now acts as an extension of a drug developer's in-house R&D group, performing tasks at various stages of the development process. With the movement of pharma companies to biologics pipeline, the needs for CMO with specialised research services in biologics discovery and development processes is expected to increase. Additionally, the expertise in biologics will allow CMOs to participate in the rapidly growing market for biosimilars, since regulators are expected to require testing and evaluation demonstrating equivalence with branded counterparts. Strong growth in the utilisation of CMOs is being driven by a variety of interrelated factors. One of the factors to outsource is to access functions and expertise they do not possess in-house as many discovery companies are virtual organisations. Others outsourced to focus on its core competencies, reduce costs or to meet temporary lack of capacity. Several strategies have been adopted to increase R&D efficiency and productivity. Some of the companies restructure their R&D divisions into smaller organisations, others implement worldwide collaboration model. Expansion of R&D outsourcing into Asia has become a key trend. Pharma companies are moving to Asia for R&D partnership to encourage innovation and reduce costs. These have reshaped the drug development services industry in Asia. What are the challenges in R&D activities that force the pharma and biotech companies for R&D outsourcing and what are the impacts of revised strategy on R&D to Asian CMO? These topics will be discussed in the presentation.

# Multicentre Clinical Research Experiences of a Thai Clinical Research Collaboration Network, (CRCN)

**R Rangsin, P Tatsanavivat, W Tulvatana, S Rattanamongkongkul**

Associate Director, Clinical Research Collaboration Network (CRCN), Thailand

## SUMMARY

Clinical Research Collaboration Network (CRCN) established in 2000, with an initial funding support from International Health Research Award of the Rockefeller Foundation, under the joint support of the Consortium of Thai Medical Schools, National Research Council of Thailand and Health System Research Institute. Being a not-for-profit organisation under the umbrella of the Medical Research Foundation, the goal is to develop and strengthen clinical multi-centre systems to help and support the research team, to create research focusing on quality of care and quality of life of the patients. Multi-centre clinical research management was developed. A total of 36 investigator-initiated projects has been conducted, 17 disease registries and 26 Clinical Research Networks were developed. Results from the studies were used as evidence for developing clinical practice guidelines in diseases and changing healthcare policy to suit the local environment. Seventy-five publications in both national and international journals and 40 poster and oral presentations at national and international conferences were produced. We created our data management software: Online Medical Research Tools: OMERET™ using an optical recognition and multiple verification system. Recently, CRCN has been commissioned to help develop clinical research centres among Medical schools throughout Thailand. Concurrently, several Medical Schools has established a clinical trial centre, which will operate both sponsor-initiated as well as investigator-initiated clinical trials. The CRCN is also acting as a mediator between funding agencies and researcher teams to facilitate clinical studies focusing on national healthcare problems.

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## Clinical Trial Contracts for Sponsored Clinical Trials - Perspectives from Investigators/Study Sites

**Henry Yau**

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## SUMMARY

Sponsored clinical trials are a kind of contract research where sponsors usually supply investigational products, funding and publication rights in return of study data collected and submitted by investigators/study sites. The rights and responsibilities of sponsors and investigators/study sites and also certain operational arrangements shall therefore be documented and agreed upon by sponsors and investigator/study sites in the form of legal contracts – usually referred to as clinical trial contracts or clinical trial agreements (CTAs). Different clinical trials may have different operational arrangements and may carry different potential risks and benefits, all of which may affect how CTAs are drafted. While developing a CTA, an investigator/study site needs to consider the following six key principles:

- Risk exposure and risk control
- Operational viability
- Clinical services priority
- Research ethics
- Compliance with regulations and other requirements
- Interests of investigator/study site.

A well-written CTA should include and clearly illustrate all major terms and conditions, with the aforesaid six principles reflected. Irrespective of the nature and arrangements of a clinical trial, a CTA should normally cover the following five content areas:

- Study management: Such as supply of investigational products, monitoring and financial arrangements.
- Study site operations: Such as subject recruitment, informed consent procedures and study documents archiving.
- Handling of study information: Such as confidentiality, ownership of study data and publication policies.
- Liability management: Such as indemnity, insurance and limitation of liability.
- Legal procedures: Such as amendment or termination of contract, disputes resolution procedures and governing law.

Whilst a CTA is a legal document, CTA management is not the sole responsibility of legal counsels. Any CTA covers a wide range of issues – from operational arrangements and resources management to ethics and legal liabilities – which should be jointly managed by investigators, study site management and legal counsels. Each of them should understand one's responsibilities and actively contribute to the development, approval and enforcement of a CTA.

# Future Asian Clinical Trial Network – Japan’s Contribution

**Y Kumagai**

Director, Kitasato University Clinical Trial Centre, Japan

## **SUMMARY**

Asian clinical trials have been promoted as part of global drug development. In Japan, the starting up was delayed owing to its long history that drug development could be managed in the country anyway when speed and cost could be ignored. However, the drug lag, which not a small amount of popular drugs in the world cannot be used in Japan by the delay of drug development, has become a important issue not only in medical society but also in general population and the government started several programs to promote international clinical trials. According to the new five year activation plan for clinical trials, ten core hospitals and 30 major hospitals were selected and supported by several grants. The purpose of the plan is to set up infrastructure, human resource development, public promotion, efficient data management and finally to join global studies. This plan seems to be working well, and a new proposal was made in the interim report. It emphasises importance of early clinical trials including phase I trials, proof of concept studies and dose finding studies to find out appropriate dosage regimen in Asian countries. A new program was started in 2009 and two universities (Keio University and Kitasato University) were accredited as Global Clinical Research Bases. In Japan, the importance of early clinical trial was already recognised by clinical pharmacologists and a network of J-CLIPNET (Clinical Pharmacology Network for Early Clinical Trials) was formed by six university hospitals. J-CLIPNET is seeking efficient way of Asian early clinical trials with Korean colleagues (CCCP, KoNECT) and Chinese colleagues (Peking Union Medical College). Kitasato University, a core hospital, a Global Clinical Research Base and a member of J-CLIPNET, has started its activity to promote Asian clinical trials. For this purpose, KitARO, an academic research organisation, was established in the University. KitARO will organise clinical researches at five clinical institutes in the university and also those in Japan. KitARO will offer web-based educational courses open to Asian clinical trial professionals and opportunities of on-the-job training at Kitasato University. KitARO aims to contribute to global drug development by networking clinical trials of early stages and also confirmatory studies. Japan is trying hard to catch up with Asian countries in global clinical trials with efforts by industries, authorities and academia.

## POSTER ABSTRACTS - PATIENT REGISTRY

- PRG01** National Mental Health Registry - Schizophrenia One Year Outcome Study
- PRG02** Very Low Birthweight Inborn versus Outborn Neonates in MNMR 2007
- PRG03** Audit And Benchmarking of Neonatal Intensive Care of Very Low Birth Weight Neonates in Malaysian NICU's
- PRG04** Clinical Features and Immediate Outcomes of Colorectal Cancer Surgery Cases in Hospital Sultanah Bahiyah
- PRG05** National Cancer Patient Registry – Hematology Malignancies
- PRG06** Colorectal Cancer in Malaysia - What Do We Know?
- PRG07** Service Utilisation of People With Newly Diagnosed Schizophrenia in Malaysia
- PRG08** Malaysian Psoriasis Registry - Results from October 2007 to December 2008
- PRG09** National Cancer Patient Registry – Breast Cancer (NCPR-Breast Cancer) 2008 Preliminary Report
- PRG10** National Cancer Patient Registry (NCPR) - Preliminary Report of Pilot Study
- PRG11** National Orthopaedics Registry of Malaysia (NORM) on Hip Fracture-Preliminary Report June to December 2008
- PRG12** National Obstetric Registry – The Unusual Route in Childbirth
- PRG13** National Obstetrics Registry - Increase in Stillbirth Rate with Increasing Maternal Age
- PRG14** National Obstetric Registry-External Cephalic Version Plays An Important Role In Breech Pregnancy
- PRG15** National Obstetrics Registry - Vaginal Delivery is Still 21st Century Mothers' Choice

# National Mental Health Registry - Schizophrenia One Year Outcome Study

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## SUMMARY

The National Mental Health Registry (NMHR) has progressed into the second phase of its study, where patients with schizophrenia are followed-up one year after their first psychiatric consultation. Outcomes in patients with schizophrenia are multi-dimensional, inter-linking patient demographics, severity of symptoms, functionality, employability, treatment and hospitalization. It has been found that certain clinical indicators which manifest early in the course of the illness such as age of onset, acute onset of disease, gender, marital status and duration of illness before treatment have prognostic significance lasting well over ten years. This was an observational study of patients followed-up as outpatients one year after initial contact with the medical services. The participants were patients that were registered in NMHR and recruited from outpatient clinics. Twenty eight percent of these patients continued follow-up in the same centre, 46% of them were transferred to other centres, 25.5% of them were lost to follow-up and 0.5% of them had passed away. This included two cases of suicide. There was no significant difference in the marital status of patients one year post treatment initiation. However, there was a significant increase in employment status ( $p < 0.05$ ). Among those who were unemployed, most of them were unable to work or to obtain employment. Significant weight gain and increase in BMI were noted in these after a year of treatment. The diagnosis of schizophrenia remained stable throughout the year. With regards to the utilization of mental health services, 89.1% of them were on regular follow-ups, 13% of them used emergency services, 17% of them had been admitted to psychiatric wards, two percent needed to be transferred to mental health institutions and 10% under community care. During the follow-up period, 14% of them sought alternative or traditional treatment, three percent of them gave a history of substance abuse, two percent admitted to deliberate self-harm, and four percent of them were arrested by the police. There were changes in medication prescribed in 40% of the study cohort over one year. There was a significant increase in the use of atypical anti-psychotics. There was a 5.1% ( $p < 0.001$ ) increase in use of atypical anti-psychotics over the year, while use of typical anti-psychotics reduced by 8.1% ( $p < 0.001$ ). There was a reduction in the use of haloperidol with increasing use of chlorpromazine and sulphiride. Twenty percent of the patients practised polypharmacy. It is hoped that findings in this report can be used to improve services given to patients with schizophrenia receiving care from various centres in this country, such as reducing polypharmacy, strengthening community care for the disabled and a more comprehensive mental health service.

# Very Low Birth Weight Inborn Versus Outborn Neonates in MNNR 2007

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## SUMMARY

Malaysian National Neonatal Registry (MNNR) is a hospital-based registry. The inclusion criteria include all pre-term infants under 1.5kg (VLBW) and under 32 weeks admitted into the Neonatal Intensive Care Unit (NICU). The very low birth weight (VLBW) data was prospectively collected using case report forms. The inborn (IB) VLBW study population was complete but only admitted outborn (OB) VLBW infants were included. The 2007 data from the 24 participating hospitals was analyzed. The overall survival for VLBW and ELBW (extremely low birth weight) (extremely LBW  $\leq 1000$ g) neonates improved slightly from 2004 to 2007. In 2007, the survival was 48.6% for ELBW group (49.4% IB versus 40.7% OB), 88.5% in the (1001-1500g) group (89.2% IB versus 83.7% OB) and 75.3% in the VLBW group (75.7% IB versus 72.6% OB). The IB had better survival rates in all the birth weight categories with a p-value of 0.003 for the (1001-1500g) group. 3650 neonates weighed less than 1500g (87.5% IB and 12.5% OB). Fifty percent of IB neonates were delivered via lower segment caesarian section compared to 19% of the OB group ( $p < 0.0001$ ). Maternal steroids use was only 59% (63% IB versus 26% OB,  $p < 0.0001$ ). Surfactant use was 49% (48% IB versus 51% OB,  $p$  value 0.22). Sixty eight percent of IB neonates received surfactant within two hours of life compared with 33% of the OB neonates ( $p < 0.0001$ ). Eighteen percent of infants required continuous positive airway pressure alone (18% IB versus 16% OB) and 80% were on conventional ventilation (80% IB versus 81% OB). Among ventilated neonates, the median ventilation duration for IB and OB neonates were both five days [IB interquartile range (IQR) was two to 13 versus OB IQR two to 14]. There was no difference in the incidence of respiratory distress syndrome (RDS) (72% IB versus 75% OB), chronic lung disease (CLD) (eight percent for IB and OB), necrotizing enterocolitis (NEC) (6%), confirmed sepsis (14%). Retinopathy of prematurity (ROP) screening was performed in only 62% and ROP was an infrequent finding (18% IB versus 13% OB,  $p$  value 0.056). Brain ultrasound was done in 70% of the neonates with intra-ventricular haemorrhage (IVH) seen in 34% of IB versus 35% of OB neonates. For those who died, the median age of death was one day for IB (IQR zero to eight) and two days in OB (IQR one to 12). Among the surviving infants, median age at discharge was 49 days, which was similar in both the IB and OB groups. In conclusion, IB VLBW and ELBW had better survival rates. The morbidity rates of RDS, CLD, ROP, IVH, NEC and confirmed sepsis were similar in both groups. Overall, the mortality and morbidity outcomes of VLBW infants still lags behind that reported in developed countries.



# Audit and Benchmarking of Neonatal Intensive Care of Very Low Birth Weight Infants in Malaysian NICU's

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## SUMMARY

Malaysian National Neonatal Registry (MNNR) was set up in 2002 to study the outcome of sick babies admitted to Neonatal Intensive Care Units (NICU's) in the country. The aim of the study was to show the mortality and morbidity among very low birth weight (VLBW) and pre-term infants below 32 weeks gestational age (GA) across 29 to 31 centres from 2006 to 2008, as well as to determine factors which determine factors which could have impacted on the variation in mortality or morbidity. Data was collected prospectively using a case report format and entered into the web-based MNNR from 29 centres in 2006 and 31 centres in 2007 and 2008. Inclusion criteria to the MNNR were all babies admitted to the centres whose birth weight was less than 1500 gm, all below 32 weeks GA, all who were ventilated irrespective of birthweight or GA and all with significant congenital anomalies. Treatment and morbidity which can alter the clinical course of a preterm infant significantly such as the use of surfactant, antenatal steroids and incidence of severe intraventricular haemorrhage (IVH) were studied. VLBW babies accounted for 33-35% of MNNR registrants with 3 586, 3 651 and 3 638 VLBW babies in 2006, 2007 and 2008 respectively. Survival rates among extreme pre-term (22 to 27 weeks GA) varied from zero to 70% across centres, while survival rates in larger babies (1001 to 1500 g birth weight) varied from 71-95%. Eighty percent of babies below 32 weeks GA had respiratory distress syndrome (RDS) of whom 91% required respiratory support. The use of exogenous surfactant to replace surfactant deficiency in RDS also varied greatly (zero to 86%) of all babies who were ventilated for RDS in each centre. There was also variable use of antenatal steroids across centres varying between 22-80% of anticipated deliveries at less than 32 weeks GA. Five centres reported severe IVH incidence of more than 40%. From the MNNR data, it can be seen that there is much variation in survival rates, especially in extremely pre-term of below 27 weeks. This may be due to varying aggressiveness in management for extreme prematurity, variable use of surfactant and antenatal steroids, skills yet to be acquired or whether a significant proportion to the unit are outborn when the extreme preterm does poorly. Other factors that account for varying outcomes are the capabilities of the NICUs which varies between state and district hospitals. This study did not take into account resources available to each unit such as staffing, space, equipment and availability of parenteral nutrition services. From our study, the variations in survival outcome are not surprising considering the variations in management practices, which includes key therapy issues such as the use of antenatal steroids and surfactant therapy. Comparison of practices have been made and self-audited. Review of policies and implementation of changes have been performed to improve outcome.

# Clinical Features and Immediate Outcomes of Colorectal Cancer Surgery Cases in Hospital Sultanah Bahiyah

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## SUMMARY

An increasingly common cancer in Asia is colorectal cancer, which is the second most common cancer in Malaysia after breast cancer. As one of the sites reporting to the National Cancer Patient Registry-Colorectal Cancer (NCPR-CC), the investigators at Hospital Sultanah Bahiyah decided to review the data pertaining to surgery, to have an overview of the colorectal cancer surgeries in the hospital and to compare elective and emergency cases. This is important because early diagnosis and treatment offers better prognosis. The objective of this study was to observe the features and presenting symptoms of colorectal cancer cases that underwent elective and emergency surgery, and to present the immediate outcomes of these cases. Data was obtained from cases reported to the NCPR-CC from 2007 to March 2010. From a total of 168 surgical cases, three cases were excluded from the study because information on urgency of the surgery, either elective or emergency was not available. Elective surgeries accounted for 74.5% of the 165 cases. Of these, 87.8% were of curative intent. In contrast, 59.5% of the emergency cases were curative, while 21.4% were palliative and 19% were diagnostic. Left-sided tumours appeared more frequently compared to right-sided tumours in both elective and emergency cases, highlighting the differences in tumour predilection site between Asians and Westerners. The rectum and the sigmoid colon were the most commonly involved sites in elective and emergency cases respectively. A majority of all cases were symptomatic at presentation. A higher proportion of the emergency cases presented with abdominal pain and diarrhea, constipation or other change in bowel habits compared to elective cases. This observation should be further explored, as early recognition of the sinister symptoms may prevent some emergencies. There were higher morbidity rates and inpatient mortality in emergency cases. Nevertheless, the overall surgical and medical complication rates were only 15.8% and 10.3% respectively. This overview provides information about colorectal cancer in one local setting. Considering that nearly all of these cases are symptomatic, it is important to recognize symptoms suspicious of colorectal cancer and initiate prompt further investigation. It is hoped that this report improves understanding of the current situation in hospitals, so that best possible care can be provided to patients battling this disease.

# National Cancer Patient Registry – Hematology Malignancies

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## SUMMARY

The National Cancer Patient Registry – Hematology Malignancy (NCPR-HM) is a patient registry initiated in 2008 with the core objective of evaluating the disease and patient characteristic, including treatment delivered and eventually long term follow-up for outcome. This registry recruited all patients newly diagnosed with hematological malignancies, namely Acute Myeloid Leukemia, Myelodysplastic Syndrome, Acute Lymphoblastic Leukemia, Chronic Myeloid Leukemia, Non-Hodgkin Lymphoma, Hodgkin Lymphoma and Multiple Myeloma. Clinical data from patients who were diagnosed from March 2008 onwards in the participating centres were captured in the registry. The registry is also designed to capture outcome data in specific intervals after the patients have been diagnosed. Up to December 2008, 467 patients with haematological malignancies were registered from the seven centres.

PRG06

# Colorectal Cancer in Malaysia - What Do We Know?

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## SUMMARY

Colorectal cancer (CC) is currently one of the most common form of gastrointestinal cancers worldwide. In Malaysia, it is the commonest and third commonest cancer affecting men and women respectively. It is evident that the disease burden attributable to these cancers is not insignificant. The National Cancer Patient Registry-Colorectal Cancer (NCPR-CC) was set up to assist the Ministry of Health to comprehensively report on various aspect of colorectal cancer in Malaysia, in our effort to more comprehensively evaluate the disease burden and management of colorectal cancer. The aim of this study was to determine the basic demographic features of patients with colorectal cancer and characteristics of the tumours in registry patients. We analyzed patients diagnosed with colorectal cancer in 2009. Analysis was carried out on 455 patients diagnosed with colorectal cancer in 2009. Patient demographic data including sex, age, and race were recorded. An overwhelming majority of patients (85.5%) presented after the age of 50 years. Twenty three patients (5.1%) presented before the age of 40. Left sided tumours were more common and constituted 75.5% of all tumours. This highlights the differences in tumour predilection site between the asians and westerners. Polyps were noted in 61 cases (61/307). Seven cases had more than 100 polyps which is consistent with a diagnosis of Familial Adenomatous Polyposis (FAP). Around 10.7% of these tumours were confined to the bowel wall (pT1N0 or pT2N0). Most (85.7%) of the tumours showed growth that extended beyond muscularis propria (pT3 and pT4). These cases had lymph node metastases. This study suggested that most of our patients presented late in the course of the disease as our data showed that the majority of tumours had spread beyond muscularis propria. Surgical data were available on 360 of the 455 patients. However, there were 77 (21.4%) cases where the surgery type is marked as other than all the standard procedures described due to various reasons. Twelve patients (3.33%) received neo - adjuvant chemotherapy first before proceeding to surgery. Most of the patients in this study presented after the age of 50 years, had left sided tumour and tumour extension beyond the muscularis propria (pT3 and pT4). While the registry data has yet to fully represent the Malaysian population, it is hoped that this registry will assist efforts to reduce the disease burden of colorectal cancer by providing an invaluable repository of data for assessments of colorectal cancer management in Malaysia.

# Service Utilisation of People With Newly Diagnosed Schizophrenia in Malaysia

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## SUMMARY

The assessment of service utilization among people with schizophrenia in Malaysia is important as they receive treatment in all different facilities in the country and at all levels including primary care. A cohort of 276 patients from National Mental Health Registry of Schizophrenia was followed up after one year of treatment at the same facilities. About 13% (n=36) were seen at emergency department, 17% (n=46) had psychiatric re-hospitalization, two percent (n=6) were transferred to a mental institution, 89.1% (n=246) found to be on regular follow-up, three percent (n=9) abused substance, 22% (n=6) attempted self harm, four percent (n=10) had been in contact or arrested by police, 10% (n=27) utilized community mental health services and 14% (n=38) of the patients continued to seek alternative treatment. Apart from being useful in assisting policy planners, administrators, and clinicians to further improving the mental health services, the study can also suggest area of future service research for people with schizophrenia in Malaysia.

# Malaysian Psoriasis Registry - Results from October 2007 to December 2008

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## SUMMARY

The Malaysian Psoriasis Registry (MPR), established in 1998 to provide data on various aspects of psoriasis in Malaysia, was revised in 2007 with the use of a new registry form and a centralized electronic database with web application. The aim of the registry is to monitor socio-demographics characteristics and burden of disease. This was a prospective cohort study where data was collected at six monthly intervals to track changes in clinical pattern and severity, treatment modalities, as well as dermatology life quality index (DLQI). During the study period, 2499 patients from 13 dermatology centres (12 government, one private) were notified to the registry. The disease affected women slightly more than men although no ethnic predilection was noted. Mean age of onset was 33.3±16.6 years. Family history was present in 18.9%, more commonly in patients with early-onset disease. Main aggravating factors identified were stress, sunlight and upper respiratory tract infection. Plaque psoriasis was the commonest clinical type. Systemic involvement was noted in the majority, the most frequent being nail changes (63.7%). A third of the adults were overweight, which was the commonest co-morbidity. The mean DLQI scores were 8.3±6.5 for adults and 7.5±5.6 for children. The most frequently used systemic therapy and topical therapy used were methotrexate (15.6%) and tar preparations (78.9%) respectively. Narrowband UVB was the most popular mode of phototherapy. As the registry cohort grows in size and with further follow-up, further research may be conducted on various aspects of the disease, including treatment outcomes and cost-effectiveness.

# National Cancer Patient Registry – Breast Cancer (NCPR-Breast Cancer) 2008 Preliminary Report

**E Nor Aina**

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## SUMMARY

Breast cancer is the most common cancer in most part of the world and it is the most common cancer among Malaysian women. In Malaysia, there is difficulty in determining the exact incidence of breast cancer because of lack of a breast cancer registry. The National Cancer Patient Registry - Breast Cancer (NCPR - Breast Cancer) was initiated in 2008 as a part of National Cancer Patient Registry (NCPR) Project. It was a multi-centre, observational cohort study designed to evaluate the health outcomes of patients with breast cancer undergoing treatment at participating clinical centres. For this pilot study, 166 patients with confirmed diagnosis of Breast Cancer were recruited into the registry from the first of January until the 31st December 2008. Most patients were recruited from Hospital Kuala Lumpur and a small number of patients were recruited from Hospital Putrajaya. All collected clinical data were analyzed to describe the current trending as well as natural history of breast cancer particularly in term of treatment modalities and subsequently to assess treatment outcome of breast cancer in Malaysia.

PRG10

# National Cancer Patient Registry (NCPR) - Preliminary Report of Pilot Study

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## SUMMARY

National Cancer Patient Registry (NCPR) which was set up in 2007 is an observational cohort study designed to evaluate the health outcomes of patients undergoing treatment for cancers in Malaysia. 1192 new patients with a definitive solid tumour diagnosis were notified from the first of June 2008 to the 31st of December 2008 in the Department of Radiotherapy & Oncology, Hospital Kuala Lumpur. Breast cancer was the most common type of cancer with 292 registered cases (24.5%) in total. Colorectal cancer ranked second at 17.6%, followed by cancer of bronchus and lung (18.6%), cervical cancer (6.5%) and nasopharyngeal cancer (6.2%). Comprehensive analysis on demographic details, performance status, solid tumour characteristics, treatment modalities such as radiotherapy and chemotherapy, patient follow up and outcome were reviewed. NCPR is the first database to provide information on the treatment and outcome of solid tumours in Malaysia. Treatment outcome obtained from this database is a useful tool to monitor the indicators of health care quality in cancer treatment and impacts on future national planning policies.

# National Orthopaedics Registry of Malaysia (NORM) on Hip Fracture-Preliminary Report June to December 2008

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## SUMMARY

The National Orthopaedic Registry of Malaysia (NORM) on hip fracture for patients aged 50 and above was established in 2008. Its main objectives are to establish a national database of patients treated for hip fracture (especially for ages 50 and above) in the 18 Orthopaedic departments (MOH hospitals) and to characterize patients' demographic and social profile, hip fracture patterns, clinical practice and outcome. This is the preliminary report for 188 case series from the first of July to the 31st December 2008. A hundred and twenty six patients were female, of which 94% were post-menopausal. Patient ethnic distribution were similar to the country's population distribution: 47% Malays, 35% Chinese and 16% Indians. The mean age was 72.6 years and the risk of fracture increased with advancing age. Majority (94%) lived in their homes and many (68%) were able to function independently before the fracture. Sixty eight percent of the study population had co-morbidities at the time of admission. The co-morbidities include hypertension (69%), diabetes (47%) and history of stroke (12%). Eighty eight percent of the patients were not on any anti-osteoporotic medications. Among those who were on medication were mainly on calcium and /or Vitamin D. Despite the increasing risk of fracture with age, only four percent of patients had previous hip fracture. No specific type was predominant. The commonest mode of injury was fall (79%), followed by road traffic accident (10%). Majority of these fractures (86%) were surgically treated. Seventy nine percent of these surgeries were planned. Although planned surgery was the mainstay of treatment, 80% were classified as 'delayed surgery', defined as more than three days. Main reasons cited were busy operating theatres, unfit patients and financial issues. The commonest form of fracture fixation was dynamic hip and condylar screw system (57%). The rest of surgically treated patients were with joint replacement. Epidural and spinal anesthesia were the preferred mode of anesthesia. The majority of surgeries were performed by consultants or specialist. Fifty seven percent of patients did not receive any form of thrombo-prophylaxis. Chemical prophylaxis, low molecular weight heparin is the most popular form. Surprisingly, 90% of patients did not receive any form of antibiotic prophylaxis. Amongst those who were on antibiotics received Cefuroxime and 98% of patients were successfully treated and discharged. In terms of duration of hospital stay, 57% of patients stayed less than two weeks. However, about 10% of them were admitted for more than four weeks.

# National Obstetric Registry – The Unusual Route in Childbirth

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## SUMMARY

The National Obstetric Registry is the largest registry to date in Malaysia. This paper looked at the incidence of caesarean sections among all the cases reported to the registry. In addition, the indications for caesarean section and outcomes are also looked at. With this review, it is hoped that guidelines can be developed for improved care. Our objectives were to (1) know the true incidence of caesarean section in major public hospitals in Malaysia ; (2) review circumstances that contribute to a caesarean delivery ; (3) study indications for caesarean sections and (4) look at delivery and perinatal outcomes from a caesarean birth. The National Obstetric Registry is a patient registry of all women undergoing deliveries at all the designated major public hospitals in Malaysia. For this review, all caesarean birth was extracted from the first of July to the 31st December 2009 and analyzed using Stata version 9.0. A total of 16 551 caesarean births were analyzed. These births were distributed by age, ethnicity and parity and compared to that of vaginal births. Caesarean births were higher among those with no previous deliveries. Seventy seven per cent of these caesarean births were performed as emergency procedures while the remaining was elective. The main indication was for 'fetal distress' and this was followed by 'abnormal labour progress'. It is interesting to note that 'maternal requests' contributed to about three percent of all cases with another 1.2% from mothers who refused a 'trial of scar'. This significant proportion suggests that mothers are now more involved in discussions and planning of their delivery. Approximately 1.4 % of all caesarean births were complicated by post-partum haemorrhage with about 30% of these mothers having significant haemorrhage of more than 1.5litres. In conclusion Caesarean births are becoming increasingly more common. The majority of these deliveries are emergencies and have significant associated morbidity especially from that of post-partum haemorrhage.

# National Obstetric Registry – Increase In Stillbirth Rate with Increasing Maternal Age

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## SUMMARY

Stillbirth is defined as death of a fetus at any time after the 22nd week of pregnancy or birth weight of >500gm in case of unknown gestation. Stillbirth data was extracted from the National Obstetrics Registry (NOR) to determine the incidence and type of Stillbirth. This would enable us to review the data with an emphasis on epidemiological factors involved and to find an association of Stillbirth in relation to maternal age, parity and the type of Hypertension. The National Obstetrics Registry is a patient registry with inclusion criteria of women with Stillbirth deliveries at all the designated hospitals in the country. For this paper, the number of Stillbirth data was extracted from the first of July to the 31st of December 2009 and analyzed using Stata version 9.0. A total of 404 cases of stillbirth (134 FSB and 270 MSB) were noted among 73,906 deliveries during this study period. The incidence of Stillbirth was 5.47 per 1000 birth. Around 66.8% of the stillbirth were macerated (MSB) and 33.2% were fresh stillbirth (FSB). Majority of cases were noted in maternal age group 30-40yrs. (46.3% for FSB and 54.4% for MSB). Significantly higher stillbirth rate were noted among the Malay race which is 75.9% for MSB and 73.1% for FSB compared to other races. The highest percentage of MSB occurred in parity 2 (22.2%) and highest percentage of FSB occurred in parity 3 (25.4%). Twenty three out of the 134 FSB (17.2%) were cases of maternal hypertension, the majority of which (56.5%) were cases of gestational hypertension. Twenty five out of 270 MSB (13.0%) were cases of maternal hypertension, of which 71.4% were gestational hypertension. There were no significant different in the mode of delivery between FSB and MSB. In conclusion, the most common cause of stillbirth is classified as “unexplained” or “unspecified.” The risk factors that are known to be associated with unexplained stillbirth include advanced maternal age, high pre-pregnancy body mass index (BMI), smoking, and low socio-economic status. A high proportion of unexplained (or unexpected stillbirths) is related to intrauterine growth restriction. The increasing trend for women to have children later in life, and the increasing rate of obesity, may impact upon the number of stillbirths that are currently defined as unexplained. It is hope that more data from the NOR can be studied and interventions can be implemented to further reduce our stillbirth rates.

PRG14

# National Obstetric Registry - External Cephalic Version Plays an Important Role in Breech Pregnancy

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## SUMMARY

The objectives of the study were to (1) study the characteristic of breech pregnancies, types of breech and mode of delivery on outcomes breech babies after birth; (2) evaluate management of breech pregnancy outcomes and subsequently develop guidelines for improved care and; (3) facilitate research on improving maternal and fetal morbidity and mortality in breech pregnancy. The National Obstetrics Registry (NOR) is a patient registry with inclusion criteria of women undergoing all type of deliveries at one of the designated hospitals. For this paper, data was obtained from NOR for all breech deliveries in the designated hospitals. These data were analyzed using Stata version 9.0 and conclusions were derived. Breech pregnancy occurred in three percent of the total pregnancies. The majority of these cases occurred in Malay women (n=269, 72.5%). Main types of breech delivery were extended breech (n=144, 72.5%), flexed (n=53, 19.7%) and footling breech (n=52, 19.3%). The majority of breech deliveries were para zero to para three pregnancies (67.1%), becoming less frequent with increasing parity. The practice of using ECV appears to be still not widely used in the management of breech pregnancies with only 4 ECV done in 371 breech pregnancies. Significant proportions of breech were delivered prematurely 42.7% (with birth weight 500gms to 2000gm) and the others at near term to term (birth weight between 2000gms to 3000gms) in 56.3% of breech pregnancy. There was no obvious difference between the type of breech and the birth weight. Baby girls appear to be more common 52.5% to 55.1% in breech deliveries than baby boys (44.7% to 46.1%). Baby girl predominance was observed in all types of breech deliveries. All types of Breech were associated with premature deliveries (15.7% - 29.4%) and fetal distress (2.1%). Breech deliveries were associated with increased risk of fetal asphyxia (7.4% to 23.8% and meconium aspiration syndrome (16.6% to 33.3%). In conclusion Breech deliveries do impose an increased risk to baby. Practice of ECV at 36 wk – 37 wk should be more widely practiced to reduce this risk. Risk factors for premature deliveries should be actively identified and appropriately managed during antenatal care to prevent it.

# National Obstetric Registry - Vaginal Delivery is Still the 21st Century Mother's Choice

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## SUMMARY

The National Obstetrics Registry [NOR] provides a comprehensive database to track patient management and outcome. The objective of this study was to identify patient factors that influence the mode of delivery and peri-partum complications and hence to develop guidelines to improve maternal and foetal outcome. A retrospective study was carried out on NOR patients with inclusion criteria being women undergoing all type of deliveries at one of any 14 designated hospitals, over a period of six months from the first of July 2009 to the 31st of December 2009. The rate and epidemiological data (age, ethnicity and parity) of patients who underwent vaginal, instrumental and caesarean deliveries, and complications that arose was extracted and analyzed using Stata version 9.0. Of the 73 906 deliveries performed during the study period, 54 176 (73.3%) were vaginal deliveries, 2737 (3.7%) were instrumental deliveries, 16 709 (22.6%) were caesarean sections. The ratio for vaginal instrumental and caesarean deliveries was approximately the same across various age groups. The ethnic distribution of all types of deliveries was approximately 65% for Malays, 7-10% for Chinese, 4-7% in Indians and less than two percent in each the other ethnic groups. With the exception of the Chinese, the distribution would have otherwise corresponded to the population distribution in Malaysia. This could be attributed to the fact that perhaps the Chinese patients are delivered in centres that are not included in the Registry. It was also noted that whereas the ratio of vaginal to caesarean section deliveries in the major ethnic groups was approximately 3:1. The ratio for the indigenous groups in East Malaysia was approximately 5:1. There was also no significant fluctuation in the ratio of type of deliveries according to the patients' parity. The incidence of genital tract trauma was 2.79% of vaginal deliveries and 1.9% of the instrumental deliveries. The rate of primary postpartum haemorrhage was higher in the caesarean section (1.4%) and instrumental delivery (1.1%) groups than the group who underwent vaginal delivery (0.42%). Despite the progressive rise in caesarean section rates worldwide over the recent years, vaginal delivery is still the predominant mode of delivery (73.3%), followed by caesarean section (22.6%). The study shows no significant variation in the ratio of the type of deliveries according to age, ethnicity or parity. However it was noted that the indigenous patients had a higher ratio of vaginal deliveries. This could be attributed to the access to healthcare and expertise. The rate of complications such as genital tract trauma was higher in patients' who underwent vaginal delivery; however the rate of primary postpartum haemorrhage was higher in patients who underwent caesarean section. It is therefore recommended that there is better antenatal screening to identify patients who are at a risk of Intra-partum complications who might benefit from a planned caesarean section. Training of healthcare personnel to ensure Intra-partum care is optimal to ensure maternal and foetal safety.

## POSTER ABSTRACTS - BIOMEDICAL

- PBM01** A Preclinical Study of Bioengineered Limbal Epithelium
- PBM02** Characterization of Human Embryonic Stem Cells
- PBM03** Pharmacogenic Study of Carbamazepine in Epilepsy in Hospital Kuala Lumpur
- PBM04** Identification of IgE-Binding Proteins of Raw and Cooked Extracts of *Macrobrachium Rosenbergii* (Giant Freshwater Prawn)
- PBM05** Retrospective Study of Antibodies to Extractable Nuclear Antibody (ENA) in Patients Suspected with Scleroderma
- PBM06** An Automated High Performance Liquid Chromatography System for the Diagnosis of Hemoglobinopathies - A Preliminary Report
- PBM07** Multiplex ARMS PCR for the Detection of Beta-Thalassemia Mutations in the Malaysian Population
- PBM08** The Novel Adiponectin-Resistin (AR) and Insulin Resistance (IRAR) Indexes
- PBM09** Comparative Analysis of Mesenchymal Stem Cells Derived from Bone Marrow, Adipose, Dental Pulp and Wharton's Jelly for Tailor Made Choice of Stem Cells for Disease Specific Therapy
- PBM10** Proliferative Effects of *Catharanthus Roseus* Aqueous Extract on Normal Human Peripheral Blood Mononuclear Cells (PBMC)
- PBM11** Reverse Transcriptase Multiplex PCR for Detection of Viral Agents in Central Nervous System Infections
- PBM12** Effects of Combined Jumping Exercise and Honey Supplementation on Bone and Immune Function in Young Rats
- PBM13** Molecular Characterization of *Mycobacterium Tuberculosis* Targeting Antibiotic Resistance Gene
- PBM14** High Occurrence of CYP3A5 Variants Among Breast Cancer and Organ Transplant Patients
- PBM15** Genetic Polymorphism of CYP2D6 and MDR1 in Breast Cancer Patients Treated with Tamoxifen
- PBM16** Blood-Based Seven-Gene Biomarker Panel for Stratifying Current Risk of Colorectal Cancer - Validation in Malaysia
- PBM17** Putative BRCA1 Founder Mutation in a Malay Patient with Breast Cancer
- PBM18** Tumour Proliferation Index Predicts Systemic Recurrence in Nasopharyngeal Carcinoma
- PBM19** Virulence Gene Typing of Methicillin-Susceptible *Staphylococcus Aureus* (MSSA) Isolates in Universiti Kebangsaan Malaysia Medical Centre (UKMMC)
- PBM20** Species Identification of Coagulase Negative *Staphylococcus* (CoNS) Isolates in Universiti Kebangsaan Malaysia Medical Centre (UKMMC)
- PBM21** Keratin Expression in Epithelial Breast Lesions Using Tissue Microarray



# A Preclinical Study of Bioengineered Limbal Epithelium

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## SUMMARY

The limbal area of human eyes contains a population of stem cells known as limbal or corneal epithelial stem cells. Under both normal conditions as well as following injury, the maintenance of the corneal epithelial cell mass is achieved by the self renewal and differentiation of these stem cells located in the basal epithelium of limbus. In severe ocular surface diseases, such as Steven-Johnson syndrome and chemical burns, partial or total damage to the limbal stem cells have severe consequences for corneal wound healing and ocular surface integrity. This syndrome which known as limbal stem cell deficiency (LSCD) is characterized by conjunctival epithelial in growth, vascularization, chronic inflammation, recurrent erosions and persistent ulcer, destruction of the basement membrane, and fibrous tissue ingrowth leading to severe functional impairment. The most recent treatment for LSCD involves the transplantation of cultivated limbal epithelial cells (CLET). This therapeutic strategy involves ex-vivo expansion of human limbal epithelial cells on amniotic membrane or other substrates for the purpose of transplantation. Although these techniques are currently introduced into clinical practice, the question whether expanded limbal epithelial cells maintain their undifferentiated nature under culture condition still remains obscure. We studied the limbal stem cells and cultivated bioengineered ocular surface tissue for transplantation. This was done for future clinical application of cultivated limbal epithelium for patients with ocular surface disorders. In this study, a total of 35 human limbal biopsies were cultivated on denuded amniotic membranes in duplicate. Cells growth and morphology were observed under inverted phase contrast microscope. After three weeks of culture, the bioengineered limbal epitheliums were paraffin embedded and sectioned for immunohistochemistry study. Real time polymerase chain reaction (RT-PCR) was conducted to study the gene expression of a panel of specific markers for limbal stem cells and corneal epithelial. Cultivated limbal epitheliums were also analyzed by scanning (SEM) and transmission (TEM) electron microscopy. Sterility tests and mycoplasma assays were also conducted to ensure the safety of products. Successful cultures were generated from all the limbal biopsies. Our results showed that a confluent layer of polygonal cells was formed in two weeks and one to three stratified layers of cells were observed after three weeks of culture. Cultivated cells were positive for p63, cytokeratins (K) 3, K19, and involucrin but negative for K14, integrin  $\alpha 9$  and ABCG2 when analyzed by immunohistochemistry. Expression of molecular markers was detectable with real-time RT-PCR. SEM showed multilayer of flat squamous polygonal epithelial cells. Desmosomal and hemidesmosomal were evident when analyzed by TEM. Majority of the cultures (91.4%) are free from microorganism contamination. Mycoplasma contamination was not detected from the cultures. The bioengineered ocular surface tissue was successfully generated in this study. Our study showed that cultivated limbal epithelium consists of a mix population of limbal progenitors as well as differentiated corneal epithelial cells. The cultivated cells demonstrated typical features of corneal epithelium as observed from the SEM and TEM analysis.

# Characterization of Human Embryonic Stem Cells

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## SUMMARY

Embryonic stem cells (hES) are derived from embryos and can proliferate indefinitely, maintain an undifferentiated pluripotent state and differentiate into any cell type. Since hES are pluripotent, they offer the possibility of a renewable source of replacement cells and tissues to treat diseases and disabilities. For example, they may provide healthy new skin for burn victims; provide new pancreas cells for diabetics; replace damaged cardiac muscle cells and arteries for heart disease victims; and replace nerve cells for conditions like Alzheimer's disease. Human ES are also immunologically incompatible, so it has been proposed that it could also be used for therapeutic cloning. The BG01 human embryonic stem cell line was established and characterized in 2001 and is listed on the NIH Stem Cell Registry. This cell line reveals normal 46, XY chromosomal complement, maintains in culture from frozen storage and exhibits a passage time of five to seven days. We are using the BG01 hES cells to elucidate a characterization scheme for the following properties; (1) stability (karyotype) and (2) maintenance of the undifferentiated state (antibody staining). It is the aim of our study to culture and maintain the BG01 hES cells and characterized the hESCs for the expression of pluripotent markers of hESC-specific as well as marker for signal transducers of TGF $\alpha$  superfamily signaling pathway that is required for maintaining hESC identity; typically morphological characteristics; the expression of alkaline phosphatase, extended proliferative capacity and maintenance of a stable male karyotype after long-term cultivation. In-vitro propagation of BG01 hES cells were conducted in culture dishes containing mouse embryonic fibroblasts. Cells were cultured in DMEM/F12, supplemented with FBS or knockout serum replacement, L-glutamine, nonessential amino acids, b-mercaptoethanol, penicillin/streptomycin, and bFGF at 37°C, 5% CO $_2$ . Colony formation was visible within two to three days. The colonies were passaged using collagenase type IV every four to five days. The embryoid bodies were transferred to an adherent culture system in serum-free medium. The karyotype analysis was performed using a standard G-banding technique; alternatively FISH analysis was done on metaphase spreads and interphase nuclei. Immunocytochemical staining for the following specific embryonic markers was conducted: NANOG, Brachyury, OCT3/4, GATA4, SOX2, SMA, MAP2, Nestin, SSEA1, SSEA4, Tra-1-81 and Troponin. Fluorochrome tagged 2 $^{\circ}$  antibodies detecting the 1 $^{\circ}$  antibodies bounded to an epitope on the molecule were visualized using a fluorescence microscope. The visual assessment of the embryoid bodies displays the appearance and growth patterns typical for embryonic stem cells. Its karyotype 46, XY verifies the stability of the cells after the derivation process or long-term growth in culture. BG01 cells express the protein markers of undifferentiated hESC: NANOG, OCT3/4, SSEA4, and Tra-1-81, and negative for early differentiation markers: Brachyury, GATA4, SOX2, SSEA1, SMA, MAP2, Nestin and Troponin. But the differentiating cells derived from the embryoid bodies expressed Nestin and SOX2, markers of neural progenitor cells. BG01 is stable at the level of resolution provided by G-banding and the undifferentiated state of the cells exhibited by immunostaining. The adoption of qPCR, transfection and FACs analysis for a comprehensive characterization scheme for hESC will improve the reliability of the cell line and related scientific results; and will provide in vitro model for genetic studies on cell proliferation and differentiation. Directed differentiation of hESCs toward a homogenous population of a specific cell type is prerequisite for their unlimited application in regenerative medicine.

# Pharmacogenomic Study of Carbamazepine in Epilepsy in Hospital Kuala Lumpur

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## SUMMARY

An epileptic seizure arises from abnormal and sustained discharge from a group of neurons which leads to a persistent increase in neuronal excitability. Fifty percent of cases are idiopathic. The rest are caused by trauma, hypoxia, tumors, infection, metabolic derangement, disorders of and neuronal migration. Three mechanisms involved in the pathogenesis are excitability, interictal-ictal transition and the neurochemical mechanism. Carbamazepine inhibits the voltage-gated sodium channels of thalamic neurons thereby reducing electrical impulse transmission. The variability in dose response or resistance to carbamazepine is related to the differences in the target site of action, drug transport and in drug metabolism which are known to be influenced by genetic factors. Single Nucleotide Polymorphisms (SNPs) in two genes, namely the ABCB1 and the CYP2C9 genes are being studied to find associations with treatment outcome. This study aims to determine the role of carbamazepine as a single drug therapy in epileptic patients in HKL and its association to single nucleotide polymorphism of two principle genes, namely, ABCB1 and CYP2C9. One hundred and twenty patients (equal number of Responders and Non Responders) were recruited from the Neurology Department, Hospital Kuala Lumpur. Blood samples were collected and DNA extracted using the Qiagen DNA extraction kit. Real-time PCR was done to detect 5 SNPs namely, Cyp2C9\*2, Cyp2C9\*3, C3435T, G2677A, G2677T. The findings showed that only two out of the five SNPs were significant. They were the G2677A and C3435T SNPs of the ABCB1 (transporter) gene. The Responders to carbamazepine showed the mutation/C3435T SNP while the Non-Responders were wild type (did not exhibit the mutation). The Non-Responders to carbamazepine showed the mutation/ G2677A SNP while the Responders were wild type. All the patients did not exhibit the SNPs, G2677T and Cyp2C9\*3. However all the patients were heterozygous for SNP Cyp2C9\*2. The results obtained concludes that the C3435T SNP was associated with Good Patient Response to carbamazepine while the G2677A SNP was associated with Poor Patient Response to carbamazepine.

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PBM04

# Identification of IgE-Binding Proteins of Raw and Cooked Extracts of *Macrobrachium rosenbergii* (Giant Freshwater Prawn)

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## SUMMARY

Prawn is one of the most common causes of IgE mediated shellfish allergy. To date, several major allergens of prawn have been identified. These include tropomyosin, arginine kinase, sarcoplasmic calcium-binding protein (SCP) and myosin light chain (MLC). For many years, reports on the identification of prawn allergens were limited to the family Penaeidae (seawater prawn). There are very few reports on allergen in *Macrobrachium rosenbergii* which is also known as the giant freshwater prawn. The aim of this study was to characterize the IgE-binding proteins of *Macrobrachium rosenbergii*. Raw and cooked extracts of the prawn were prepared. Protein profiles and IgE-reacting allergens were then detected using sodium dodecyl sulfate-polyacrylamide gel electrophoresis (SDS-PAGE) followed by immunoblotting with sera from 20 skin prick test (SPT) positive. SDS-PAGE of the raw extract showed 23 protein bands (15-250 kDa) but those ranging from 40 to 100 kDa were not found in the cooked extract. From immunoblotting experiments, raw and cooked extracts demonstrated 11 and 5 IgE-binding proteins respectively, with a molecular mass of between 15 to 155 kDa. A heat-resistant 36 kDa protein, corresponding to prawn tropomyosin, was identified as the major allergen of both extracts. In addition, a 42 kDa heat-sensitive protein believed to be arginine kinase was shown to be a major allergen of the raw extract. Our findings indicate that the allergen extract used for diagnosis of freshwater prawn allergy contains both the 36 kDa and 42 kDa proteins.

# Retrospective Study of Antibodies to Extractable Nuclear Antibody (ENA) in Patients Suspected With Scleroderma

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## SUMMARY

Scleroderma is a connective tissue disease (CTD) that involves changes in the skin, blood vessels, muscles and internal organs. Disease course, severity, and organ involvement vary from patient to patient, and overlap syndromes with other autoimmune conditions can occur. Antibodies to extractable nuclear antigens (ENA) are of use in the classification of clinical subsets of CTD and assist in prognostic information. ENA antibodies profile includes anti-SM, anti-RNP, anti SS-A (Ro), anti-SS-B (La), anti-Jo-1 and anti Scl-70(anti-topoisomerase I). Other antibodies classically associated with other autoimmune disease such as antiphospholipid, antineutrophil cytoplasmic and antimitochondrial antibodies, also have been described in patients with scleroderma. The aim of the study was to investigate the frequency of various autoantibodies in ENA profile (anti-SM, anti-RNP, anti SS-A (Ro), anti-SS-B (La), anti-Jo-1 and anti Scl-70 (anti-topoisomerase I) in patients suspected with scleroderma. In this retrospective study, laboratory records of 137 patients from 2007 to 2009 suspected with scleroderma were collected and reviewed. Of all 137 samples, 94.2% were positive and 5.8% were negative in ENA screening. Of the positive samples, 72.3% were found to be positive for anti-Scl, 43.8% for anti-Ro, 24.8% for anti-RNP, 8.0% for anti-La, 7.3% for anti-SM and 1.5% for anti-Jo. around 88.3% of all patients were female. In this study, anti Scl-70 antibodies showed highly associated with scleroderma.

# An Automated High Performance Liquid Chromatography System for the Diagnosis of Hemoglobinopathies - A Preliminary Report

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## SUMMARY

The hemoglobinopathies can be subdivided into the thalassemias and structurally abnormal hemoglobins (Hbs). The alpha and beta thalassemias are characterized by the reduction or absence of the synthesis of the alpha and beta chain respectively. Most of the abnormal structural Hb variants and thalassemias in the carrier status show no clinical symptoms. The methods for the diagnosis of hemoglobinopathies include red cell indices and morphology, Hb separation, and quantitation of Hb fractions. Screening for Hb variants may be performed by cellulose acetate electrophoresis, isoelectric focusing, high performance liquid chromatography (HPLC), and capillary electrophoresis. The objectives of the study were to use a fully automated HPLC system, (Variant IITM, Bio Rad Laboratories) to monitor storage changes of blood samples for hemoglobin analysis and show that the system can detect the various types of abnormal Hbs such as HbE, Hb Barts, Hb Constant Spring, HbS, etc. This study was carried out because the Variant II would be used for routine diagnosis of hemoglobinopathies in our Hemoglobinopathy Laboratory and blood samples received by our Laboratory also comes from East Malaysia. It takes about a week for these samples to arrive at our laboratory. The Variant II can be used to separate and determine area percentages for hemoglobin A2 and F, and to provide qualitative determinations of abnormal hemoglobins. It utilizes the principles of ion-exchange HPLC. Common Hb variants such as HbD, HbS, HbC and HbE can be identified by their retention time windows, such as a D-Window, S-Window, and C-Window. HbE elutes within the HbA2 retention time. About 1.5 – 2.0 ml of peripheral blood was collected in a vacutainer containing potassium EDTA. Hemoglobin analysis was performed on the blood samples using the Variant II. Peripheral blood samples from 20 individuals: 13 normal, 4 HbE trait, one HbE/HbS, and two beta thalassemia trait were kept at 4°C. Hb analysis of these samples was carried out on days 0, 1, 2, 3, 4, 7, and 8 to determine storage effects. Hb analysis was also performed on 32 peripheral blood samples: 12 beta thalassemia trait, 10 HbE trait, four HbE-beta thalassemia, two homozygous HbE, three HbH disease, one HbH with Constant Spring to verify that the variant II is able to detect these Hb variants. There was no significant change in the levels of HbF, HbA2 and HbE during storage at 4°C for 8 days. However, there was a slight decrease in the levels of HbA2 and HbE on day 7 and day 3 respectively. Partial lysis was observed in some of the samples on day 4. The Variant II was able to identify all the Hb variants from the 32 blood samples accurately. The Variant II can separate and measure the common Hb fractions. It can also be used to analyse samples that are about a week old.

# Multiplex ARMS PCR for the Detection of Beta-Thalassemia Mutations in the Malaysian Population

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## SUMMARY

Due to the heterogeneity of  $\beta$ -thalassemia and multi-ethnicity of Malaysians, molecular diagnostics can be costly and time consuming. To establish a cost effective molecular detection of  $\beta$ -thalassemia in Malaysia, we developed six sets of multiplex amplification refractory mutation system (Multiplex ARMS) to detect 22 beta thalassemia/globin gene mutations. Out of 140 carriers tested with the multiplex ARMS, Cd 41/42 (-TCTT), Cd 26 (A-G), -28 (A-G), IVS 1-1 (G-T), and IVS 1-5 (G-C) were the most common mutations accounting for 87.8% among Malaysian. Among Malays, Cd 26 (A-G), IVS 1-1 (G-T), and IVS 1-5 (G-C) were the most common mutations accounting for 70%, whereas Cd 41/42 (-TCTT), IVS2-654 (C-T), and -28 (A-G) mutations were very common in Chinese (95%). We propose the use of these multiplex ARMS for molecular diagnostics of  $\beta$ -thalassemia among Malaysians.

PBM08

# The Novel Adiponectin-Resistin (AR) and Insulin Resistance (IRAR) Indexes

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## SUMMARY

Serum hypoadiponectinemia and hyperresistinemia independently links insulin resistance (IR) to type 2 diabetes (T2DM) and metabolic syndrome (MS) which eventually increased the risk of cardiovascular disease. The aim of this study was to propose a novel adiponectin-resistin (AR) index by unifying the effect of adiponectin and resistin. Then, a novel insulin resistance (IRAR) index was proposed by taking into account the AR index. Serum adiponectin and resistin levels were determined in 208 controls, 427 T2DM (171 without MS, 256 with MS), and 430 MS (174 without T2DM, 256 with T2DM) Malaysian male subjects with ages 40-70 years old. MS subjects defined according to International Diabetes Federation (IDF) 2005 diagnostic criteria. Experimental results showed the AR index was stronger correlated with insulin resistance indexes and risk factors particularly serum insulin, plasma glucose, and whole blood HbA1C levels rather than serum adiponectin and resistin levels alone. Besides, the AR index showed stronger association (df=5; F=51.917; P=3.90x10<sup>-50</sup>) with type 2 diabetes and metabolic syndrome susceptibility rather than serum adiponectin (df=5; F=15.680; P=4.16x10<sup>-15</sup>) and resistin (df=5; F=40.648; P=1.55x10<sup>-39</sup>) levels alone. Meanwhile, the IRAR index showed insulin resistance was strongly associated (df=5; F=78.396; P=6.03x10<sup>-74</sup>) with type 2 diabetes and metabolic syndrome. The AR index was stronger in linking insulin resistance with type 2 diabetes and metabolic syndrome rather than serum adiponectin and resistin levels alone. The IRAR index is a potent useful index of insulin sensitivity in subjects with type 2 diabetes and metabolic syndrome.

# Comparative Analysis of Mesenchymal Stem Cells Derived from Bone Marrow, Adipose, Dental Pulp and Wharton`s Jelly for Tailor Made Choice of Stem Cells for Disease Specific Therapy

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## SUMMARY

The success of cell replacement therapy depends on the ability of mesenchymal stem cells (MSCs) to stimulate endogenous pool of organ resident stem cells and generation of an adequate number of cells for therapy. However, lack of understanding of the nature and characteristics of these cells such as the differentiation potential usually end up in treatment failure. Thus, an understanding of their instinctive behavior is fundamental for development of successful cell-based therapies. In this investigation, we compared the characteristic of MSCs isolated from bone marrow (BM-MSCs), adipose tissue (AD-SCs), dental pulp (DPSCs) and Wharton`s Jelly (WJ-MSCs) to elucidate their inherent proliferation and differentiation potential. We characterized these cells in terms of their morphology, DNA content, population doubling time and antigen surface markers. We have found that cells from WJ-MSCs and DPSCs proliferate much better than BM-MSCs and ADSCs. All cells were also able to differentiate into osteogenic, chondrogenic and adipogenic lineages. Next, we checked their pluripotent markers through pluripotent gene array study. We observed that many pluripotent markers (OCT4, SOX2, LIN28, and NANOG) were retained and conserved in WJ-MSCs as compared to BM-MSCs, DPSCs and ADSCs. Higher gene expression of endoderm markers such as GATA6, GATA4, and SOX17 were also seen in cells from WJ-MSCs as compared to the rest of the cells. Surprisingly, DP-MSCs showed higher expression in neuron/ectoderm (NESTIN, PAX6,  $\beta$ III-TUBULIN, NF, TH, GFAP, NUUR1) markers. We also found that both bone marrow and adipose tissue derived MSCs expressed most of the tri-lineage markers making them attractive candidates for stem cell therapy. On the other hand, DPSCs and WJ-MSCs are more prone towards ectoderm and endoderm respectively. In conclusion, our study revealed that although all these cells have similar characteristics which made them to clustered as mesenchymal stem cells; they expressed inherent characterization which clearly offers a choice of selection of stem cells in the treatment of specific disease.

# Proliferative Effects of Catharanthus Roseus Aqueous Extract on Normal Human Peripheral Blood Mononuclear Cells (PBMC)

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## SUMMARY

The application of herbal plants has flourished due its natural properties, increased efficiency and the concerns about the side effects of conventional medicine. One of the herbal remedies that are commonly used to treat various diseases is *Catharanthus roseus* G. Don (Apocynaceae). However, there have not been many studies reported on its immunomodulatory effect. This study was conducted to evaluate the chromatogram profile of the standardized aqueous extract by high performance liquid chromatography and to study its effect towards the normal human peripheral blood mononuclear cells (PBMC). The isolated PBMCs were stimulated with various concentrations of *C.roseus* aqueous extract at 10,500 and 1000  $\mu$ g/ml and incubated for 24, 48 and 72 hours. The immunomodulatory activity of PBMC was studied by immunophenotyping using a panel of double staining monoclonal antibodies for CD3/CD4, CD3/CD8 and CD3/CD19 and analyzed by flow cytometry. The correlation between the B cells proliferation and immunoglobulin production was further studied by measuring quantitatively level of IgG, IgA and IgM in isolated plasma from the treated whole blood. Furthermore, the concentration of C3 and C4 were also evaluated. The concentration of immunoglobulins and complements were determined by using biochemistry analyzer. The possible alkaloid compounds were detected by the comparison of the UV spectra for each peak with previous studies done by Tikhomiroff and Jolicoeur 2002. Our findings identified four of the representative peaks as catharanthine, vinblastine, serpentine and vindoline while others are unknown compounds and will be further investigated. We found that this aqueous extract at 500 and 1000  $\mu$ g/ml have induced the proliferation of T-helper (CD4+), followed by T-cytotoxic (CD8+) and B-cells (CD19+). The growth pattern showed the highest proliferation was at 48 hours of incubation. The increase level of B-lymphocytes was correlated with the increase level of immunoglobulins especially IgG. The results from this study indicate that aqueous extract of *C. roseus* may have immunomodulatory properties. Since the aqueous extract of *C.roseus* can mediate the proliferation of the immune cells, our results suggest that the extract may potentially provide useful applications in management of immunosuppressive diseases.

# Reverse Transcriptase Multiplex PCR for Detection of Viral Agents in Central Nervous System Infections

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## SUMMARY

Viral infections of the central nervous system (CNS) may result in clinical syndromes like aseptic meningitis, encephalitis, and myelitis. These are often difficult to diagnose using conventional laboratory methods, such as viral culture and serology, because they are time consuming and unsatisfactory. Therefore rapid techniques should be employed to detect the etiologic agent. The study was aimed to standardize reverse transcriptase (RT) multiplex PCR aimed to detect viral etiology in CNS infections. An RT multiplex PCR designed to detect, viral etiologies, enterovirus, herpes simplex and varicella zoster viruses in CNS infections has been standardized. Three sets of primers were been employed for their detection. Amplification of target sequences was qualitatively analyzed by looking for the presence or absence of amplicons on agarose gel. The RT multiplex PCR was standardized. Sensitivity of the PCR has been ascertained. Analysis of cerebrospinal fluid samples from pediatric patients is underway. The RT multiplex PCR standardized can be employed to detect infections caused by herpes, varicella and entero viruses.

# Effects of Combined Jumping Exercise and Honey Supplementation on Bone and Immune Function in Young Rats

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## SUMMARY

Physical activity is believed to have close relationship with bone and immune function. To date, the combination effects of jumping exercise with honey supplementation on bone and immune function have not been determined. Thus, this study was carried out to investigate the effects of jumping exercise and honey supplementation on bone and immune function. Forty 12-week old Sprague Dawley female rats were divided into four groups: control group (C), honey group (H), jumping group (J), and combined jumping and honey group (JH). Jumping exercise consisted of 40 jumps/day for five days/week at a height of 40 cm. Honey was given to the rats at a dosage of 1g/kg body weight/rat/day via force feeding for seven days/week. After eight weeks of experimental period, rats were sacrificed in order to measure the right hind leg tibial and femoral maximal load (bone strength), blood was collected to measure the concentrations of alkaline phosphatase (ALP) and C-terminal telopeptide of type 1 collagen (1CTP)(bone metabolic markers), red blood cell, haemoglobin, white blood cell, monocytes and basophil (immune function parameters). Statistical analysis was performed using one-way ANOVA and LSD post-hoc test. Tibial and femoral maximal load were significantly ( $p < 0.05$ ) increased in combined jumping exercise and honey supplementation group. These findings were along with significantly ( $p < 0.05$ ) reduction in serum 1CTP (bone resorption marker) in JH group. Combination of jumping exercise and honey supplementation significantly increased the red blood cell level, but not the immune function parameters. The results of the present study suggest that a combination of jumping exercise and honey supplementation elicited discernable beneficial effects on tibia and femur bone strength, and reduction in bone resorption marker when compared to jumping exercise or honey supplementation alone in young female rats. However, significant changes in immune function parameters were not observed in the present study. Further study is warranted to confirm the findings of the present study.

# Molecular Characterization of Mycobacterium Tuberculosis Targeting Antibiotic Resistance Gene

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## SUMMARY

Tuberculosis is an airborne infectious disease caused by pathogenic bacteria species called Mycobacterium tuberculosis Complex. According to the Ministry of Health Malaysia, in 2008, the incidence rate of tuberculosis per 100,000 populations is 63.10 with the mortality rate of 5.49. This number supports the statement that there has been a steady increase in the number of TB notifications for the past 10 years. This may be due to immunosuppressive diseases such as HIV/AIDS and emergence of the Multidrug resistance (MDR) strain of Mycobacterium tuberculosis. MDR-TB is defined as resistance to at least rifampicin (RIF) and isoniazid (INH), with or without resistance to other drugs. Genetic studies have shown that resistance to antimicrobial drugs is the consequence of spontaneous mutations in genes that encode either the target of the drug or enzymes that are involved in drug activation. Resistance to the first line drugs have been linked with mutation in at least 10 genes. According to previous studies, there is a high correlation between mutations in *rpoB* and *pncA* with phenotypic drug resistance. Thus, *rpoB* and *pncA* are important components for drug resistance analysis in Mycobacterium tuberculosis. The purpose of this study is to determine the specific mutation of the M. tuberculosis Complex isolated from human specimens by utilizing DNA-based sequencing as well as to associate mutation profile with demographic data and determine frequency and type of occurring mutation. Thirty-two clinical isolates of Mycobacterium tuberculosis were obtained from the Institute of Respiratory Medicine, Kuala Lumpur. Two-temperature polymerase chain reaction (PCR) utilizing two sets of primers were applied for amplifying *rpoB* and *pncA* gene. The band of interest from gel electrophoresis was excised and purified before subjected to DNA sequencing. The DNA sequencing data were compared to reference sequence of *pncA* and *rpoB* to check if there were any mutation. Subsequently, the mutations data will be correlated with the isolates drug susceptibility data. A total of four isolates were detected with six different *rpoB* mutations. These were (1) deletion G at codon 2 ;(2) deletion C at codon 11; (3) deletion A at codon 12; (4) nucleotide substitution T→A at codon 15; (5) nucleotide substitution G→A at codon 16 ; and (6) deletion TAG at codon 45-47. As for *pncA*, 5 different mutations have been detected in 3 isolates. The types of mutations detected were nucleotide substitution T→C at codon 54, C→A at codon 55, G→A at codon 58 and insertion A at codon 56.

PBM14

# High Occurrence of CYP3A5 Variants Among Breast Cancer and Organ Transplant Patients

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## SUMMARY

CYP3A5 is an important drug metabolising enzyme and its polymorphism shows marked differences in protein expression and catalytic activities between different geographical ethnic groups. Both tamoxifen and tacrolimus are substrates of CYP3A5 and thus the polymorphism may cause pharmacokinetics variation which explains the wide variation in the dose requirement and patients' responses. CYP3A5\*3 (A22893G) allele resulted in a truncated protein with loss of CYP3A5 expression whilst the CYP3A5\*6 (G 30597A) allele caused deletion of exon 6 from the splice variant and was associated with lower CYP3A5 catalytic activity. Both of these polymorphisms lead to the inability of an individual to express full functional CYP3A5. This study aimed to determine the frequency of CYP3A5 haplotypes among healthy volunteers, breast cancer and kidney transplant patients in selected hospitals. Twelve breast cancer patients (tamoxifen therapy), six organ transplant patients (tacrolimus therapy) and 264 healthy blood donors (98 Malay and Chinese; 74 Indian) that met fit the requirement criteria were recruited after obtaining informed consent. 5ml of blood was drawn from each patient DNA extracted for genotyping of CYP3A5 variants. Multiple PCR were designed with novel primers specific to 3' end that amplify the variants of A6986G and G14690A. The optimized method was validated by direct sequencing.

# Genetic Polymorphism of CYP2D6 and MDR1 in Breast Cancer Patients Treated With Tamoxifen

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## SUMMARY

Tamoxifen is the drug of choice for the treatment of estrogen-positive breast cancer patients. It is metabolized by cytochrome P450 2D6 (CYP2D6) and the variations in CYP2D6 activity has been reported to have important therapeutic consequences which include development of adverse events or therapeutic failure in susceptible individuals. Tamoxifen is known to inhibit P-glycoprotein while active metabolite of this drug activates the expression of MDR1 in MCF-7 cells. This affects the intracellular concentrations tamoxifen and its active metabolites inside the tumour cells. Understanding the impact of this variability is useful to determine the choice and monitor response to therapy. Genotyping methods for CYP2D6 and MDR1 were developed using multiplex allele specific PCR (ASPCR) approach. Selected samples were randomly sent for direct sequencing for validation of the ASPCR results. Twenty breast cancer patients were screened for CYP2D6 (CYP2D6\*4, CYP2D6\*10, CYP2D6\*14) and MDR1 (G2677A/T, C3435T and C1236T). CYP2D6\*4 and CYP2D6\*14 were absent in patients. The most common variants detected were CYP2D6\*10 with 25% of homozygous CYP2D6\*10/\*10 and 45% heterozygous CYP2D6\*1/\*10 in breast cancer patients. Heterozygous C3435T was present at the highest frequency at 60%. G2677A/T and C1236T was found in 44.4% and 50% of the 18 samples successfully amplified. More than half the patients carry CYP2D6\*10 and MDR1 variants which reduce the metabolic activity and expression of the efflux transporter. However, the clinical implications of the variation in dose adjustment and therapeutic effect require further confirmation from the ongoing study with a larger sample size.

# Blood-Based Seven-Gene Biomarker Panel for Stratifying Current Risk of Colorectal Cancer - Validation in Malaysia

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## SUMMARY

Colorectal cancer (CRC) is the second most common cause of cancer mortality worldwide, with an incidence of approximately one million cases per year and more than 500,000 deaths. Although CRC has long been considered a western world disease, this perception is changing. In several Asian countries including Malaysia, colorectal cancer has been increasing to levels comparable to North America and Europe. CRC is now commoner than lung cancer and is the most common cancer in men and the second most common cancer in women. Screening is key to prevention and mortality reduction, but patient adherence to faecal testing and endoscopy is low. We have previously reported our patient-friendly blood-based test for colorectal cancer current risk stratification (Marshall KW, Mohr S, El Khebbabi F, Nossova N, Chao S, Bao W, et al. Blood-based biomarker panel for stratifying current risk for colorectal cancer. *Internat J Cancer* 2010;126:1177-86). The test utilizes a seven-gene panel of biomarkers which was validated using blood samples collected from North American patients who have a moderate risk for colorectal cancer. This study, evaluated this seven-gene biomarker panel in blood samples collected from patients in Malaysia. Blood samples were collected from 216 patients (105 colorectal cancer and 111 controls) meeting defined inclusion and exclusion criteria and matched for gender and age. Total blood RNA was isolated for the CRC biomarker expression study and data analysis. The test employs quantitative RT-PCR (qRT-PCR) to analyze gene expression of seven biomarkers (ANXA3, CLEC4D, TNFAIP6, LMNB1, PRRG4, VNN1 and IL2RB which served as the duplex partner or reference gene) that are differentially expressed in patients with colorectal cancer as compared with controls. Differential gene expression between colorectal cancer and controls was estimated using the "comparative cycle threshold ( $\Delta Ct$ )" method of relative quantification. All six biomarkers were significantly up-regulated in colorectal cancer as compared with the control samples. The data were evaluated using the Mann-Whitney independent sample rank sum tests and the results were highly significant ( $p < 0.001$ ). Logistic regression performance characteristics at the optimum cut-off value yielded a specificity of 76%, sensitivity of 64% and accuracy of 70%. The area under the receiving operating characteristic curve was 0.75 (95% confidence interval: 0.69 to 0.81). These results are comparable to data obtained from the North American samples. Our results confirmed and validated the study previously conducted in North America and demonstrate the performance of the seven-gene biomarker panel in discriminating between colorectal cancer and control blood samples in Malaysia.



# Putative BRCA1 Founder Mutation in a Malay Patient With Breast Cancer

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## SUMMARY

Based on the 2006 Malaysian National Cancer Registry, breast cancer is the most common cancer affecting women across all major ethnic groups in Peninsular Malaysia. Despite the fact that Malays are the major ethnic group in Malaysia, the age-standardized incidence (ASR) in the Malays is lower than in Chinese and Indians. Genetic components contributing to breast cancer in Malays have not been well-described. The aim of this study was to determine the BRCA1 and BRCA2 mutations in Malay women with breast cancer. A cohort of 152 Malay breast cancer patients were identified from three main breast cancer referral hospitals; PPUKM, HKL and HPJ but only 42 patients who fulfilled the criteria for high-risk breast cancer were recruited for this study. Written informed consent was obtained from all the patients. Ten milliliters of peripheral blood was taken from each of the patients. Mutational analysis for all coding regions and intron-exon junctions of the BRCA1 and BRCA2 gene was performed using direct DNA sequencing. The analysis revealed the presence of 21 BRCA1 and 27 BRCA2 genetic variants, of which 20 are novel (10 BRCA1 and 10 BRCA2). Twenty-one genetic variants of the BRCA1 gene consist of three deleterious mutations, four unclassified variants and 14 polymorphisms. Of 27 BRCA2 genetic variants, one is a deleterious mutation, six unclassified variants and 20 polymorphisms. All of the deleterious mutations (BRCA1: 2845insA, E402X and 5118A>T; BRCA2: 5301insA) have been reported previously; of which one (2845insA) has been described as a founder mutation among Singaporean Malays with breast cancer. The prevalence of BRCA1 and BRCA2 mutations in this study is 7.1% (3/42) and 2.4% (1/42) respectively. In conclusion, our results showed that the prevalence of BRCA1/2 mutations are similar with other studies, however, the spectrum of BRCA1 mutations in this study is distinct from that reported in Caucasians. Further investigations of the putative BRCA1 founder mutation (2845insA) in a larger cohort are important to clarify the distribution and possible founder effect of this mutation in breast cancer patients of Malay ethnic background.

# Tumour Proliferation Index Predicts Systemic Recurrence in Nasopharyngeal Carcinoma

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## SUMMARY

Nasopharyngeal carcinoma (NPC) is the second most common cancer among men in Malaysia. It is a tumour that frequently present at an advanced stage. However, the behaviour of this tumour remains an enigma and its pathogenesis continues to be poorly understood. Factors such as tumour stage, Epstein-Barr virus DNA load and Interleukin IL-8 receptor expression have been implicated to influence its clinical outcome. Cell proliferation is another parameter that has been suggested that could potentially modify tumour behaviour. Nevertheless results concerning its prognostic value remain equivocal. The objective of this study was to investigate the relationship between cell proliferation index, as indicated by Ki67 protein expression, and the clinicopathological features in NPC. This is a descriptive cross-sectional study using archival tissue samples from 88 cases of NPC. At least 6 months post-treatment follow-up data were available in 60 patients. Immunohistochemistry was used to study the proliferation marker Ki67 protein expression. The proliferation index was scored as low (< 30% of nuclei Ki67-positive) or high (> 30% of nuclei positive). Epstein-Barr virus encoded RNA (EBER) was detected by in situ hybridisation. Among the clinical findings, 70 patients were male and 18 were female. Six patients (6.8%) were in stage I, 15 (17.0%) in stage II, 29 (33.0%) in stage III and 38 (43.2%) in stage IV. Twenty-two of 60 (37%) patients developed tumour recurrence at least six months after completion of treatment. Of these, 9/60 (15%) patients developed local recurrence and 11/60 (18%) developed systemic recurrence and 2/60 (3%) developed both local and systemic recurrence. Immunohistochemistry for Ki67 showed that the proliferation index was high in 59/88 (67%) cases and low in 29/88 (33%) cases. Of interest is our result on the relationship between Ki67 expression and the status of tumour recurrence which showed a general trend towards tumour recurrence in cases with low proliferation index. 11/13 (85%) cases with systemic recurrence showed low Ki67 expression. In contrast, only 13/47 (22%) cases without recurrence had low Ki67 expression. A significant correlation was found between NPCs with low proliferation index and those with systemic recurrence ( $p < 0.05$ ). However there was no significant correlation between proliferation index and other clinicopathological parameters including tumour histology type, status of EBV infection and tumour stage. Our results suggested that tumours with low proliferation index have a tendency toward systemic recurrence. One explanation is that these tumours have a large subpopulation of cells that are not in cycle and are possibly resistant to radio- and chemotherapy. We hypothesized that, despite treatment, this subpopulation of tumour cells continue to survive and proliferate at a later stage to subsequently cause tumour reappearance.

# Virulence Gene Typing of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Isolates in Universiti Kebangsaan Malaysia Medical Centre (UKMMC)

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## SUMMARY

*Staphylococcus aureus* has long been recognized as an important pathogen in human disease. Methicillin-susceptible Staphylococcus aureus (MSSA) isolates have commonly been the subject of general surveillance studies. On the other hand, there are relatively few studies on MSSA molecular typing, even though they are often more genetically variable. The pathogenicity of MSSA has been attributed to their possession of a large number of virulence genes. The objective of this study were to determine: (i) the prevalence of MSSA in UKMMC; (ii) the prevalence of collagen binding adhesin (cna), staphylococcal enterotoxin H (seh), Panton-Valentine leukocidin (PVL) and toxic shock syndrom toxin-1 (TSST-1) genes of MSSA isolates; (iii) the association between the virulence genes (cna, seh, PVL, TSST-1) of MSSA isolates; (iv) the association between antibiogram and virulence genes of MSSA isolates. 1206 single isolates of Staphylococcus aureus were collected from January to December 2009 in UKMMC. 880 single isolates of MSSA were selected for virulence gene typing. Antibiotic susceptibility of the strains was determined using disk diffusion method and the presence of virulence genes (cna, seh, PVL, TSST-1) were investigated by multiplex PCR. The prevalence of MSSA infection in UKMMC was 72.9% (880/1206). Virulence gene typing for 730 MSSA strains has been completed. From 730 MSSA strains, 45.2% (330) have cna, 17.2% (125) possess seh, 6.2% (45) have PVL and 5.9% (43) have TSST-1. None of the above virulence genes were detected in 21.3% (187) of MSSA strains. There was no association between antibiogram and virulence gene typing. Among the four virulence genes detected in this study, the most common virulence gene found in UKMMC MSSA isolates is cna, whereas TSST-1 was the rarest gene detected.

# Species Identification of Coagulase Negative Staphylococcus (CoNS) Isolates in Universiti Kebangsaan Malaysia Medical Centre (UKMMC)

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## SUMMARY

Coagulase negative Staphylococcus (CoNS) are common colonizers of human skin but has become increasingly recognized as agents of clinically significant infections. *S. epidermidis* is the offending pathogen in bacteraemia, prosthetic valve endocarditis and prosthetic joint infections while *S. haemolyticus* is more frequently seen in septicemia, wound and bone infections. *S. saprophyticus* has also been recognized as an opportunistic pathogen in urinary tract infections. Methicillin-resistant Coagulase Negative Staphylococcus (MRCoNS) are clinically important due to their  $\beta$ -lactam resistance. *S. epidermidis* and *S. haemolyticus* are more likely to be multidrug resistant compared to other CoNS species. The objectives of this study were to determine (1) the prevalence of CoNS among staphylococcus genus; (2) the prevalence of *S. epidermidis*, *S. saprophyticus* and other CoNS species and (3) the distribution of species among the MRCoNS. Staphylococcus isolates from 2426 patients were collected from January to December 2009 in UKMMC. Antibiotic susceptibility tests were carried out using disc diffusion method and species identification was done using multiplex PCR with species specific primers. Our result showed that *S. epidermidis* is the most common species in MRCoNS and CoNS isolates in UKMMC. The prevalence of CoNS among staphylococcus genus in UKMMC was 50.3%. Among 689 CoNS strains, 86.4% were *S. epidermidis* species, 1.02% were *S. saprophyticus* species and 12.6% were non-typeable (other species). 423 MRCoNS strains have been identified and 85.3% were *S. epidermidis* species, 1.41% were *S. saprophyticus* and 13.2% were other CoNS species. *S. xylosus* species was not identified among the isolates.

# Keratin Expression in Epithelial Breast Lesions Using Tissue Microarray

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## SUMMARY

Cytokeratines (CK) constitute of at least 20 proteins which are valuable markers for studying epithelial tissue differentiation and CK expression patterns are largely retained during neoplastic transformation. CK AE1/ AE3 is defined by its broad reactivity and detects almost all other type of CKs in the lumino-basal layer of epithelium. This mixture of CK AE1/AE3 has two different clones of anti-monoclonal antibodies, AE1 and AE3 which detects the low molecular weight cytokeratin 19 and CK7 respectively. The aim of this study is to evaluate keratin AE1/AE3, CK19 and CK7 expressions in breast lesions and their correlation with clinicopathological parameters. We performed immunohistochemistry (IHC) for keratins AE1/AE3, CK19 and CK7 on tissue microarray consisting four usual ductal hyperplasia (UDH), two atypical ductal hyperplasia (ADH), 104 fibroadenomas (FA), 62 phyllodes tumours (PT), five cases of ductal carcinoma in situ (DCIS) and 64 infiltrating ductal carcinomas (IDC). Cytoplasmic immunoreactivity was divided into four groups where +1 staining represented <10% positive cells; +2, >10% and <50% positive cells; +3, >50% and <90% positive cells and +4 shows >90% positive cells. We considered +2 immunoreactivity and above as a positive staining. Expression of CK AE1/AE3 was extensively stained in 98.8% (164) luminal layers of fibroadenomas and phyllodes tumour with only 4.2% expressed in basal cells. All the UDH, ADH and DCIS cases showed +4 cytoplasmic and membrane staining for keratin AE1/AE3. Each case of ADH and DCIS showed no staining for CK19 and CK7 respectively. Expressions in IDC are 96.9% positive for AE1 / AE3, 75% for CK19 and 66.9% for CK7. Two cases of IDC showed no staining for both CK19 and CK7 and were also negative for CK AE1/AE3 ( $p<0.05$ ). Our findings showed all selected CKs were over-expressed in grade 1 IDC, and positive lymph nodes but were not statistically significant. In addition, there was no correlation between CKs expression and ER, PR and c-erbB-2. Two malignant PT and 10 benign PT showed positivity for CK AE1/AE3 and CK7, but were negative for CK19. One case of benign PT showed no staining for all CKs ( $p<0.05$ ). The expression of CK7 was statistically significant with both CK19 and CK AE1/AE3 ( $p<0.05$ ) in PT, which showed a correlation with malignancy. The expression of CK19 was not correlated with CK AE1/AE3 in PT cases but was well-correlated in IDC ( $p=0.001$ ). Monoclonal antibodies keratin AE1/AE3 immunostained all the luminal cells but scanty immunoreactivity was seen in basal cells. CKs expression showed no correlation with clinico-pathological parameters. Besides, CK19 co-expressed with CK7 in 69.7% of ductal epithelia as shown in other studies.

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# Anaesthesia Rotation for Undergraduates – A Johor Experience

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## SUMMARY

Fifth year medical students underwent a two weeks anaesthesiology posting from January to November 2009. The three main objectives of the posting were to teach the undergraduates the principles in caring for the unconscious or critically ill and ensuring airway patency and protection; the principles of resuscitating, monitoring and supporting vital organs; and the principles of caring for patients in acute pain. On day one of rotation, all of them would practise mask ventilation and intubation on manikin. This is followed by videoscope demonstration of the airway structures and live demonstration of intubation techniques in patients receiving general anaesthesia. Subsequently, they were allocated to the operating theatres where under supervision, they observed and took part in anaesthesia management as and when opportunity arose. Tutorial and bed side teaching focused on airway management, oxygen therapy, patient monitoring, peri-operative pain management, fluid and blood transfusion as well as resuscitation medication. During the posting, each student recorded all the cases he/she encountered and all the procedures he/she performed or observed on a structured log sheet. At the end of posting, the students sat for a test of 20 short essay questions (test 1). The aim of the study was to describe the degree of exposure experienced by the undergraduates and to assess their theoretical knowledge retention. The log sheets were collected and their experience analyzed. At the end of the year 5, a short essay test (test 2) where seven questions of the test 1 were repeated. The results of the test 1 and test 2 were compared to assess the knowledge retention among the undergraduates. A total of 48 year 5 medical students went through the two week anaesthesia rotation in 2009. Of these students, 39 (81.3%) of them sat for both test 1 and test 2, and the mean marks were 64.8% (SD 12.7) and 58.8 (SD 10.4) respectively. The mean difference was a drop of 6.0% (CI 2.5 – 9.6). Two students (5.1%) had improvement of ten percent or more, while 13 (33.3%) dropped ten percent or more. There were 39 log sheets collected. On average, during the 8.4 days in operation theatre, the students encountered 26.1 patients, and performed 12.3 bag mask ventilation, 10.5 intubations (7.2 successful) and 4.6 peripheral intravenous cannulations. The two week anaesthesia rotation provided good hands on experience to undergraduates. However, theoretical knowledge retention among them was disappointing.

# Acute Coronary Syndrome Secondary Prevention Pharmacotherapy - A Comparison to the First National Multi-Centre Audit

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## SUMMARY

Double Antiplatelets, Beta-Blockers (BB), HMG-CoA Reductase Inhibitors ('Statins') and Angiotensin Converting Enzyme Inhibitors/Angiotensin Receptor Blockers ('ACEI/ARBs'), have been shown to improve cardiovascular outcome in Acute Coronary Syndrome (ACS) patients. The first national multi-centre ACS audit in 2008-2009 revealed that some of these medications were prescribed to <90% of patients discharged. The objective of the study was to identify trends in medication prescribed as part of ACS secondary prevention in Ministry of Health (MoH) hospitals. Ward and pharmacy documentation of 537 ACS patients from 16 hospitals admitted with ACS between the first audit cycle (FAC: December 2008-January 2009) and second audit cycle (SAC: November 2009-December 2009) were compared. We looked at their age, gender, ethnicity, smoking status, ACS Stratum and concurrent diseases and medication given. The data was then analyzed using SPSS version 16.0. ACEI/ARB prescriptions saw the biggest increase of 4.2% with perindopril and valsartan as the most common ACE- I and ARB prescribed in both audit cycles. Aspirin was the commonest medication prescribed in both audit cycles, there was a 3.7% increase in clopidogrel prescription which also contributed to the overall 6.6% increase in ACS patients discharged with double anti-platelets. Statin prescriptions were consistently high in both audit cycles. Simvastatin has replaced lovastatin as the most common prescribed in the SAC. There was no significant change in number of patients discharged with beta-blockers. Metoprolol was still the most common type of beta blocker prescribed. There is an increasing trend in the utilization of evidence-based ACS secondary prevention pharmacotherapy in MoH hospitals. However, new strategies could be explored to increase the translation of evidence-based guidelines to direct patient care.

# Identification of Children Infected with 2009 Pandemic Influenza A (H1N1) in Government Hospitals

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## SUMMARY

The first outbreak of influenza A (H1N1) first occurred in Mexico around March 2009. Limited data is available on disease characteristics and outcomes of children with influenza A (H1N1) in temperate countries. The objective of the study was to describe morbidity and mortality of hospitalized pediatric patient with pandemic 2009 influenza A (H1N1). Clinical information was retrospectively retrieved from medical records to collect data on hospitalized patients with laboratory confirmed A (H1N1) by reverse-transcriptase polymerase chain reaction. From the 18th of June 2009 until the 16th of February 2010, a total of 1362 pediatric cases of confirmed influenza A (H1N1) infection were identified in government hospitals nationwide. Among 1362 patients, the mean (SD) age was 3.7 (1.9) years and 44.1% were female. Clinical symptoms reported were similar to those published worldwide. Clinicians should be attentive for the influenza A (H1N1) infection as it may progress to severe conditions in variety of patient demographics without any known co-morbidities. The measure of influenza A (H1N1) severity in temperate countries complement with available information which will enable exact implementation of infection control in the future.

# Malaysia Shape Of The Nation (MySoN) - A Primary Care Based Study Of Abdominal Obesity In Malaysia

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## SUMMARY

Abdominal obesity (AO), measured by waist circumference (WC), is a stronger predictor of cardiovascular disease (CVD) than generalized obesity (elevated body mass index [BMI]). This study is aimed at measuring WC and prevalence of AO among Malaysians in a primary care setting. In this multi-centre, cross-sectional, observational study, patients (18-80 years) attending primary care clinics in Malaysia were enrolled on two predefined half-days. Pregnant women were excluded. Socio-demographic data and medical history were collected. Weight, height and WC were measured. From 93 clinics, 1,893 patients (mean age: 44±14 years) were enrolled. The prevalence of co-morbid conditions were (1) four percent for CVD, 17% for lipid disorders, 26% for hypertension, 14% for diabetes, and 38% for any of the clinical characteristics of CVD/lipid disorder/hypertension/diabetes. The mean BMI for men and women was 25.62±4.73 kg/m<sup>2</sup> and 26.63±5.72 kg/m<sup>2</sup> respectively. Based on WHO criteria for BMI (overweight, 25-29.9 kg/m<sup>2</sup>; obese, >30 kg/m<sup>2</sup>), 34.2% were overweight and 20.4% were obese. The mean WC for men and women was 89.03±13.45 cm and 84.26±12.78 cm, respectively. Overall, 55.6% had AO and there was higher prevalence among women (based on International Diabetes Federation criteria: WC >90 cm for men and >80 cm for women). AO was present in approximately 71% patients with lipid disorder, in 76% with hypertension and in 75% with diabetes. Patients with AO were also at a higher risk of developing co-morbidities. In conclusion, Malaysia has a high prevalence of AO and other risk factors for cardiovascular disease. This needs to be addressed in public health programmes, which should also include routine measurements of WC.

# Incidence, Risk Factors and Clinical Epidemiology of Melioidosis - A Complex Emerging Infectious Disease in the Alor Setar Region of Kedah, Malaysia

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## SUMMARY

Melioidosis, a severe and fatal infectious disease caused by *Burkholderia pseudomallei*, is believed to be an emerging global threat but information on the natural history, risk factors and geographic distribution of infection is still limited. We undertook a retrospective analysis of 145 confirmed cases extracted from a Melioidosis Registry set up from 2005 in Alor Setar, Kedah, Malaysia, to evaluate for the first time the contemporary incidence, epidemiology and outcomes of the disease in this region. Melioidosis is shown to be a complex, fatal, environmentally-mediated socio-ecological disease in vulnerable populations in Kedah, being associated with host age and occupation, bacteremia, rainfall and predisposing chronic diseases, such as diabetes mellitus. The burden disease is likely to grow in this region unless better informed interventions targeted at high-risk groups, such as rice farmers, and associated diseases that enhance susceptibility to infection or death, such as diabetes, pneumonia or abscesses, are implemented in susceptible areas.

# Control and Treatment Profiles in 20,646 Adult Diabetics

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## SUMMARY

The epidemic of type 2 diabetes mellitus continues both globally and in the country. Good glycaemic control undisputedly leads to lesser complications and health care cost in the long run. Awareness of health care providers' performance in delivering treatment of diabetes is the first step towards successful control. Thus, the Audit of Diabetes Control and Management-Diabetes Registry Malaysia (ADCM-DRM) was started and became an online real-time audit of diabetes care provided by the Ministry of Health primary health care clinics and hospitals in the country. The aim of the study was to determine the diabetes control profile in relation to its management in the initial cohort, ADCM from July to December 2008. This is a registry based study where participation was not mandatory. The inclusion criterion was all patients with diabetes aged 18 years old and above. The information was updated annually to enable the monitoring of control and progression of diseases from the baseline at notification. Demographic data, details on diabetes and treatment modalities, as well as various risk factors and diabetes complications were reported. Data was handled and analyzed by statisticians from the Clinical Research Centre, Hospital Kuala Lumpur using the Data Analysis and Statistical Software (STATA) version 9. A total of 81 centres, 6 of which were hospitals, participated in this registry as of 31st December 2008 contributing a total of 20,646 patients. Majority (89.6%) of the patients were from Negeri Sembilan followed by Selangor (9.8%). Most of the cases registered were Type 2 Diabetes Mellitus (99.2%). There were 56.8% female, Malay consisted of 56.6%, Chinese 19.5%, Indian 22.5% and other races 0.2%. The mean age was 58.0 years (SD 11.49) with 77.6% of them aged 50 years old and above. There were 82% overweight patients with body mass index (BMI)  $\geq 23$  Kg $m^{-2}$ , 42.3% of them were at least obese I (BMI  $\geq 27.5$  Kg $m^{-2}$ ). The mean age at diagnosis was 54.8 years old (SD 11.47) and the mean duration of diabetes was 4.7 years (SD 4.20). The control profile was fair with mean HbA1c of 8.0% (SD 2.10), 30.1% and 17.9% of the patients attained HbA1c  $< 7\%$  and HbA1c  $< 6.5\%$  respectively. The mean systolic blood pressure and mean diastolic blood pressure were 137.7 mmHg (SD 19.56) and 80.1 mmHg (SD 10.51) respectively. A total of 11,414 (58.6%) were still hypertensive with blood pressure (BP) more than 130/80 mmHg and of those who were under treatment, 16.1% were treated to target BP  $\leq 130/80$  mmHg. The means low density lipoprotein-cholesterol was 3.3 mmol/L (SD 1.08) with 30.3% of patients were treated to  $\leq 2.6$  mmol/L. Metformin (75.9%) was prescribed more than sulfonylurea (60.8%) while only 11% had insulin. There were 64.1% had either an ACE inhibitor or ARB followed by a beta-blocker (35.3%), and a calcium channel blocker (34.3%). There were 14.2% on more than two anti-hypertensive agents. There were 7,885 (38.2%) patients on anti-lipid agent with statin (93.7%) being the mostly prescribed agent. In these 20,646 patients, diabetes care was good but the control rates were less satisfactory with only 18% achieved HbA1c  $< 6.5\%$ . More effort and resources are needed to improve the diabetes care especially in primary care.



# Pharmacist-Managed Warfarin Clinic - A Single-Centre Experience in Operational Transformation and Performance Evaluation

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## SUMMARY

This study evaluated the performance of warfarin clinic by observing individual patients' achievement of target INR before and after the implementation of a revised clinic work flow and protocol with emphasis on collaboration between health professionals (clinicians, pharmacists & nurses). A retrospective, observational study involving all patients attending the Warfarin clinic in January 2010. Patients' data such as target INR (International Normalized Ratio), INR results for year 2009 and their review dates. Data was analyzed by comparing Period 1 (January-June 2009) to Period 2 (July-December 2009). The parameters analyzed include number of days managed in the warfarin clinic, number of days within target INR and percentage of time spent within target INR. Inclusion criteria include patients seen in both Period 1 and Period 2. Patients seen in only either one of the two periods, defaulted patients & unavailability of complete data was excluded from data analysis. Data was analyzed using Microsoft Excel statistical tool and SPSS 16.0. The total number of patients included in the study was 126 with 59 patients excluded. Clinical diagnoses include atrial fibrillation and mechanical prosthetic valves replacement. Of the 126 patients included, 80 (63.5%) patients were female with the remaining 46 (36.5%) were male patients. The mean age of patients involved was 54 years, with the youngest being 19 years and the eldest being 79 years. Findings from the study are summarized in the following table. There is an average improvement in patients' number of days spent within target INR (6.02%,  $p=0.23$ ). The overall average number of days managed in Warfarin Clinic was 286 days. The measuring parameter for the achievement of individual patients' target INR was the number of days spent within target INR. An improvement was seen from Period 1 to Period 2 (6.02%,  $p=0.23$ ). This first year result is comparable to that obtained from an overseas Anti-Coagulation Clinic setting (2.7% at Year 1). In this same overseas setting, 13.8% improvement was seen after a 5 year period. The study concluded that individual patients' target INR achievement is more adequately addressed by observing the number of days spent within target INR. This also addresses the performance of the warfarin clinic. Continuous audit is important to ensure the effectiveness of the workflow and protocol is improved, by addressing shortfalls identified at each point of audit.

# Web-Based Monitoring of Ophthalmology Key Performance Indicators at Ministry of Health Hospitals

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## SUMMARY

Monitoring clinical practice performance at Ministry of Health (MOH) facilities using key performance indicators (KPI) was launched in February of 2008. Ophthalmology service listed eight KPI to be monitored. Of the eight, three are related to cataract surgery and data required for KPI are captured in the cataract surgery registry (CSR). In 2009, the ophthalmology service launched the eKPI where data on eight KPI can be entered and processed via a web based application and the three related to cataract surgery are taken automatically from the CSR. The KPI achieved by all the participating ophthalmology departments can be viewed on line. The overall KPI based on all the 36 ophthalmology departments for the rate of post-operative infectious endophthalmitis has improved from 0.15% in 2007 to 0.10% in 2008 and 0.07% in 2009. However, the number of departments with rates higher than national standard of 0.2% has not changed significantly (eight departments in 2007, seven in 2008 and eight in 2009). As for the rate of posterior capsular rupture, the aggregate KPI for all MOH facilities has improved over the years (4.09% in 2007, 3.68% in 2008 and 3.54% in 2009). The number of departments with KPI worse than national standard of five percent has also decreased from eight in 2007 to six in 2008 and six in 2009. As for post-operative best corrected vision better than 6/12, the KPI for all departments has improved from 86.7% in 2007 to 87.5% in 2008 and 90.4% in 2009. The number of departments below the national standards of 85% was eight in 2007, 11 in 2008 and four in 2009. eKPI improves the efficiency of KPI monitoring. In addition, display of centre performance on simple charting accessible on the website allows policymakers to set bench-marking standards.

## Refractive Error Among Sarawakian School Children in Betong Division

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### SUMMARY

Refractive error is a major cause of visual impairment among Malaysian schoolchildren. The aim of this study is to determine the incidence of refractive error among school children in the rural area of Sarawak. Retrospective data of vision screening in 2008 for Betong Division were collected from optometric school health service record books, medical records and school health service database of Betong Division. The optometric findings were based on 306 school children in grade 1, grade 6 and form 3. Mean age of the children was 12.31±2.93 years. Most common vision problems found included refractive error (45.4%), amblyopia (3.6%), strabismus (0.6%) and other ocular problems (1.6%). All amblyopic and strabismic cases had uncorrected high refractive error. About 44.2% of the children were myopic (myopia range: -0.75D to -14.50D) and 1.3% were hyperopic (hypermetropia range: +1.50D to +4.50D). Mean spherical equivalent of myopia was 2.07±1.71DS and hyperopia was 1.66±1.85DS. Chi-square analysis showed that the incidence of myopia among Iban schoolchildren were significantly higher in female ( $\chi^2 = 8.886$ ,  $p = 0.003$ ). It is concluded that a high incidence of refractive error among school children in the rural area suggests a need of vision school health programmes in rural areas for more effective preventive eye care.

PCR10

## Effect of Pharmacist Interventions on Cost of Drug Therapy in Surgical Wards

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### SUMMARY

Pharmacist's role has shifted from a primary focus on medication dispensing to providing patient care. Direct involvement of a clinical pharmacist on physician rounds, drug reconciliation at admission or discharge, and medication therapy adherence clinic helps to reduce the frequency of adverse drug events and medication errors. The services provided also improve medication adherence, patients' knowledge about their medications, and medication appropriateness. The aim of this study was to determine the types of clinical pharmacist interventions in two surgical wards and to estimate the actual cost savings arising from the interventions. This was a two month prospective, cross-sectional study conducted on two surgical wards in a Malaysian government funded hospital, between the first of January and the 28th February 2009. All the interventions and therapeutic drug classes involved were documented on the standard Ministry of Health clinical pharmacy form (CP3). The results of interventions were categorized into discontinuation of, initiation of, change in drug therapy, interventions involving therapeutic duplication, the detection and avoidance of problems-related to drug therapy and the suggestion on laboratory monitoring and serum drug concentration determinations. The effect of these interventions on the costs of drug therapy was evaluated by utilizing drug acquisition costs. A total of 402 pharmacist interventions were documented during the study period and 368 interventions of these resulted in cost savings of RM 11,499.51. Intervention involving antimicrobial agents had the greatest cost savings. The common types of interventions were discontinuation of unnecessary drug therapy (30%), changes in dose regime (16.9%) and modification in route of administration (14.4%). Fifteen (3.7%) interventions resulted in the avoidance of adverse drug events (ADEs). Thus, clinical pharmacist interventions in the surgery department produced economic benefits, improved the overall patient's medication management and also support the expansion of clinical pharmacy services.

# Duration of Untreated Psychosis, Ethnicity, Educational Level and Gender in a Multi-Ethnic South-East Asian Country - Report from Schizophrenia Registry in Malaysia

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## SUMMARY

Duration of untreated psychosis (DUP) determines the outcome of schizophrenia. We do not have information about the DUP among patients in Malaysia with schizophrenia. The aim of the study was to study the association between DUP to patients' demographic, social cultural background and clinical features. This is a cross-sectional study on patients who presented with first episode schizophrenia. Data from 74 primary care centres and hospitals between the first of January 2003 and the 31st of December 2007 was included in the analysis. All patients with first-episode schizophrenia were enrolled in the study. The mean DUP was 37.6 months. The indigenous community appeared to have the shortest DUP compared to Malays, Chinese and Indians. Female, people with lower educational level and co-morbidity with medical illness during contact had longer DUP. DUP in this multi-ethnicity country was found significantly short among the indigenous people may indicate a possibility of traditional value and strong family and community ties shorten the DUP. Educational level may need to be looked into as upgrading the general educational level could lead to shorter DUP among the patients as well.

# Frequency of Skin Prick Test Reactivity to Common Fruits in Adults and Children with Rhinitis

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## SUMMARY

Allergic reactions to fruits have become increasingly common and represent a growing clinical problem. Allergy to plant-derived foods is a frequent cause of food allergy and it has been explained by cross-reactivity to pollen and grasses. Allergic rhinitis is the most common form of atopic disease in primary care practice, affecting 10% to 20% of the general population. The objective of this study is to determine the skin prick test reactivity to common fruits (watermelon, honeydew, banana and orange) in adults and children with rhinitis. Skin prick test were carried out on two hundred and fifty five allergic rhinitis patients using commercialized allergens for orange and banana and in-house extracts of watermelon and honeydew. Skin prick test reactivity was found against watermelon (7.1% n= 18), honeydew (3.1% n=8), orange (1.6% n=4) and banana (0.8% n=2). Fifty six (22%) patients were identified with an oral allergy syndrome and we also found that 25 (9.8%) had positive skin prick test reactivity to pollen while 26 (10.2%) reacted against mixed grasses. There is also correlation of skin prick test reactivity between orange with honeydew and orange with banana and this may be due to cross reactivity. Sensitization to watermelon among allergic rhinitis patients is common compared to honeydew, orange and banana in both adults and children. These results however are not statistically significant.

# Allergic Reaction to Eurycoma Longifolia Jack – A Case Report

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## SUMMARY

Eurycoma longifolia Jack locally known as Tongkat Ali, has been used traditionally as an aphrodisiac. Currently, it is widely available as an herbal supplement. It claims to boost male sexual performance and is taken as a beverage such as coffee or tea. We report here a 38 year old Malay man who developed generalized itchy erythematous rash a few hours following ingestion of Tongkat Ali, either fresh or contained in herbal extracts or beverages. This reaction was not associated with other systemic reactions such as wheezing, angioedema, dizziness, hypotension or gastrointestinal symptoms. He had no previous history of atopy. Since this patient was not available for skin prick (SPT), scratch or patch testing of the alleged offensive herb, in vitro specific immunoglobulin E (Ig E) immunoblotting test (dot blot method) was performed on the patient's sera with several herbal extracts (containing Tongkat Ali) taken by the patient namely Tongkat Ali Orang Kampung, Pak Tani (Pusaka Ubat Kuat), Indo Coffee and fresh Tongkat Ali. Blood was also tested for full blood count and for total Ig E. The dot blot tests showed a positive reaction to Tongkat Ali Orang Kampung, Pak Tani (Pusaka Ubat Kuat), Indo Coffee and a strong positive reaction to fresh Tongkat Ali. Total Ig E was also raised at 1559 kU/L while his full blood count showed no eosinophilia. Based on the clinical symptoms of allergic reactions and the strong Ig E immunoblotting result to fresh Tongkat Ali, it was very likely that the patient had a type I hypersensitivity reaction to Eurycoma longifolia Jack.

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# Anti-Amphiphysin 1 Antibodies In Patient with Paraneoplastic Neurological Syndrome Associated with Prostatic Cancer - A Case Report

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## SUMMARY

Paraneoplastic neurological syndrome (PNS) is defined as neurological syndrome of unknown cause that often associated with cancer. PNS may be associated with antibodies against neural antigens expressed by the tumour (onconeural antibodies) which includes anti-amphiphysin. We report a case of PNS in an 80-year old male, who presented with progressive lower limb numbness up to his mid thigh. His symptoms started in 1990s, coincide with the diagnosis of colonic cancer for which he undergone colonectomy. Recently he was diagnosed to have adenocarcinoma of the prostate, Gleason 4+5 with stage 1/2. Neurological examination revealed absent ankle and knee reflexes. The vibration and position senses were reduced. The electrodiagnostic study showed evidence of a predominant sensory axonal polyneuropathy. Immunoblot test for onconeural antibodies which consists of anti-amphiphysin, anti-Ri/ANNA-2, anti-PNMA2 (Ma2/Ta), anti-Yo/PCA-1 and anti-Hu/ANNA-1 was carried out. Immunoblot test was positive for anti-amphiphysin and negative to other onconeural antibodies. Antibodies against amphiphysin (128 kDa) are directed against the protein amphiphysin, which is responsible for vesicle endocytosis. The antibodies against amphiphysin play an important diagnostic tool in PNS. Although anti-amphiphysin is typically associated with mammary carcinoma, small cell bronchial carcinoma, colon carcinoma and Hodgkin's disease, in this case study, the patient had a different tumour association i.e. adenocarcinoma of prostate. In conclusion, we emphasize the importance of onconeural antibodies as a diagnostic tool for paraneoplastic neurological syndrome.

# The SCIDOTS Project - Impact of an Integrated Tobacco Cessation Intervention in Tuberculosis Care on Treatment Outcomes and Quality of Life in Malaysia

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## SUMMARY

Studies from different parts of the world have unequivocally documented consistent evidence of the association between tobacco smoking and tuberculosis (TB) infection, morbidity, mortality, and poor treatment outcomes. Most smoking-related immunological abnormalities are reversible within six weeks of smoking cessation. Therefore, a combined TB-tobacco treatment strategy may positively impact TB treatment outcome. Recently, guidelines on the provision of tobacco cessation in TB settings have been developed but, no study has extensively documented the benefits of such integrations. The objective of this study was to evaluate the impact of an integrated TB directly observed therapy short-course (DOTS) with smoking cessation intervention (SCI) on clinical outcomes and health-related quality of life (HRQoL) among Malaysian TB smokers. Healthcare professionals providing DOTS to TB patients were trained on tobacco cessation competencies during Phase 1 of the study and were involved in providing the integrated intervention during Phase 2. The study was a prospective non-randomized controlled intervention using quasi-experimental design. Using Transtheoretical Model approach, 120 eligible participants who were current smokers at the time of TB diagnosis were assigned to either of two groups: conventional TB DOTS plus SCI (integrated intervention group) or conventional TB DOTS alone (control group). Eleven sessions of individual cognitive behavioral therapy with or without nicotine replacement therapy (NRT) were provided to each participant in the integrated intervention group, while the control group received the same number of sessions of usual counseling for TB. The effects of the novel intervention on biochemically verified smoking cessation, TB therapeutic outcomes and HRQoL were measured by comparing the both groups. Quitting smoking was determined using a seven-day point prevalence abstinence (PPA) and continuous abstinence (CA) at different times over the 6 months follow-up period. Abstinence was biochemically validated using expired carbon monoxide (CO) and saliva cotinine testing. A linear effect on both PPA and CA was observed over time in the intervention group. At the end of 6 months, patients who received SCI-DOTS had a significantly higher rate of success in quitting smoking when compared with those who received DOTS only (77.5% vs. 8.7%;  $p < 0.001$ ). Furthermore, at 6 months, there were significantly higher rates of treatment default (15.2% vs. 2.5%;  $p = 0.031$ ) and treatment failure (6.5% vs. 0%;  $p = 0.031$ ) in the DOTS group than in the SCI-DOTS group. Overall, the cure plus treatment completion rates (success rates) at 6 months or later were 97.5% and 78.3% in the intervention and control groups, respectively ( $p = 0.019$ ). Participants in the SCI-DOTS group had a better HRQoL (measured using EuroQol-5D questionnaire) than the DOTS group. The integrated intervention group had a greater increase in EQ-5D utility index score when compared to control group at 6 months follow-up (mean =  $0.98 \pm 0.08$  vs.  $0.91 \pm 0.14$ ,  $p = 0.006$ ). The present study is evidence that an integrated TB-tobacco treatment strategy could potentially improve TB treatment outcomes and HRQoL. Further studies is needed to investigate the long-term outcomes of such using this strategy before implementing them on a larger scale. The findings of the study has an important implication on current local and international TB treatment guidelines .

# Pre-Hospital Delay and Associated Factors Among Stroke Patients in Klang Valley

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## SUMMARY

Early presentation to hospital is important deciding factor in the management of stroke. There is usually a major delay in the time taken for patients to arrive at the hospital. The aim of this study is to determine percentage of pre-hospital delay and the factors influencing it. A cross-sectional study involving 302 stroke patients admitted to Hospital Kuala Lumpur and Hospital Klang was carried out from July 2007 until August 2008. Data was collected during face-to-face interviews with patients or family members and review of hospital records. The median time between onset of stroke and arrival at hospital was 30.8 hours. Almost three quarters (74.8%) of the respondents reported delay in seeking treatment. Even though the majority (64.6%) of respondents do not know the symptoms of a stroke, more than two-third (69.5%) knew that stroke needed immediate treatment. More than half the patients (56.7%) lived 20km or more away from the hospital. The majority (73.5%) of these patients used their own transport to go to the hospital. Immediate family members had the most influence (77.6%) on the decision to seek treatment. Only distance from health facility ( $p = 0.02$ ) and decision maker ( $p = 0.04$ ) showed significant associations with pre-hospital delay. Distance from hospital and decision to seek treatment are major factors causing delay in seeking treatment in stroke. There is a need to create better awareness on seeking early treatment for stroke.

# Association of Socio-Demographic Factors, Family History and Diabetic Profile with Glycaemic Control Among Type 2 Diabetes Patients at a Health Clinic in Kuala Lumpur

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## SUMMARY

Diabetes mellitus is a global health problem and a major concern with high morbidity and mortality in Malaysia is expected to have 1.3 million people living with diabetes mellitus in 2010. An estimated 1,492,665 people suffered from diabetes mellitus in 2006 (NHMS3, 2006) compared to between 700 000 and 900 000 in 1996 (NHMSII, 1996). Previous studies in Kelantan found prevalence of diabetes control of 28% (Eid et al., 2003) and 14% (Suhaiza et al., 2004) using HbA1c cut-off point of 7.0%. The aim of this study was to determine the prevalence of good glycaemic control and the association of socio-demographic factors and family history among type 2 diabetes mellitus patients. Systematic sampling was used to select the respondents. A total of 307 patients with type 2 diabetes mellitus aged 18 years and above attending a Health Clinic, Kuala Lumpur participated in the study from the first of July to 31st December 2009. All were Malaysian citizens and had received treatment for at least one year. A pre-tested structured questionnaire with guided interview was used to collect the data. Determination of glycaemic control was based on HbA1c levels (within a period of three months). Chi-square test was used to determine the association of socio-demographic factors, family history and diabetic profile with glycaemic control. All hypothesis testing used two sided test and level of significant was set at  $\alpha=0.05$ . Good glycaemic control was defined as HbA1c level  $<6.5\%$ , and poor control if HbA1c  $\geq 6.5\%$ . The prevalence of good glycaemic control was only 27% (n=83). The highest percentage of good glycaemic control were male (29.1%), age 60 and above (33.3%), race Chinese (38.2%), marital status were single/ divorced/ widower (32.9%), educational level was primary school (35.4%), income 1001 until 1500 (32.0%) and profession was unemployed (30.7%). The result showed that age ( $\chi^2 = 7.944$ ,  $p=0.047$ ) and occupational status ( $\chi^2 = 4.272$ ,  $p=0.039$ ), had significant association with glycaemic control. The highest percentage of good glycaemic control for diabetic profile were duration of diabetes mellitus  $\leq 5$  years (31.3 %), family history had no diabetes was (33.3%) and type of treatment was diet control (83.3%). The result showed that type of treatment as Monotherapy (Oral), Multiple drug (Oral), Oral +Insulin/ Insulin, Oral +Insulin/ Insulin ( $\chi^2 = 42.940$ ,  $p= <0.001$ ) had significant association with glycaemic control. More than half of the patients (54.1%) have had diabetes for  $\leq 5$  years, of whom a total of 114 respondents (68.7%) had poor control (HbA1c  $\geq 6.5\%$ ). Research of diabetic profile influence also revealed that no significant association between duration of illness and family member also a patient of diabetes except type of treatment ( $\chi^2 = 42.940$ ,  $p= <0.001$ ), with the control of glycaemic (HbA1c). Based on family chronic disease history, no significant association between asthma, kidney failure, stroke and heart disease except for hypertension ( $\chi^2 = 4.385$ ,  $p=0.036$ ) with the control glycaemic (HbA1c). Intervention is important at the early stage treatment of diabetes mellitus patients for effective control of glycaemic. Better treatment strategies and method such as intensifying education and adopting more intensive monitoring and treatment, should be used to achieve good glycaemic control.

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# Management of Dengue Infection in Adult - How Effective is the Clinical Practice Guidelines?

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## SUMMARY

The objective of the study was to assess the current practice in the management of Dengue Infection in Adults and effectiveness of the new CPG in Ministry of Health facilities. A minimum of 50 adult patients in four hospitals representing the North, South, East and Central Peninsular Malaysia and with the admitting diagnosis of suspected dengue infection between June–August 2008 were studied. Patients referred from other government or private hospitals were excluded. Data was collected on the management of these patients in three locations: outpatient (OPD), emergency and trauma (ETD) and ward. Cross-auditing on the correctness of various aspects of management was done by clinicians from the studied hospitals. The knowledge of attending doctors in these four hospitals was also studied using self-administered questionnaire. Eight months after the launching, a repeat study was conducted in August to December 2009. In the OPD, 205 outpatient clinic records were reviewed pre-CPG launch and 172 post-CPG launch. There was no significant improvement in documentation of all warning symptoms and signs as well as in making a correct diagnosis (65.4% pre vs 63.4% post,  $p=0.687$ ). Fluid advice and intravenous fluid were given inappropriately (16.6% vs 3.4%,  $p=0.000$ ). The percentage of patients managed satisfactorily with a score  $> 80\%$  worsened (16.6% vs 2.3%,  $p= 0.000$ ). For the ETD, 219 and 202 records were reviewed pre and post CPG launch respectively. In the post CPG group, less patients were triaged into the Green zone. (84.7% vs 47.0%,  $p=0.000$ ). Significant improvement was noticed in the documentation of abdominal pain (43.4% vs 55.0%,  $p=0.018$ ), abdominal examination (68.9% vs 78.7%,  $p=0.023$ ) and hydration status (45.7% vs 60.9%,  $p=0.002$ ). However the documentation of pulse pressure was neglected (42.0% vs 3.5%,  $p=0.000$ ). Correct diagnosis was made in 67.1% pre vs 72.3% post-CPG, ( $p=0.251$ ). Intravenous fluid therapy was appropriate only in 36.5% pre vs 35.6% post-CPG. The overall management score was poor (8.7% vs 16.3%,  $p=0.017$ ). For the ward, there were 311 and 291 in-patient records for review pre and post-CPG launch respectively. Significantly more errors were made in the diagnosis (32% vs 22.8%,  $p=0.013$ ). Documentation of symptoms did not change much while that of signs improved significantly (weight 9.7% vs 88.3%  $p= 0.005$ ; respiratory rate 51.8% vs 71.5%  $p= 0.001$ ; cold or warm extremities 14.5% vs 41.6%  $p=0.001$ ; and 3rd fluid space loss 45% vs 65.3%  $p=0.001$ ). The frequency of Full Blood Count (FBC) monitoring also improved significantly (68.8% vs 78.7%,  $p=0.006$ ). The overall management showed a score of 52% pre-CPG vs 51% post-CPG. Regarding the knowledge of doctors, the percentage of correct answer to the questions had all improved. However two questions, when to transfuse red cells and when to transfuse platelets were answered correctly by only 63.3% and 43.8% respondents respectively. In conclusion, the effectiveness of the CPG in the management of dengue infection in adults could not be convincingly demonstrated in this study. It showed that improvement in knowledge did not translate into better patient management of dengue patients.

# A Preliminary Study on Effectiveness of Conventional and Symmetrical Weight Training in Stroke Patients to Prevent Falls

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## SUMMARY

Stroke is the leading cause of disability in the elderly. In stroke patients, the incidence of a fall hinders the rehabilitation process. Asymmetric weight bearing is the major cause of frequent falls in stroke patients. To achieve the symmetrical weight bearing in stroke patient, we needed to assess the efficacy of symmetrical standing training and repetitive sit-to-stand training in preventing falls. Ours was a pre- and post- test experimental study involving 30 patients randomly selected from a government hospital in Warangal, India. Informed consent was obtained and patients were assigned into an experimental (group I) and control group (group II). These patients were newly diagnosed stroke patients with hemiparesis between the ages of 45 and 65 years old. Group I underwent symmetrical standing and repetitive sit-to-stand training in addition to the conventional stroke rehabilitation training. Group II underwent conventional stroke rehabilitation training alone. The study duration was 12 weeks. The results in terms of fall frequency as well as balance one week before and after training in both groups were compared. The calculated t value (paired t test) of experimental group was 31.8. The calculated t value (paired t test) of control group was 14.3 and the calculated t value (unpaired t test) of experimental group versus control group was 8.061. The calculated t values for pre- and post-test value of fall frequency in Group I and II were proven to be significant. Therefore, we concluded that symmetrical standing training and repetitive sit-to-stand training incorporated into the stroke rehabilitation was more effective than the conventional stroke rehabilitation training as it has shown to significantly reduce the frequency of falls in stroke patients with hemiparesis.

# The Impact of Elective Lower Segment Caesarean Section (LSCS) Clinical Pathway on Hospital Cost and Clinical Outcome at Tertiary Hospital- A Non-Randomized Single-Blind Controlled Study

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## SUMMARY

The health care system is expected to improve its services according to advances in the medical field while maintaining cost affordability. Health care providers have to examine and restructure their clinical management systems in order to meet these expectations. Clinical pathway (CP) has been introduced to the clinical management system and has been said to be beneficial in consistently providing high quality care. However, the impact of CP on clinical outcome has yet to be tested locally. The objective of our study was to develop, implement and evaluate the use of a CP for elective LSCS patients managed in Universiti Kebangsaan Malaysia Medical Centre (UKMMC). The CP for elective LSCS was jointly developed by UKMMC Department of Community Health, International Centre for Case-Mix and Clinical Coding, Department of Obstetrics and Gynecology and UNU-IIGH. All admissions for elective LSCS in 2009 followed this CP. This was a non-randomized single blind controlled study involving 169 patients { 69 patients following the CP (experimental group) and 100 patients not following the standardized CP (control group)} admitted between January and December 2008. The impact of clinical pathway outcome was evaluated based on average length of stay (ALOS), re-admissions, complications and hospital cost. The results were analyzed using descriptive and advanced analyzes. The mean age of patients was  $31.38 \pm 4.29$  and  $32.36 \pm 5.25$  in CP and non- CP patients respectively. There was a significant difference in average length of stay between the two groups ( $4.04 + 0.61$  for CP and  $4.99 + 2.94$  for non-CP,  $P < 0.01$ ). The cost encountered by the non- CP was higher (RM  $1741.80 \pm 172.28$ ) than the CP group (RM  $1617.95 \pm 85.36$ ) ( $t = 2.06$ ,  $P < 0.04$ ). There was no difference between the groups in terms of patient age, comorbidity, re-admission and complication rate. The purpose of clinical pathway is to improve the clinical outcome by coordinating care and reducing cost. Our results demonstrated that the CP has successfully reduced the length of stay and hospital cost. Implementation of CPs is beneficial and does not negatively impact the quality of health care.

# Stentless Endoscopic Dacryocystorhinostomy – A Five Year Review

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## SUMMARY

Dacryocystorhinostomy (DCR) is a procedure performed to drain the lacrimal sac in cases of nasolacrimal duct obstruction or in chronic dacryocystitis. It can be performed externally or endoscopically. The aim of this study was to describe endoscopic dacryocystorhinostomy with full sac exposure and primary mucosal anastomosis without stenting the lacrimal ostium and to report perioperative and follow-up results achieved with this procedure between January 2005 and January 2010. Fourty seven consecutive patients (38 females and nine males; mean age 46.7y; range 14-74y) who presented to the DCR clinic with epiphora secondary to nasolacrimal duct obstruction and recurrent infection were included in this study. All these patients underwent primary powered endoscopic DCR. A total of 53 procedures were performed using a standardized surgical technique. Post-operatively, symptom evaluation and endoscopic assessment of the newly created lacrimal ostium were done. Forty six of the 53 primary DCR's were patent after a mean follow-up of 24 months, yielding a success rate of 87%. The other seven procedures were revision cases. Patency was assessed by symptomatic evaluation and endoscopic visualization at each post-operative visit. Powered endoscopic DCR with mucosal flaps without stenting has a success rate comparable to that achieved with stents and external DCR.

# Pilot Radiographic Study of Preprosthetic Implant Supported Obturator

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## SUMMARY

Retention and stability of the obturator prosthesis is a major problem with edentulous patients and depends on the satisfactory resolution of presented condition and the precision in the fabrication of the prosthesis. The use of Osseointegrated implants has been suggested to improve retention and stability in the conventional obturator prosthesis for edentulous patients. Two surgical placement procedures, Two stage surgery or submerged and One stage surgery or non-submerged were recommended. They differ in the temporal sequence selected for the implant integration in hard and soft tissues. This study was designed for radiographic evaluation of Titanium root form implants system with \*implant extender (10 mm length and 3.7 mm diameter). Ten male patients were selected. All the cases were completely edentulous and had maxillary defects not crossing the midline of the palate. Three titanium root form implant with implant extender were placed in the residual premaxilla for each patient as the premaxillary segment is the key site for implant placement in the maxilla. All placed implants showed radiographic evidence of bone integration but with different degrees. The changes around the implants were significantly different compared to the base line image ( $p < 0.05$ ). Titanium root form advent implant system with implant extender has the advantages of both one- stage and two stage surgical techniques. It has patented implant extender which can be used to maintain tissue opening even when the top of the implant is placed below the soft tissue. This allowing for formation of esthetic, subgingival margin that proved a natural looking emergence profile. It can be used for one stage surgery technique and help locating the site of implants when used for two stage surgery reduce the extent of surgical manipulation. In the same time the implant was submerged to avoid motion of the endosseous screw which could result in connective tissue proliferation and fibrous encapsulation of the screw with impaired osseointegration.

\*Paragon implants company USA



# Profiles of Maxillofacial Injuries Seen in an Urban Hospital in Mainland Penang, North Malaysia

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## SUMMARY

Maxillofacial injuries are common injuries seen in Malaysian hospitals. The aim of this study was to determine the profiles of maxillofacial injuries seen in an urban government hospital of mainland Penang. This cross-sectional study involved 194 cases that presented to the Oral and Maxillofacial Surgery Department of an urban hospital between May 2007 and May 2008. A case report form was developed and completed by the attending clinicians. Data was analyzed using SPSS version 12.0. The majority of patients were males and the mean age was 27.8 years. The main cause was motorcycle accidents. The most common injury involved the soft tissues, dento-alveolar and facial bones. Those involved in motorcycle accidents had a significantly higher incidence of sustaining facial bone fractures. More males were involved with the highest occurrence among those in the 20-29 age group. The main cause was motorcycle accidents. Soft tissue injury was the most common. Bone fracture was found to be significantly higher among those who were involved in motorcycle accidents.

# Endoscopic Gastrocnemius Recession for the Treatment of Equinus Contracture

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## SUMMARY

Equinus contracture has been postulated to be an important factor in foot and ankle pathology. Many surgical techniques have been described to treat the contracture. Due to the current interest in minimally invasive surgery, endoscopically assisted techniques have utilized carpal tunnel and endoscopic tissue release systems which are expensive and may not be universally available. The objective of the study was to evaluate the safety and efficacy of a simple new method of endoscopic gastrocnemius recession. This retrospective review included nine cases with equinus contracture surgically treated concurrently with other foot and ankle procedures. The endoscopic procedure involves two portals based on simple surface markings. The instruments utilized included a standard 4.0 mm arthroscope and an arthroscopic narrow punch. Minimum follow up was five months. Seven patients with a mean age of 52.9 (range 42 to 66) and a BMI of 28.3 (range 22.8 to 32.8) were operated on. Two patients had bilateral procedures. Mean pre-op dorsiflexion was  $-5.33^\circ$  (range  $-16^\circ$  to  $0^\circ$ ) and post-op dorsiflexion was  $5.78^\circ$  (range  $-4^\circ$  to  $12^\circ$ ). Average gain in dorsiflexion was  $11.11^\circ$  (range  $6^\circ$  to  $18^\circ$ ) [p value < 0.0001]. Average lengths of scars were 9.78mm (range 8 to 12mm) medially and 9.56mm (range 8 to 13mm) laterally. There were no sural nerve injuries. Endoscopic gastrocnemius recession is safe and effective in equinus contracture. It is a cheap and viable technique for hospitals with minimal budget and equipment.

# To Investigate the Impact of Pharmacist-Assisted Hypertension Clinic on Healthcare System (IMPRESS)

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## SUMMARY

The provision of practice-based support by pharmacist in hypertension clinic is currently not often emphasized in Malaysia. The aim of this study was to investigate the impact of pharmacist-assisted hypertension clinic on health care system. A five months prospective, randomized cohort study was conducted out at the out-patient pharmacy department of Queen Elizabeth Hospital. The study population involved 70 patients aged 18 years old and above, having stage 1 or stage 2 hypertension, have been on at least one anti-hypertensive drug, no cardiovascular events within the past six months. Patients were randomly assigned to an intervention arm and control arm. Pharmacist interacted with patients in a total of five visits. During the monthly visits, patients received medication refill, measuring of blood pressure, counseling on hypertension including antihypertensive medications, drug compliance, goals of lifestyle modification, and increased of patient awareness by providing relevant education about hypertension and associated/related diseases. There was a significant reduction in mean systolic blood pressure in the intervention group ( $11.17 \pm 5.26$ mmHg) as compared to the control group ( $6.36 \pm 8.61$ mmHg) ( $p=0.008$ ). The difference in diastolic reduction between the two groups was not statistically significant ( $p=0.07$ ). There was significant difference in mean overall knowledge score between intervention ( $32.38 \pm 2.31$ ) and control groups ( $16.43 \pm 5.00$ ) ( $p<0.001$ ). The general knowledge score (in terms of definition of hypertension, goal of hypertension, cardiovascular risk factors and consequences of high blood pressure) of the intervention group and control group were  $10.26 \pm 1.52$  and  $6.07 \pm 1.78$  respectively ( $p<0.001$ ). Mean score of knowledge on medication management of intervention group and control group were  $2.97 \pm 0.17$  and  $2.5 \pm 0.86$  respectively ( $p=0.003$ ). Mean score of knowledge on non-drug management of intervention and control arms were  $18.85 \pm 1.16$  and  $7.83 \pm 3.22$  respectively ( $p<0.001$ ). There was no tremendous improvement in the mean scores before and after study in the control group for general knowledge on hypertension, knowledge on medication management and knowledge on non-drug management. Compliance level was better in the intervention group as compared to the control group at the end of the study. Overall result of the Morisky Scale was significantly higher for the intervention group as compared to the control group ( $5.71 \pm 0.52$  vs.  $4.43 \pm 1.14$ ;  $p<0.001$ ). Pharmacist-assisted hypertension clinic brings about significantly greater benefit to the health care system in terms of improvement of blood pressure control, patients' knowledge on hypertension and compliance to antihypertensive medications.

# A Study of Risk Factors for Pneumonia Among Children Under Five

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## SUMMARY

Pneumonia is a major cause of morbidity and mortality especially in developing countries. It is an important cause of death in children under five years old. This study hopes to raise awareness about this disease. This observational case control study was conducted at the Pediatric Institute, Hospital Kuala Lumpur. The cases and controls were matched in gender and age. Cases were selected by convenience sampling. The controls were recruited from children hospitalized at the same hospital during the same period for causes other than respiratory infection. Confirmed pneumonia cases were chosen based on final discharge diagnosis. Differentiation between viral and bacterial pneumonia depended on the final discharge notes of the treating physician. This is mainly based on the deferential white cell count, fever grade, chest X-ray finding and to lesser extend on culture and sensitivity and also serology results in some of the cases. Data was analyzed by SPSS version 15 Analysis was preceded by normality test. Chi-square test followed by binary logistic regression was used for the analysis.  $P < 0.05$  was depended as a significant. Two hundred sixty subjects were diagnosed with pneumonia have been included in the case group. Of them, 147 (57%) had bacterial pneumonia and the rest (113, 43%) had viral pneumonia. Risk factors that had significant association with pneumonia were: incomplete immunization with  $\chi^2 = 35.03$ ,  $df = 1$ ,  $p < 0.001$  followed in a decreasing manner by low weight for age  $\chi^2 = 20.74$ ,  $df = 1$ ,  $p < 0.001$ , lack of breast feeding  $\chi^2 = 16.29$ ,  $df = 1$ ,  $p < 0.001$ , day care attendance  $\chi^2 = 14.79$ ,  $df = 1$ ,  $p < 0.001$ , smoking habit of father  $\chi^2 = 8.71$ ,  $df = 1$ ,  $p < 0.005$  and preterm birth  $\chi^2 = 5.16$ ,  $df = 1$ ,  $p < 0.05$ . The variables that were a significant predictors of pneumonia in the regression model are incomplete immunization ( $p = 0.001$ ), day care attendance ( $p = 0.001$ ), low weight for age ( $p = 0.001$ ), lack of breast feeding ( $p = 0.016$ ) and smoking habit of father ( $p = 0.04$ ). In conclusion, the odds of having pneumonia were more than three times higher for those with incomplete immunization, more than two times higher for those who attend day care or those with low weight for age, about two times higher for those who are non breast fed, more than one and half times higher for those who have exposure to paternal smoking. Maintaining normal weight for age, increasing rates and duration of breastfeeding, ensuring up to date immunization, providing educational programs for young people to highlights the harmful effects of parents smoking habits on child's health and development all of these with other interventions to reduce possibility of infection among children attending day care centres are essential to reduce pneumonia burden.

# The Impact of Medication Reconciliation in Medical Ward of Tertiary Hospitals

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## SUMMARY

Medication reconciliation is a technique used to identify discrepancies in drug regimens prescribed to a patient. It can be used in different care setting which includes during patient admission, transfer or discharge. Studies have shown there was strongly coherent relationship between medication reconciliation techniques in reducing discrepancies in the hospital setting. Among the discrepancies identified were omissions, duplications, dosing error or drug-drug interactions. In this study, the same technique was used but only applied during admission care setting. Previous studies involving the application of this technique at all three stages identify that most medication errors occur during the admission stage. Our study intends to identify common medication discrepancies occurring during admission and determine the effectiveness of this medical reconciliation technique at this level. The study involved 92 patients from Serdang hospital medical wards over eight months. This prospective cross sectional study involved chronic disease patients on at least four types of medications. Results were analyzed using descriptive statistics and statistics using SPSS. Data analysis showed that a total of 56.5% of unintended discrepancies were recorded, the highest types being omission (94.6%) followed by frequency error (2.4%). Dosing error and interaction contributed to 1.2%, and unauthorized drug use accounted for 0.6% of the total. After intervention, the numbers of discrepancies were reduced from 56.5% to 47.8% ( $p < 0.05$ ). Our study proved that medication reconciliation techniques does help in reducing discrepancies in the hospital care setting.

# Antihypertensive Drug Use - A Study on Direct Cost and Patients Compliance

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## SUMMARY

The utilization patterns and overall drug cost of hypertensive patients in a government health care setting and their level of compliance towards their medications were assessed. [http://ovidsp.tx.ovid.com/spb/ovidweb.cgi?&S=DHKCFPJBLNDDODADMCGLECOKNDFPAA00&Link+Set=S.sh.50%7c8%7csl\\_10](http://ovidsp.tx.ovid.com/spb/ovidweb.cgi?&S=DHKCFPJBLNDDODADMCGLECOKNDFPAA00&Link+Set=S.sh.50%7c8%7csl_10) - 20. This was a cross sectional study on the utilization of anti-hypertensive drugs, patients compliance and the direct drug cost on prescriptions from a government health outpatient clinic. The patients were recruited when they were diagnosed with primary hypertension, Malaysian and aged between 21 years and 65 years, reviewed and follow-up at Shah Alam Health Clinic for at least three visits. [http://ovidsp.tx.ovid.com/spb/ovidweb.cgi?&S=DHKCFPJBLNDDODADMCGLECOKNDFPAA00&Link+Set=S.sh.50%7c8%7csl\\_10](http://ovidsp.tx.ovid.com/spb/ovidweb.cgi?&S=DHKCFPJBLNDDODADMCGLECOKNDFPAA00&Link+Set=S.sh.50%7c8%7csl_10) - 27. A total of 2138 prescriptions containing 917 items were collected. Anti-hypertensive and other co morbidities drugs accounted for 25.35% and 17.54% respectively. CCBs, ACE inhibitors and BBs were the most popular anti-hypertensive drugs used. Sulphonylureas were the most frequently prescribed anti-diabetic agents. Memory, duration of therapy and age were significantly associated with compliance. Average cost per prescription was RM12 and amlodipine accounts for the highest use with cost of RM 879,499.68  $\pm$  69,625. The use of the more expensive anti-hypertensive agents has a significant impact on drug expenditure. Monitoring drug use and their correlations with clinical outcomes are warranted. Counselling should be conveyed more effectively to improve patient compliance regardless of their poor memory, duration of therapy or age.

# Diabetic Patients' Knowledge and Understanding of Diabetic Foot and its Management

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## SUMMARY

To describe the relationship between disease and patients knowledge on diabetic foot in a defined studied population. This was a descriptive cross sectional study which aimed to assess diabetic patients' knowledge and understanding of diabetic foot and its management in a government health clinic. The study was carried out at the Shah Alam Health Clinic. The study population consisted of 100 diabetic patients, who were randomly selected. The inclusion criteria were adult diabetic patients aged between 18 and 80 years and diagnosed with diabetes mellitus (exception gestational diabetes). Consented respondents will be asked to answer a structured questionnaire on diabetes mellitus and its complication. The results showed no significance difference between diabetic patients with and without diabetic foot problems on their knowledge on diabetic foot and foot care practices. Similar findings were also observed in both adherence and non-adherence diabetic patients toward medication. The finding showed that continuing patient education on diabetes mellitus, diabetic foot and the correct foot care practice is important in ensuring quality diabetic care for both with and without diabetic foot complications.

# Two-Year Outcome of Quality of Life among Heroin Dependants at Methadone Maintenance Therapy Clinic, Hospital Tengku Ampuan Afzan

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## SUMMARY

The commencement of Methadone Maintenance Therapy (MMT) in 2005 has made a quantum leap in the management of heroin dependence in Malaysia. The objective of the study was to examine the two year change in quality of life (QOL) among heroin dependants at MMT clinic, Tengku Ampuan Afzan Hospital (HTAA). This was a cohort study in which the second administration of QOL was conducted with two year interval from the baseline. From a total of 172 patients enrolled into the MMT programme at the point of entry at HTAA, we examined 107 patients who were retained in the programme after two years (62.6% retention rate). Analysis of repeated measurement of paired t-test demonstrated significant improvements in all four domains of QOL (physical, psychological, social relationships and environment) ( $p < 0.001$ ). The most marked improvement was noted in psychological domain. The MMT programme at HTAA is effective in improving the QOL among heroin dependants.

# Menstrual Characteristics - Is it Genetic or Environmental?

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## SUMMARY

The impact of women's menstrual cycle on her quality of life, health, work and community is substantial. Menstrual disturbance is linked with general ill conditions such as migraine, asthma and endocrinopathies. The clinical significance of medical interventions to prevent these conditions becomes clear if the role of genetic or environment is clarified. Twin studies are the best method to identify these issues. Two cohorts of monozygotic and dizygotic twins (born between 1945-1988, n=122) and (1951-1993, n=71) were taken as volunteers. Homogeneity testing was performed to ensure the ability to collapse data. A standard questionnaire was designed inclusive of socio-demographic characteristics of subjects as well as menstrual history. Menstrual history included duration, interval, amount of menstruation, history of amenorrhea and finally irregular menstrual bleeding was recorded. Quantitative variables were analyzed using Falconars' formula (1996) as well as maximum likelihood analysis. Structural modeling was then applied to the MZ and DZ twins correlations to provide estimates of the relative genetic and or environmental factors contribution in determining the trait. Menstrual characteristics were found to be under environmental influence where the best fitting model for menstrual interval and duration was Common Environment (CE) (C33%, E67% for interval) and (C5%, E95% for duration). CDF plotting confirmed the results for both variables. Proband wise concordance analysis for amount of menstruation, amenorrhea and irregular menstruation revealed no genetic influence. The best fitting model for menstrual irregularity was CE (C73%, E27%). The same model was defined for amenorrhea (C48%, E52%). Environmental factors are most likely responsible for determining the menstrual flow, its integrity and regularity. These factors need to be studied further.

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# A Model of Care - Addressing Breast Cancer as a Chronic Illness

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## SUMMARY

Patient self-management is a crucial component of care in chronic non-oncology conditions but to date is mostly absent in oncology settings. The aim of this study was to test the efficacy of the four-week Staying Abreast Moving Ahead (SAMA) program using outcomes of quality of life (QOL), participation and psychological distress. Women with early-stage breast cancer (n=147) participated in a quasi-experimental clinical trial, whereby the experimental arm received usual care plus a self-management intervention whilst the control arm received usual care only. The participants were assessed at baseline, post-intervention and at follow up, on Quality of life (SF36), limitation in participations (Social Relationships, Family role) and on psychological distress (DASS). Multi-variate analysis of covariance and uni-variate repeated measures analyses of variance were conducted to examine the comparative efficacy of the four week self-management intervention. This was followed by examining for significant changes across time in the 'within experimental' group. Effects on QOL showed a trend towards significance (p=0.056). Significant differences were found between groups for limitation in Social Relationships (p=0.015), and psychological distress [Stress (p=0.001), Anxiety (p=0.003) and Depression (p=0.003)] at immediately post-intervention. At follow up, significant differences were maintained for limitation in Social Relationships, Stress and Anxiety (p<0.001), although not for Depression. Differences between groups for QOL and Family roles were not statistically different at any time. The intent-to-treat analyses supported the efficacy of the self- management intervention, with significant improvement in social relationship and psychological distress. The four-week SAMA program is a potent addition to usual care for Malaysian women with breast cancer and a potential blueprint for a feasible, timely and effective self-management program for women with breast cancer.

# Quality of Life and Cost of Illness in Patients with Psoriasis in Malaysia - A Multi-Centre Study

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## SUMMARY

Psoriasis is an immune mediated chronic inflammatory skin disease which affects approximately two percent of the world's population. It has a major impact on patient quality of life, influencing their career, social activities, family and all other aspects of life. Many studies have described the various ways in which psoriasis can affect patients' life. Very little is known however about the impact of psoriasis on the quality of life of patients treated in Malaysia and the cost of illness in this region. This study aimed to describe the extent of psoriasis affecting the quality of life of patients treated in the government dermatology clinics in Malaysia and to estimate the cost of illness. A total of two hundred and fifty patients with psoriasis treated at eight dermatology clinics in the government hospitals Malaysia were studied. The severity of psoriasis was assessed by dermatologists. Quality of life was evaluated using the Dermatology Life Quality Index (DLQI) and the second version of 12-Item Short Form Health Survey (SF12v2). The SF12v2 of healthy subjects and patients with other medical conditions such as depression, diabetes mellitus, hypertension and ischaemic heart disease were also assessed for comparison. The costs of dermatology outpatient consultant fees, medications, investigations, procedures, transportation fees, over-the-counter medications and hospitalizations were retrospectively estimated using questionnaires. The studied cohort had median PASI of 9.9 and a median DLQI of 10.0. The average SF12v2 were 43.68 (SD 9.23) and 42.25 (SD 10.7) for physical health summary and mental health summary respectively. The impact of disease on the quality of life is greater in those with more extensive psoriatic lesion involvement, in younger patients and in those with psoriatic arthropathy. Psoriasis affects the quality of life in both genders equally. Body mass index has no effect on the severity of psoriasis and the quality of life. Patients with psoriasis had a significantly lower SF12v2 score than healthy subjects. The comparison with other chronic medical conditions demonstrated that psoriasis imparts a negative health related quality of life similar to the impact of other chronic conditions. The estimated cost of illness for psoriasis in the current cohort was RM1,307.47 per person per year excluding hospitalization. Patients were noted to spend a large amount of money on over-the counter products without doctors' prescriptions. The quality of life of patients with psoriasis was significantly impaired compared to healthy subjects and was comparable to patients with other chronic medical illnesses. The estimated cost of illness for psoriasis in the current study was lower than other countries mainly because the public hospitals health care cost was heavily subsidized by government and also low usage of newer but more expensive treatment options.

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 PCR34

# Burns in Epileptics - Experiences in Saudi Arabia and Malaysia

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## SUMMARY

The aim of the study was to investigate the conditions of burns and find the best way to avoid major disasters for epileptic patients. We present 14 epileptic patients who sustained deep burn injuries and were managed in our burns centre in King Khalid Civilian Hospital Tabuk Saudi Arabia and Burn Centre in University Malaya Medical Centre, Malaysia, over a period of ten years. One patient had a chemical burn and two had scald burns while having their shower, and eleven had fire burns. Ten patients were males, and four were female. Eight patients were compliant with their epilepsy medication, four patients were not and two had not been diagnosed before. The depth of burns ranges from 40% up to 90%. One patient died. Other morbidities included amputations in three cases, severe facial scarring in two patients.

# Necrotizing Fasciitis of the Eye Lid - A Case Report

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## SUMMARY

Necrotizing fasciitis (NF) is a serious infection that compromises subcutaneous tissue, fascia, and adipose tissue with a high mortality rate and sequelae. Extremities, trunk and pelvis are the most common body sites affected. Peri-orbital cellulitis with necrotizing fasciitis of the eyelid is rare. A thirty two year old male patient received a trauma by tennis ball to his right upper part of the orbit. Within ten days developed black discoloration of the right upper eye lid and huge swelling of the whole orbit. Patient was subjected for debridement and followed later by grafting. The timing of surgeries and the medication given to the patient were good new issues to be recorded. The eschar was successfully removed keeping the tarsal plate which was viable and later, it was easy to close the remaining superficial wound.

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PCR36

# Facial Cellulitis of Odontogenic Origin in Children

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## SUMMARY

Facial cellulitis of odontogenic cause requires early diagnosis and prompt management due to its potentially life-threatening complications. This study investigated the clinical characteristics of odontogenic facial cellulitis in children referred to the Paediatric Dental Department of Hospital Raja Perempuan Zainab II, Kota Bharu. All patients who were diagnosed with this condition between January 2008 and August 2009 were included in this study. Patient demographics, clinical history and disease characteristics, including symptoms, location of cellulitis, past dental history, history of caries, length of hospitalization, mode of treatment, and long term management of the patient. Descriptive analysis was used to analyze data using Windows SPSS version 13.0. Of the 39 patients, the majority were boys and the mean age was 6.69±3.50. 94.5% experienced toothaches prior to swelling and 51.3% complained of fever. A significant number had caries. Around 61.5% required hospitalization and 28.6% of these required treatment under general anaesthesia. The clinical characteristics of odontogenic facial cellulitis were easily identified and the majority of patients gave a history of toothache. Over half of these patients developed systemic illness requiring hospitalization. Our study concluded that this condition imposes an unnecessary burden on the health care service.

# Association of ABCB1 Haplotypes Derived from C1236T/G2677TA/C3435T with the Risk of Resistance to Sodium Valproate in Malaysian Epileptic Patients

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## SUMMARY

Resistance to antiepileptic drugs (AEDs) has been observed in approximately 30% of patients with epilepsy. Over-expression of P-glycoprotein (P-gp), the product of the multidrug resistance gene (ABCB1;MDR1), has been implicated in drug-resistance epilepsy. Genetic variation may be a critical pharmacogenetic determinant in response to AEDs. The present study was aimed at investigating the possible association of common C1236T/G2677TA/C3435T variations of the ABCB1 gene with the risk of resistance to sodium valproate (VPA) in Malaysian patients with epilepsy. The study hypothesis was examined in a retrospective study of 531 patients with epilepsy including 260 drug-resistant and 271 drug-responsive subjects on VPA monotherapy. Genomic DNA from the patients was extracted and genotyped by polymerase chain reaction (PCR) followed by restriction fragment length polymorphism (RFLP) method. The three ABCB1 polymorphisms were not associated with the risk of resistance to sodium valproate (VPA) in the patients studied. Analysis of haplotypic frequencies indicated significant linkage disequilibrium between the two ABCB1 polymorphisms C1236T and C3435T ( $D' = 0.017$ ). The frequency of 1236/2677/3435 TTC haplotype in drug-resistance patients compared with drug-responsive subjects was significantly higher (15.4% versus 9.6%,  $p = 0.003$ ) but lower for TTT and CAC haplotypes [(18.0% versus 23.9%,  $p = 0.023$ ) and (1.6% versus 4.2%,  $P=0.010$ ), respectively]. The drug-resistant epilepsy patients with ABCB1 1236/2677/3435 TTT and CAC haplotypes were less prone to resistance to VPA while those with TTC haplotype were more so.

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# Core Decompression with Reverse Bone Graft Technique and Hydroxyapatite Granules in Avascular Necrosis of the Femoral Head

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## SUMMARY

Core decompression is used in precollapse lesions to forestall disease progression in avascular necrosis (AVN) of femoral head (FH). The author reported a new technique using reverse bone graft technique to effectuate core decompression. The aim of the study was to prevent precollapse in Ficat Type 1 and 2 and re-vascularization using synthetic bone graft material. An 18 year female police trainee with Magnetic Resonance Imaging (MRI) confirming AVN Stage 2 Ficat, clinically painful hip not evident in x-rays consented to undergo this new technique. Reverse bone graft technique with a Coring reamer – Patent 5423823. A minimally invasive technique with lateral two cm incision introducing 8.5 mm core reamer to remove a core of bone up to the subchondral bone. The subchondral cyst decompressed and curetted under video recorded Image Intensifier. Demarcated avascular bone segment excised and bone graft reversed and inserted with cortical bone acting as a support to prevent collapse and the distal segment augmented using five grams of osteo-conductive granular synthetic bone graft material based on calcium phosphate hydroxyapatite (HA 2500-5000  $\mu\text{m}$ ). Avascular segment histopathologically confirmed AVN. Core tract started at sub-trochanteric area, prevented from stress riser by protected weight bearing for two months. HA granules named as GranuMas™ developed under Intensified Research in Priority Areas (IRPA) Research Project (No. 03-01-03-0000-PR0026/05) and invented by the Advance Materials Research Centre (AMREC) and manufactured by GranuLab – Patent P1 20040748 fulfilling the criteria for American Society for Testing and Materials (ASTM) F1185-88(1993) Standards which is 'Standard Specification for Composition of Ceramic Hydroxyapatite for Surgical Implants' derived from Malaysian limestone, ranging from 200 to 5000  $\mu\text{m}$  gamma sterilized. After six months, there was no collapse of subchondral bone and the FH showed re-vascularization along bone grafted site with viable graft and increased radiotracer activity using  $^{99}\text{Tc}$  MDP WB Bone Planar Scintigraphy. Clinical success was defined as Harris hip Scores of 80 points with a x-ray evident incorporated graft. Reduction in intraosseous pressure is achieved by using large bore 8.5mm coupled with HA granules promoting re-vascularization. In conclusion, this technique is minimally invasive and effective in young patients with early stage of FH AVN and has shown re-vascularization along the bone grafted site.



# Assessment of Conjunctival Microorganisms – Are We Using the Correct Culture Media?

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## SUMMARY

Reduction of the periocular bacterial load prior to cataract surgery has been shown to be an essential step in decreasing the rate of postoperative endophthalmitis. Thus, various methods have been instituted to reduce the periocular bacterial load prior to cataract surgery. The usage of povidone iodine remains one of the cornerstones in preoperative ocular surgical site preparation and its effectiveness has been proven. The most commonly used culture media to assess the ocular and periocular microorganisms are the agar plates. The aim of the study was to look at the difference in culture positive rates of conjunctival swabs when inoculated into enriched media such as Brain-Heart Infusion (BHI) broth and chocolate agar and assess the suitability of this media as a primary culture media in isolating ocular pathogens. This was a cross-sectional observational study. Two hundred samples of conjunctival swabs were taken prior to commencement of phacoemulsification surgery 3 minutes after instillation of povidone iodine 5% on the periocular skin and into the conjunctival fornices. Identical swabs were then inoculated onto chocolate agar and BHI broth. There were 14 (7%) positive cultures from the chocolate agar group and 90 (45%) positive cultures from the BHI group. The distribution of microorganisms in both media reflected the preponderance of gram positive cocci in the conjunctival flora. Though povidone iodine has been proven in various studies to be an effective surgical site disinfectant, this study shows that even after instillation povidone iodine 5% onto the periocular skin and into the conjunctival fornices, 45% of swab samples yielded a positive culture with BHI. Routine culture media may not be adequate in assessing microbial growth in environments that contain disinfectants or other inhibitors of microbial growth. Thus povidone iodine alone does not completely eliminate the periocular microbial load and additional measures to prevent postoperative infections after phacoemulsification surgery need to be instituted. The choice of culture media used in assessing ocular microorganisms is crucial.

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 PCR40

# Cerebellar Degeneration - One Litre of Tears

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## SUMMARY

An eight year old Malay girl presented at Hospital Sultanah Bahiyah eye clinic with history of bilateral congenital nystagmus and deterioration of vision for the past one year. Her developmental milestone was normal until the age of six and slowly experienced motor regression. She started to have difficulty to walk in a straight line, becoming unsteady and clumsy. Her vision is becoming poorer instead of having slurred and slowed speech. Her 15-year-old elder brother has the same problem and was bed bound, with no speech and being dependent in all activities of daily living. On examination, her best visual acuity was 6/36 and 6/9 for right and left eye respectively. There has been deterioration in her general condition. At present, she needs help to walk, dress and is unable to write even though MRI result shows no significant of abnormality. Her initial examination by medical team showed a non dysmorphic child with bilateral nystagmus, dysarthria, past pointing, dysdiadokokinesis, ataxia gait and truncal ataxia. She was diagnosed to have rare neurological disorder, cerebellar degeneration, a condition where the area of the brain that control muscles coordination and balance degenerates-deteriorate and die.

# Polypharmacy of Antihistamines in Cough and Cold Products Used in Children Below the Age of Six

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## SUMMARY

There are high incidences of concurrent use of two or more antihistamines in cough and cold treatment among children at Klinik Kesihatan Maharani, Muar. Since common cold is a mild viral infection that children can usually recover in time on their own, it is advised not to give more than one cough and cold product to a child aged below six. The aim of the study was to reduce the polypharmacy of antihistamines in common cold treatment among children aged below six, and to evaluate its magnitude and characteristic prior to and following pharmacist intervention. This was a cross-sectional, quasi-experimental, two-phase (pre/post) study. Phase I occurred between the third of November and 31st December 2008 prior to pharmacist intervention, and Phase II occurred between the 2nd of February and 31st of March 2009 following pharmacist intervention. All prescriptions comprised of cough and cold product(s) to be given to children aged below six were recruited during these periods. Incomplete and indecipherable prescriptions were excluded. The endpoints were total number of polypharmacy in Phase I and II, in different category of prescribers, and in different combinations of polypharmacy. 559 prescriptions were enrolled in Phase I and 605 in Phase II. Total polypharmacy of antihistamines in Phase II was significantly reduced to 82 from 238 in Phase I ( $p < 0.01$ ). The rate of polypharmacy prescribed by doctors was 10.3% in Phase II compared to 46.5% in Phase I ( $p < 0.01$ ). The most common polypharmacy occurred appears to be combination use of diphenhydramine and chlorpheniramine in both phases, which were 21.5% and seven percent respectively ( $p < 0.01$ ). The reduction in polypharmacy of antihistamines in cough and cold products used among children aged below six can be achieved by means of a systematic and comprehensive intervention and collaboration between healthcare staffs though the results obtained may be limited by certain factors.

# Acinetobacter in Pre-Term Labour

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## SUMMARY

Genital infection is the most common cause of pre-term labour. Acinetobacter infection is associated with several adverse fetal outcomes including high mortality. Acinetobacter sp causing pre-term labour is inadequately studied. The infection is resistant to commonly used antibiotics, but is responsive to gentamycin, amikacin or tobramycin. The aim of this study was to study the incidence of women with pre-term labour due to Acinetobacter species, as compared to normal term pregnancies. Sixty-two normal term pregnant and 50 pre-term labour patients were recruited. The patients were recruited from the labour rooms, obstetric wards and antenatal clinics, of the Selayang Hospital, from May 2009 to June 2009. Vaginal swabs were collected and analyzed by microbiological cultures, biochemical tests and PCR done at the microbiology labs of the faculty of medicine UITM and HUSM, Kubang Kerian, Malaysia. Student T tests and SPSS1 were used for analysis. The organisms isolated from the control group were Staph Aureus in 94%, Klebsiella pneumonia in 3% and E Coli in 3%. In the study group the organisms cultured were GBS in 10% (5/50), Staph aureus in 2.5% (5/50), E Coli in 2% (1/50), Pseudomonas in 2% (1/50), Candida in 24% (12/50) and Acinetobacter in zero cases. There were 36/112 cases where no growth was found. There were no isolates positive for Acinetobacter sp. in either group. The peri-natal outcome in pre-term labour cases was poorer as compared to normal labour—the birth weight being 2.15 kg as compared to 3.2 kg, and apgar score 8 versus 7.69 ( $p < 0.05$ ). In conclusion, Acinetobacter is not a common isolate in cases of pre-term labour.

# The Risk Factors Differ Between Ischemic Stroke and Haemorrhagic Stroke - We Anticipate A Higher Proportion of Ischemic Patients Have Higher Lipid Levels With Smoking Habits

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## SUMMARY

This study analyzed the demographics and risk factor prevalence in Penang General Hospital and to test the hypothesis which states that there is a higher proportion of ischemic patients have higher lipid levels with smoking habits. This was a cross-sectional retrospective study. All patients admitted to Penang General Hospital (PGH) between 1 January 2008 and 30 June 2008 with a clinical diagnosis of stroke were included in the study. Data from the study was collected from the stroke registry. The stroke registry was made up of a series of well-designed questionnaire and the form was filled up by a trained medical personnel. We also looked back into patients' case notes and carried out telephone interviews to fill up some missing data from the stroke registry. Retrospectively, the demographics of patients were analyzed. The data gathered included the name, identity card number, date of birth, gender, ethnicity, stroke event, types of stroke, classifications of stroke, risk factors, LDL-levels, medications and status at discharge. 266 patients were included in the study. 220 (82.7%) have ischemic strokes and 46 (17.3%) patients have intracerebral haemorrhage strokes. 90 (40.9%) patients have LACI, 47 (21.4%) patients have PACI, 8 (3.6%) patients have TACI, 7 have POCI and 68 (30.9%) patients were unable to be classified. The mean age was 62.52 with a standard deviation of 12.05. 26.7% of patients were 70 years old and above. There were 161 (60.5%) male patients and 105 (39.5%) female patients. There were 158 Chinese patients (59.4%), 77 Malay patients (28.9%) and 31 Indian patients (11.7%). There were 222 (83.5%) patients who were hypertensive, 125 (47%) had diabetes mellitus, 180 (67.7%) had high LDL levels, 77 (28.9%) ( $P < 0.01$ ) had prior stroke, 13 (4.9%) had atrial fibrillation, 21 (7.9%) had Ischaemic Heart Disease, 4 (1.5%) had Valvular problems, 14 (5.3%) consumed alcohol regularly and 86 (32.3%) of them smoked cigarettes ( $P < 0.01$ ). The number of patients who were alive at discharge was 232 (87.2%). We concluded that hypertension, hyperlipidemia and diabetes are the major risk factors which are prevalent in this region. There seemed to be an upward trend towards ischemic strokes. We also concluded that hyperlipidemia does not favour any subtypes of stroke and smoking favours haemorrhagic stroke in this study.

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# Distinguishing Dengue Fever from Other Febrile Illnesses Using Logistic Regression Analysis

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## SUMMARY

The aim of this research paper was to determine the early indicators in the beginning of the febrile phase. Specifically, it intends to identify early markers for dengue within the first 72 hours from the onset of fever among the adult patients enrolled in the Early Predictors of Dengue (EPOD) study. This is to avoid late recognition of the disease and mismanagement of the patients because it is hard to differentiate dengue cases from other febrile illnesses (OFI) at the early phase. The method of logistic regression was applied to distinguish the patients into dengue and OFI groups based on the clinical symptoms and laboratory parameters. The result shows that history of neighbour exposure, flushing, total white blood cells and the interaction term of history of neighbour exposure with serum osmolality correctly classify dengue cases from OFI with an optimal sensitivity of 81.25% and specificity of 81.67%. The area under the receiver-operating-curve (ROC) also shows that the model has an excellent discrimination. The interaction effect implies that patients from an endemic area are more likely to be infected by the disease. The counterpart of the interaction term, serum osmolality is a novel discovery for dengue. One possible cause is the altered appetite of the dengue patients. The final model is competent with the suggestions for early indicators of the disease stated in various guidelines and other researchers' works.

# The Study of Correlation of Quality of Life Assessment with Visual Function Among Kelantan Glaucomatous Patients

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## SUMMARY

Glaucoma not only affects visual function but it also affects patient's health related quality of life. Only minimal information is known about the impact of glaucoma on the quality of life of the patients. Quality of life is an outcome measure which is difficult to quantify by the doctors but for the patients it is very important. Every patient should be asked about his or her perception of on current status and also the difficulties he or she faces with daily tasks. Currently, questionnaires are used as the health related quality of life instruments. Only few studies have done to assess the correlation between the two. The aim of the study was to evaluate the reliability of the modified National Eye Institute Visual Function Questionnaires (NEI VFQ 25) in the Kelantan glaucomatous patients and to correlate the modified NEI VFQ 25 and utility analysis to the visual field and visual acuity impairment. A cross sectional study of the correlation of quality of life assessment with visual function among Kelantan glaucomatous patients was conducted from April to October 2006. A pilot study was done for reliability assessment on the translated questionnaires. After that a study was conducted on 134 glaucomatous patients using the modified NEI VFQ 25 and utility analysis questionnaires. Cronbach's  $\alpha$  for the modified NEI VFQ 25 was 0.740, indicating moderate internal consistency. The total modified NEI VFQ 25 showed significant positive correlation with Esterman binocular visual field ( $P < 0.001$ ). A significant negative correlation noted between modified NEI VFQ 25 score with LogMAR visual acuity in the better eye ( $P = 0.009$ ) and also with LogMAR visual acuity in the worse eye ( $P < 0.001$ ). Modified NEI VFQ 25 subscale showed higher correlation with the visual acuity in worse eye compared to better eye. Modified NEI VFQ 25 subscale showed low to strong correlation with Esterman binocular visual field. A significant negative correlation was noted between modified utility analysis with LogMAR visual acuity in the better eye ( $P = 0.010$ ) and also with LogMAR visual acuity in worse eye ( $P < 0.001$ ). A significant positive correlation was noted between modified utility analysis with Esterman binocular visual field ( $P < 0.001$ ). The validity and reliability of the modified NEI VFQ 25 were shown to be sufficient. This questionnaire is applicable to the Malay-speaking population as quality of life instrument. A significant correlation noted between modified NEI VFQ 25 with visual field and visual acuity of glaucoma patients. The modified utility analysis also showed significant correlation with visual field and visual acuity of glaucoma patients.

# Improving Asthma Care in Ministry of Health Primary Care Clinics

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## SUMMARY

The goal of asthma treatment should be optimum asthma control. This study was carried out to improve asthma management among adolescents and adults attending Ministry of Health Primary Health Care clinics, in Kinta and Batang Padang Districts with the use of the Asthma Control Test (ACT) as part of asthma plan and asthma handbook to educate and patient self empowerment. This was a non-controlled convenient quota sampling community trial. A total of 634 asthmatics were intervened using the intervention package which consist of the Management of adult asthma based GINA Revised 2006, Modified management approach based on asthma control, PEF monitoring at every clinical visit and the use of Peak Flow Chart for the health care provider to determine the level of lung function, Asthma Control Handbook to reinforce education to the patient which include Asthma Action Plan based on ACT score for patient self assessment and Asthma treatment Record. Of the total 634 respondents, 516 (77.1%) completed the study. Comparing the baseline and post intervention sociodemographic characteristics, there is no significant difference between gender, ethnicity and age group between these two groups. Majority of them were Malays, female and aged between 40 to 50 years old. At baseline 35.8% of asthmatics were controlled, 35.6% had a Peak Expiratory Flow Rate less than 60% (of best predicted value) and 67.5% were on preventer medication. Post intervention, the proportion of those with asthma controlled significantly increased to 52.9%, those with a Peak Expiratory Flow less than 60% (of best predicted value) decreased to 26.8% and those on preventer medication increased to 85.9%. Furthermore proportion of patients with uncontrolled asthma reduced from 25.6% (95%CI 22-29) to 13.8% (95%CI 11-17). After the intervention, the asthmatic control among those of Indian ethnicity significantly improved from 25% (95%CI 18-31) to 42% (95%CI 35-50). Those aged 41-50 years also showed a significant degree of improvement from 41% (95%CI 33-49) to 59% (95%CI 51-67). Only one third of the asthmatics were controlled at baseline. The overall rate of asthmatic control for those patients who complete the intervention improved from 39.7% (95% CI 35 - 44) to 52.9% (95% CI 49-57). The proportion of patients with uncontrolled asthma reduced from 25.6% (95% CI 22-29) to 13.8% (95% CI 11-17) and the used of preventer medication increased from 67.5 to 85.9%. After the intervention, the asthmatic control showed a significant degree of improvement especially among those of Indian ethnicity and 41-50 years age group. Overall, the intervention package used in this study was effective in improving asthma control.

# Clinical Characteristics of Patients with Leprosy in Hospital Kuala Lumpur

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## SUMMARY

Leprosy is a chronic granulomatous infection, caused by *Mycobacterium leprae*, principally affecting the skin and peripheral nervous system. In Malaysia, leprosy remains to be a disease burden despite a tremendous reduction in its prevalence in the past 20 years. The proportion of foreigners diagnosed with leprosy from the total new cases in Malaysia was rising from 24.5% to 44.0% from year 2000 to 2007. The increasing trend was attributed to the influx of foreign workers. We aim to compare the clinical characteristics of patients with leprosy between the Malaysians and foreigners. A retrospective review was conducted using data retrieved from medical records of all patients diagnosed with leprosy in the 'Hansen Clinic' between year 2006 and 2009. This review focused on demography, classification, deformity, lepra reaction and drug resistance. A total of 75 patients (aged from 10 to 75 yrs) were reviewed. Fifty-one percent of the patients were foreigners who originated from Indonesia (92%), Thailand (5%) and Myanmar (3%). Malaysians distribution by race ; Malay 38%, Chinese 38%, Orang asli 16%, Bumiputera 5% and Indian 3%. Thirty-five percent of Malaysians were diagnosed with Lepromatous Leprosy (LL) followed by 24% with BT, 22% BL, 8% TT, 5% indeterminate, 3% each with BB and neural leprosy. Foreigners were diagnosed with BL 34%, followed by LL 29%, BT 21%, BB 10 %, and 3% each with TT and neural leprosy. Fifty percent of Malaysian were diagnosed with grade 1 neurology deformity and 8% were diagnosed with grade 3. Twenty-one percent of foreigners presented with grade 1 deformity and 8% with grade 3 deformity. In overall patients who developed reactions, 22 patients were diagnosed with type 1 reactions, 27 patients with type 2, and 2 patients with lucio reaction. Full dapson resistance was confirmed by mouth foot-pad culture in one Malaysian. The disease severity, and occurrence of deformity, reaction and drug resistance among the Malaysian and foreigners (permanent resident and non-Malaysian) was comparable. Surprisingly most Malaysian presented later than 1 year since onset of symptom, hence may contribute to the similar percentage of Malaysian patient found to have grade 3 deformity at presentation with those of foreigners. Percentage of full drug resistance to the first line multi drug therapy in Hospital Kuala Lumpur is well below 5% even without fully implementing the "Directly Observe Therapy".

# Central Aortic Systolic Pressure and Biochemical Profile of Young Hypertensives in Rural Malaysia

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## SUMMARY

Hypertension is being identified in younger population. The prevalence of hypertension in Malaysia is 42.6% which contributes to the rising incidence of cardiovascular disease. The objective of the study is to assess the central aortic systolic pressure (CASP) and cardiovascular risk profile of young hypertensives in rural Malaysia. A total of 484 subjects were screened at a primary health care clinic in Kuantan, Malaysia. 97 subjects between the ages of 20 and 40 with systolic and diastolic blood pressure ranges of between 120 - 159 mmHg and 80 - 99 mmHg respectively and age-matched controls were enrolled into a cross-sectional, observational study. The cardiovascular risk-factor profile and CASP was assessed and compared in both groups. A total of 57 subjects and 40 controls were enrolled. The mean age were  $32.74 \pm 5.78$  versus  $31.05 \pm 5.45$  years ( $p=0.151$ ), mean values for arterial pressure  $102.10 \pm 7.37$  versus  $82.24 \pm 6.11$  mmHg ( $p < 0.001$ ), total cholesterol  $5.82 \pm 0.96$  versus  $5.46 \pm 0.97$  ( $p=0.076$ ), low-density lipoprotein  $3.73 \pm 0.86$  versus  $3.28 \pm 0.86$  ( $p=0.015$ ), fasting blood sugar  $4.67 \pm 0.75$  versus  $4.35 \pm 0.42$  ( $p=0.013$ ), body mass index  $28.72 \pm 5.24$  versus  $23.18 \pm 3.96$  ( $p < 0.001$ ) and CASP  $122.83 \pm 9.58$  versus  $100.28 \pm 6.94$  mmHg ( $p < 0.001$ ). In conclusion, both the cardiovascular risk factor profiles and the CASPs were significantly higher in young hypertensives compared to age-matched controls.

# Acute Coronary Syndrome in Women of Reproductive Age

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## SUMMARY

There is scarce or no data on prevalence and presentation of acute coronary syndrome (ACS) among women of reproductive age. Furthermore, whether women of reproductive age presenting with ACS have the same risk factors from men and older women is not known. The objective was to analyze factors associated with ACS in women of reproductive age in comparison to older women and men of similar age group. Acute coronary syndrome were analyzed over a three-year period (2006-2008) from the NCVD database covering 9702 cases with focus on the women of reproductive age (20-<40 years), looking into association with ethnicity, co-morbid illness and the ACS stratum. Comparison with older women (40-<60 years) and men of similar age group were made and analyzed using Fisher's exact test and chi-square test when necessary. From a total of 9702 cases, 2344(24.2%) were women. Of these, 45(1.9%) were women between 20-<40years, which is significantly lower than the two controls (30.8% and 6.2% respectively),  $p<0.0001$ . The distribution of ethnicity shows similar pattern between the study group and the controls, but patients of Indian ethnicity were over-represented (31.1% vs 40% for Malays and 22.2% for Chinese) when compared to the Malaysian demographics of general population. ACS in women of reproductive age was associated with diabetes mellitus in 37.8%, hypertension in 40.0% and dyslipidemia in 24.4% of cases, similar to men of the same age but significantly lower than the older women ( $p<0.0001$ ). Smoking is not a major risk factor in the study group where only 6.7% ever smoked, similar to older women (6.8%,  $p=1.000$ ) and significantly much less compared to men of same age (84.1%,  $p<0.0001$ ). Regarding the ACS stratum, significantly higher percentage of women in the study group had STEMI compared to older women ( $p=0.0085$ ) but less than that of men of similar age ( $p=0.0187$ ). In conclusion, ACS is rare in women of reproductive age. Diabetes, hypertension and Indian ethnicity were identified as important contributors.

# Obesity is Prevalent Among Patients with Colorectal Cancer

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## SUMMARY

Obesity is a significant contributor to several chronic diseases including some cancers. Colorectal cancer (CRC) is the commonest cancer among males (21.6%) and second among females (15.4%) in Peninsular Malaysia and Chinese recorded the highest incidence (21.4%). Nutrition surveys show an increase in the prevalence of obesity from 10% in 1996 to about 14% in 2006 in Malaysian adults. This study aimed to determine the prevalence of obesity in patients with CRC and to examine the prevalence of obesity in relation to sex, ethnicity and cancer characteristics. Subjects ( $n=113$ ) were CRC patients who were recruited for a case control study from Hospital Kuala Lumpur, Hospital Selayang and Hospital Putrajaya in between January 2008 to January 2010. Obesity was determined using body mass index (BMI) ( $>30\text{kg/m}^2$ ), waist hip ratio (WHR) ( $>0.9$  in men and  $>0.85$  in women), waist circumference (WC) ( $\geq 90\text{cm}$  for men and  $\geq 80\text{cm}$  for women) and percentage of body fat (BF) ( $>25\%$  in men and  $>35\%$  in women). The study included 58% males and 42% females with a mean age of  $60.6 \pm 13.3$  years and  $56.9 \pm 14.6$  respectively. The subjects comprised of 43.3% Chinese, 39.8% Malay and 15.9% Indians. The mean BMI, WC, and BF were  $24.0 \pm 4.7\text{ kg/m}^2$ ,  $91.0 \pm 2.3\text{ cm}$  and  $30.3 \pm 9.8\%$ , respectively. The mean duration of cancer diagnosis was  $18.3 \pm 2.4$  months. Our study showed that WC detected a higher prevalence of obesity of up to 71.1% than BMI, WHR and BF (38.9%, 53.1% and 65.5% respectively). The prevalence of obesity was higher among male CRC patients using BMI (41.6%), WHR (34.5%), BF (44.2%) and WC (43.4%). There was a steady increase in the prevalence of obesity with advancement in age both in men and women. Gender (male) was significantly associated with obesity where BMI ( $\downarrow 2=4.661$ ,  $p=0.031$ ), WHR ( $\downarrow 2=7.488$ ,  $p=0.006$ ) and ( $\downarrow 2=4.887$ ,  $p=0.027$ ). Abdominal obesity was highest in subjects with stage 1 CRC (36.3%), ascending CRC (44.2%), in those diagnosed more than 12 months ago (25.7%). Most obese subjects did not have a history of malignancy (54.9) and no association was observed ( $\downarrow 2=2.667$ ,  $p=0.862$ ). The study showed that the stage and site of CRC were significantly associated with obesity ( $\downarrow 2=15.328$ ,  $p=0.000$  and  $\downarrow 2=5.912$ ,  $p=0.042$  respectively). Two common symptoms (rectal bleeding and abdominal pain) were significantly associated with WC ( $\downarrow 2=2.234$ ,  $p<0.05$ ) and WHR ( $\downarrow 2=4.122$ ,  $p<0.05$ ). Abdominal obesity as defined by WC or WHR has been shown to be more strongly related to common symptoms of CRC. No association was observed between ethnicity, stage and duration of cancer diagnosis with obesity. This study showed a high prevalence of obesity among CRC patients and stage, site and symptoms are associated with it. A prospective study design should be done to examine the association between various indicators of obesity with CRC.

# Nutritional Status, Diet and Lifestyle Practices Among Patients with Colorectal Cancer

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## SUMMARY

A cross sectional study was conducted to assess the nutritional status, diet and lifestyle practices among 122 newly diagnosed patients with colorectal cancer (59% male and 41% female). This study was carried out at Hospital Kuala Lumpur, Hospital Selayang, Hospital Putrajaya and Hospital Pulau Pinang. Height and weight were measured using the SECA Bodymeter and the TANITA weighing scale respectively, and compared to body mass index (BMI) classifications by World Health Organization. Data was obtained on socio-demographic background and lifestyle behavior through interviews using a pre-tested questionnaire. Dietary intake was determined using the 24 hour dietary recall. Physical activity was assessed using the Global Physical Activity Questionnaire (GPAQ). The data was analyzed using SPSS version 6.0 and Nutritionist Pro version 2.0 was used to analyze subject's nutrient intake. The mean age of the respondents was 58.33±13.84 years old. The majority of the respondents were Chinese (41.8%) followed by Malay (37.7%) and Indian (20.5%). About 44.3% patients were diagnosed with stage one cancer, 40.2% patients with stage two and 15.6% patients with stage three cancer. The results showed that the prevalence of underweight and normal weight were 8.2% and 33.6% respectively, while the prevalence of overweight and obesity were 17.2% and 7.4% respectively. For dietary practices, only 0.8% of respondents consumed fat less than 30% from total energy intake/day and majority of the respondents consumed fiber less than 25g/day. While for lifestyle practices 31.2% of respondents smoked more than 20 cigarettes/day, 23.8% of respondents consumed alcohol more than two drinks/day and only 19.7% of respondents did physical activity (moderate-intensity sports) for at least 30 minutes/day. In conclusion, colorectal cancer is considered a disease that can be prevented through a well-balanced diet and proper levels of exercise. Therefore, a diet and lifestyle intervention is recommended for this group in order to improve their nutritional status which may help in reducing their risk of cancer recurrence and metastasis in the future.

# Preliminary Data from a Study on C. Trachomatis Cervical Infection in Pregnant Women with Pre-Term Complications and Still Birth

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## SUMMARY

Chlamydia trachomatis is a bacteria that affects both sexes, although a high proportion remain asymptomatic. It primarily infects the fallopian tube, urethra and cervix of women and urethra of men resulting in a spectrum of clinical manifestation including pelvic inflammatory disease, ectopic pregnancy and infertility. It may also be a risk factor for antenatal complications and low birth weight. The objective of our study was to determine the prevalence of C. trachomatis cervical infection in pregnant women who had pre-term complications and still birth. Our diagnosis was made based on DNA amplification using polymerase chain reaction-enzyme-linked immunosorbent assay (PCR-ELISA) and nested PCR methods. We also compared the sensitivity and specificity of both methods. A cross sectional study was carried out from August 2008 to December 2009 in the maternity wards of Kajang and Serdang hospitals. A total of 70 pregnant women of less than 36 weeks of gestation diagnosed as having PPRM, pre-term contraction, pre-term delivery and still birth agreed to participate in the study. Endocervical cells obtained were subjected for DNA isolation and amplification using PCR-ELISA (Roche, USA) and Nested PCR (BioSewoom, Korea). The majority of patients presented with pre-term contraction (n=37), followed by PPRM (n=16), pre-term delivery (n=12) and still birth (n=5). Thirty six out of 70 specimens (51.4%) were detected as positive for C. trachomatis. Mean age for positive and negative respondents were 27.75 (+5.83) and 29.29 (+6.22) years old respectively. Nested PCR was compared with PCR-ELISA for sensitivity and specificity in detecting C. trachomatis DNA. Kappa statistics obtained was  $\kappa=0.086$  suggesting that very poor agreement was seen between both methods. Fisher's Exact Test showed no significant relationship between these two methods at p-value =0.356. In conclusion, these preliminary results showed that PCR-ELISA performed better than nested PCR. As a high prevalence rate of C. trachomatis was found in pregnant women with pre-term complications and still birth, routine screening and treatment of C. trachomatis infection, especially in high risk pregnant women are necessary to reduce perinatal mortality and morbidity.

# Laparoscopic Surgery in the Emergency Setting - The HTAR Experience

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## SUMMARY

Laparoscopic surgery is fast becoming a gold standard for many surgical procedures. Since its inception in the 1980s, a wide range of surgeries can now be carried out safely and effectively with laparoscopy. The types of surgeries range from simple appendicectomies and cholecystectomies to more complex anterior resections and Whipple's procedures. However, the role of laparoscopic surgery in the emergency setting is still unclear. We present our experience in Hospital Tengku Ampuan Rahimah (HTAR) on the use of laparoscopy in emergency surgeries in 2009. The role for laparoscopic surgery in emergency can be generally divided into two; firstly as a diagnostic laparoscopy in cases with unknown pathology and secondly performance of the appropriate surgery laparoscopically in those with confirmed diagnoses. The objective of our study was to show that laparoscopic surgery in the emergency setting is effective, safe and carries a low complication and mortality rate based on the different types of emergency laparoscopic procedures carried out. Data was prospectively collected from all patients who underwent emergency laparoscopic surgeries from January until December 2009. Patient demographic including age, racial distribution, sex, diagnosis, surgical procedure, operative findings, length of hospital stay, complications and follow-up reviews were all entered into our proforma sheets. These data was then entered into our computer and tabulated using Microsoft Office Excel 2007. A total number of 62 patients were collected. There were 22 diagnostic laparoscopies, four laparoscopic drainage and lavage, 18 laparoscopic appendicectomies for perforated appendicitis and six for acute appendicitis, nine laparoscopic repair of perforated peptic ulcer, and seven laparoscopic adhesiolysis. Our results noted a reduction in hospital stay and low complication rates and only three documented mortalities. Laparoscopic surgery in the emergency setting is recommended in certain common conditions such as appendicitis, adhesiolysis and perforated peptic ulcers. Diagnostic laparoscopy is shown to be highly sensitive and specific in diagnosing patients with unclear pathologies. Laparoscopic surgery is safe, effective, less painful for the patient, reduces hospital stay and patients have a more cosmetically acceptable scar. However, its role in unstable patients and more complex conditions is still unclear. More studies need to be done to assess its efficacy and to justify its use in such patients.

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# Sorry for not Smiling at You - Moebius Syndrome

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## SUMMARY

We report a case of an extremely rare congenital neurological disorder, Moebius Syndrome. An eight year old Malay girl presented in our eye clinic at Hospital Sultanah Bahiyah with congenital bilateral small esotropia and restricted lateral gaze. She was a normal term baby. On examination, the patient was discovered to have a complex deformity of a complete facial paralysis. She cannot smile, frown, or suck and she is a partial blinker. Besides that, the patient also having left limb and chest abnormalities so called "Poland Syndrome". Patient who been diagnosed to have Moebius Syndrome by eye team is a neurological genetic disorder, typically affecting the sixth and seventh cranial nerves that responsible for lateral eye movement and facial expression. However, her mental development was normal and she performed quite well in school. Visual acuity in both eyes were 6/9. Patient attitude and social interaction was similar other normal children. Despite the inability to smile or to form facial expressions, their intelligence is normal. Moral support and public awareness of understanding Moebius Syndrome patients will diminish all misinterpretation of them being unfriendly.



# Disease Extent and Resection Margin Involvement in Colorectal Cancer Patients - A Pathologic Report from NCPR-Colorectal Cancer

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## SUMMARY

Surgical resection is the primary treatment modality for early stage colorectal cancers (CRC). Accurate staging is important to determine the best treatment for individual patient. The most powerful tool for assessing prognosis, following potentially curative surgery, is accurate pathologic analysis of the resection specimens. This helps to predict risk for local recurrence and survival, as well as in identifying patients who need adjuvant therapy. The aim of the study was to assess the extent of disease based on pathologic staging of resected CRC specimens and the rates of histopathologic involvement of surgical margins (cut end and circumferential/non-peritonealized) in CRC resection specimens. Data was gathered from National Cancer Patient Registry (NCPR)-Colorectal Cancer, involving 15 Source Data Providers throughout Malaysia. Information on proximal and distal (cut end) margins, including doughnuts, non-peritonealized/circumferential margin and pathologic tumour stage were obtained from pathology records of patients who had had bowel resection for CRCs. For this study, a total of 751 records between October 2007 and April 2010 were analyzed. Pathologic tumour (pT and pN) stage was assessable in 693 cases. Of that, only 79 (11.4%) had tumours that were confined to bowel wall (pT1N0 or pT2N0). The majority of patients (88.6%) presented with tumours that had either locally spread beyond the muscularis propria (pT3N0, pT4N0) or metastasized to regional lymph nodes (pT1N1/N2, pT2N1/N2, pT3N1/N2, pT4N1/N2). Separately considered, 84.7% of these patients were in either pT3 or pT4 stage and 52.1% had regional node metastases. Tumour involvement at resection ends was noted in 45 out of 751 cases (6%). Information on circumferential margin was available for 216 rectal cancers and 43 (19.9%) were reported as involved. Records on non-peritonealized margin for colonic cancers were available for 300 cases, of which, 42 (14%) were involved. Most of the CRC patients in this registry had tumours that had extended beyond muscularis propria (pT3 and pT4), and approximately half had lymph node metastases. Only 11.3% had tumours confined to the bowel wall, suggesting that the majority had either presented late or had had more aggressive tumours. A significant proportion of cases had involvement of circumferential/non-peritonealized margin (19.9% of rectal and 14% of colonic cancers). Many studies have shown that positive circumferential margin predicts both tumour recurrence and survival. Involvement of non-peritonealized/circumferential margin may also indicate the quality of surgery that was performed. For rectal tumours, total mesorectal excision (TME) technique and preoperative neo-adjuvant chemoradiotherapy are important contributory factors to optimum surgical treatment. Making oncology services more easily available, at least in all tertiary hospitals, may help to improve in management of these deadly cancers.

## POSTER ABSTRACTS - HEALTH BEHAVIOR

- PHB01** The Effectiveness of COMBI (Communication for Behavioural Impact) in Controlling and Preventing Dengue in Hulu Langat District, Selangor 2008
- PHB02** Knowledge And Attitude of Dental Health Care Workers Towards Smoking

# The Effectiveness of COMBI (Communication for Behavioural Impact) in Controlling and Preventing Dengue in Hulu Langat District, Selangor 2008

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## SUMMARY

Communicable diseases represent a significant proportion of the health burden in developing countries. Different approaches to encourage the adoption of healthy behaviors among individuals, in households and at a community. The World Health Organization (WHO) has begun applying an approach known as COMBI (Communication for Behavioral Impact) in the design and implementation of behavioral-focused social mobilization and communication programmes in tackling communicable diseases. The main objective of this study was to evaluate the effectiveness of the COMBI programme in preventing and controlling dengue in section 3 and 4 of Bandar Baru Bangi. A cross sectional study was carried out on a total of 250 respondents were selected from Section 3, 4 and 5 of Bandar Baru Bangi, Selangor. The study had qualitative and quantitative components which compared perception (knowledge, attitude and practice) between community with COMBI (Section 3 and 4) and community without COMBI (Section 5). The study showed that the programme was a success only during the implementation weeks. After five years, there was no significant different in KAP between the groups. (knowledge  $p = 0.30$ , attitude  $p = 0.38$  and practice  $p = 0.83$ ). The COMBI programme did not have a positive behavioural impact on dengue prevention and control in Hulu Langat Selangor. In order to make the programme more effective and sustainable, the health authorities should improve awareness and empower the community with knowledge on the important of dengue prevention and disease complications.

PHB02

# Knowledge And Attitude of Dental Health Care Workers Towards Smoking

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## SUMMARY

Smoking is a common problem in the underdeveloped and developing countries. Dental health care workers as part of the health care workers as a whole, must have good knowledge regarding smoking so that they can convey messages to the public. The aim of this study was to investigate the association between knowledge, attitude and smoking habits among dental health care workers using a self administered questionnaire. Sixteen statements were given to assess the participant's knowledge and attitude regarding smoking. The mean difference between the smokers group and non-smokers group were compared. A total of 720 out of 780 responded to the questionnaire giving a response rate of 93.3%. The prevalence of current smokers was 13.8%. It was found out that knowledge and attitude was significantly associated with smoking status, gender, level of education, income and occupation ( $p < 0.05$ ). The study concluded that dental health care workers have a good understanding regarding smoking where their score for 15 out of 16 questions were above 70%. Knowledge and attitude of non-smokers were found to be higher as compared to the smokers. Continuous health education might help in increasing their knowledge.

## POSTER ABSTRACTS - HEALTH SYSTEM

- PHS01 Willingness to Use Insulin in Type 2 Diabetic Patients
- PHS02 Service, Facility, Procedure and Equipment-Profiles of Malaysian Primary Care Clinics
- PHS03 Sharps Injuries - How Do We Manage?
- PHS04 Dispensing - The Quest for Zero Defect
- PHS05 Getting Research into Practice – Vaccine Storage in MOH Health Clinics
- PHS06 Boleh Balik!
- PHS07 Fallers and Near Fallers – Who are They?
- PHS08 Wheelchairs – Give Me A Brake!
- PHS09 How Safe are our Hospital Washroom Floors?
- PHS10 Hospital Beds - How Safe are They?
- PHS11 Hospital Washrooms – Dare you go in?
- PHS12 Walking Aids – What do we have in MOH Hospitals?
- PHS13 Inpatient Preferred Footwear - Shoes or Barefoot?
- PHS14 Safety Culture in Elective Surgery - Do Patients Participate?
- PHS15 The Patient’s Perception - Patient Safety and Rights
- PHS16 Improving Notification of Critical Laboratory Results
- PHS17 Prescribing Errors – How do Hospital Outpatients Fare?
- PHS18 Facilitating Equity and Efficiency in Malaysian Primary Health Care Through the Application of the ACG® Case Mix System
- PHS19 National Medical Research Registration - An Innovation

# Willingness to Use Insulin in Type 2 Diabetic Patients

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## SUMMARY

Insulin therapy has proven benefits in type 2 diabetic patients when oral therapy fails. However, initiation of insulin therapy is often delayed due to a various reasons including patients' reluctance to accept insulin therapy. This reluctance has been termed 'psychological insulin resistance' or PIR. As very little is known about the local incidence of PIR, a study was conducted this study to examine patients' willingness to take insulin if prescribed and to identify perceived attitudinal barriers to insulin therapy. A cross sectional descriptive study was conducted in two outpatient health clinics in Kuala Lumpur and Putrajaya. There was a total of 404 type 2 diabetic patients who were not on insulin therapy. A pre-designed self-administered questionnaire was used to obtain patient demographic characteristics, diabetic status and, insulin knowledge and perception. The questionnaire was tested for reliability and validity. Eighteen attitudinal belief items were used to assess patients' perceptions of insulin treatment on a five -point Likert scale. Total score may range from zero to 72. Two way tabulation were obtained to compare the willingness to accept insulin therapy between different socio-demographic characteristics. Step-wise logistic regression was used to identify predictive factors of patients' willingness to accept insulin. The results revealed that 50.7% of the respondents were unwilling to accept insulin therapy, if prescribed. From the 18 negative attitudinal beliefs, the mean number of negative belief counts that the respondents have was 5.89 (5.55, 6.23). Total score of attitudinal beliefs assessment ranged from six to 61 with a mean score of 36.2 (35.4, 37.0). The most frequently expressed negative attitudes about insulin were personal failure (59.2%), feeling of embarrassment (55.9%) and anticipated pain (50.7%). Unwilling subjects had a higher percentage of negatively stated items . Predictors for willingness to accept insulin were gender, diabetic status, how patient's perceived insulin benefit, and negative belief counts. Males were two times more willing to accept insulin than females. Those who perceived and understood the benefits of insulin were four times more willing to accept insulin . The experimental diabetic group showed 60% resistance towards insulin treatment compared with those in the control group. One strong negative belief will reduce the patient willingness by 15%. The Nagelkerke R Square for this model was 0.24 which indicated that this model explains 24% of the difference of willingness to accept insulin between respondents. The results identified several remedial misconceptions regarding insulin therapy and suggest targets for educational interventions.

PHS02

# Service, Facility, Procedure and Equipment-Profiles of Malaysian Primary Care Clinics

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## SUMMARY

Private general practitioners and government health clinics are the main providers of primary health care in Malaysia. The aim of this study was to provide clearer information on the resources at these centres in terms of facilities available ,services provided, procedures performed and equipment-profiles of these two sectors. This was a cross sectional study conducted on 114 private and 100 public clinics. Data was obtained using a self administered questionnaire. The response rate was 82% and 33% in the public and private sectors respectively. We found that the proportion of clinics providing a comprehensive range of facilities, services, procedures and equipments, was higher in the public sector (98 from a total of 152 variables). These included the provision of emergency, wellness and health promotion services, use of chronic disease registries, and being equipped with HIV test kits and sharps disposal bins. Private clinics, conversely, were more likely to provide certain specialized services (like occupational and sports medicine, and foreign worker medical examination), use information and communications technologies (ICT), and keep family-centred patient records. These findings revealed a gap between public and private sectors services. We suggest that these findings could be explained by economic and social (e.g. legal or administrative) reasons. Compared with earlier studies, the proportions of private clinics providing some services (such as addiction services or vaccinations) have in fact reduced. The challenge to universal coverage that these findings represent suggest that remedial policy options that involve both public and private sectors might need to be considered, which could alternately expand or constrict either of these sectors. The challenges to the generalizability of this study, however, limit the usefulness of these findings.

## Sharps Injuries - How Do We Manage?

**M Siti Haniza\***, **K Suresh\*\***, **U Noorhaida\***, **Z Jameela\*\*\***, **A B Nor' Aishah\*\*\*\***, **N M Nik Jasmin\*\*\*\*\***, **R Priya\*\*\*\*\***, **H Sirajuddin\*\*\*\*\***, **A Surinah\*\*\*\*\***, **M S Siti Aisah\***, **B Norsiah\***, **K Siti Azlina\***, **K N Thien\***

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### SUMMARY

Management of occupational hazards has been a priority to most organizations and sharp injuries is a known potential risk to health care workers (HCW). With the risks of infections to the workers and patients alike, the aim of the study was to protect the safety of our workers. This study was undertaken in 2007 and looked at the measures taken by the hospital management in handling these situations. A cross sectional survey using a self-administered questionnaire was sent to 55 hospital directors in four states in Malaysia. They were required to detail their management practices relating to sharps injuries. A response rate of 75% was obtained. The findings showed that there were variations in the management of sharps injuries during and after office hours; variation in the site of keeping the records; person responsible and variation in the frequency of data analysis and presentation to hospital directors. It was recommended that a uniform management of sharps injuries protocol be established to improve reporting. There is a need for an avenue to present data on sharps injuries regularly so that these workers can be managed appropriately.

PHS04

## Dispensing - The Quest for Zero Defect

**A Samsiah\***, **Z Ramli\***, **S P Leona Tan\*\***, **S V Ong\*\*\***, **H Hafizah\*\*\*\***, **S Siti Fauziah\*\*\*\*\***, **R Norsilawati\*\*\*\*\***, **M A Norliza\*\*\*\*\***, **M D Mohammad Nazri\*\*\*\*\***, **M J Zawiyah\*\***, **M A Kadariah\*\*\*\*\***, **S Saripah\*\*\*\*\***, **G Nor Sharliza\*\*\*\*\***, **M N Mohd\*\***, **M Norhamizah\*\***, **A Muhamad Rashid\*\*\*\*\***, **B Nor Azlina\*\*\*\*\***

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### SUMMARY

Drug dispensing error is a sentinel event which may lead to severe adverse reactions or even patient death. The Pharmaceutical Services Division, Ministry of Health Malaysia (MOH) has been monitoring the "proportion of prescriptions wrongly filled but detected before dispensing to the total number of prescriptions counter-checked at the out-patient pharmacy" as an indicator under its quality assurance programme. The indicator monitors the potential dispensing errors that may happen and the set goal was zero percent which we have yet to achieve. Our objective was to reduce the incidence of potential dispensing errors through appropriate interventions. An intervention study was carried out at three government hospitals under the MOH. Selection was based on the highest shortfall in quality as reported in 2007. Pre-intervention data was obtained by reviewing errors documented from the months of September to November 2008. A cross sectional study was conducted to identify the possible contributing factors. Strategies for improvement were then formulated. An interventional package which consisted of 5S Operational System (5S), Awareness of Best Practice Approach (BPA) and Centralised Quality Dispensing Control (CQDC) were introduced from December 2008 to February 2009 followed by a three-month period to evaluate the impact of these interventions. Of the 97 894 prescriptions in the pre-interventional phase, a total of 354 (0.36%) prescriptions with potential dispensing errors were detected. Human factors, working environment and product packaging were the major factors contributing to errors. Results from post-interventional phase showed a marked reduction in the number of potential dispensing errors at all study centres by 14 to 57%. Intervention package was able to reduce the errors. However, not all components could be institutionalized in all hospitals. Continuous monitoring is needed to ensure sustainability of the remedial measures.

# Getting Research into Practice – Vaccine Storage in MOH Health Clinics

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## SUMMARY

At least two thirds of the Malaysian population, especially children, obtain immunization at Ministry of Health (MOH) primary care facilities. A fault in the cold chain system can lead to an increase in morbidity and mortality from vaccine preventable diseases. There is no available formal data on the quality of vaccine storage practices within the MOH. Although there is a system within the MOH for proper storage of vaccines, policy makers felt there was a need to assess current vaccine storage practices after an audit of vaccine storage in Private Clinics showed inadequate practices. This study's aim was to assess to vaccine storage practices in MOH primary care facilities with respect to WHO guidelines for vaccine storage. We conducted a cross sectional study in three randomly selected administrative regions in Malaysia. All government primary care facilities in the region proving vaccination were evaluated. Audit of storage practices were done by trained government public health nurses from outside that region. Assessment was done based on six assessment criteria taken from WHO guidelines, which included appropriate refrigeration; dedicated refrigerator for vaccines; correct placement of refrigerator and vaccines and; maintenance and monitoring of refrigerator temperature. Although this was a cross sectional study, the audit form used incorporated an immediate feedback component. Hence, nurses and managers were provided immediate feedback by research nurses on the status of vaccine storage and the requirements for good storage practice. A total of 701 primary care units was audited (99.7% response rate). Almost two thirds were a Community Clinic (Klinik Desa). Most units (83.5%) had a designated staff to handle vaccines, majority of who were community nurses. The study provides evidence that 73.8% of clinic refrigerators were in the recommended 2-80C temperature range, 91.9% had temperature monitoring and 95.1% correct placement of vaccine. However, up to a quarter of clinics do not have the recommended refrigerator type, and almost one quarter stored other things besides vaccines in their vaccine refrigerator. Only an negligible 1.9% were able to fulfill all 6 essential criteria. There is a need to improve the quality of vaccine storage in MOH primary care facilities. Results were presented to regional and top level management MOH in 2009 for remedial measures. Actions that have been taken include (1) immediate rectification of vaccine storage methods in the audited states; (2) application for funding for new refrigerators and; (3) training of staff. Future initiatives should include the introducing and routine use of data loggers (continually temperature monitors) to enhance safe vaccine storage.

## Boleh Balik!

**C K K Lim\***, **A A F Lim\***, **M H Ainul Nadziha\***, **A Roslinah\*\***, **S Sararaks\*\***, **S K Chan\*\*\***, **E L Chew\*\*\*\***, **L S Tan\*\*\***, **L L Low\*\***, **A B Azman\*\***, **A H Maimunah\*\*\*\***, **H Irdayu\*\***

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## SUMMARY

Discharge communication involves the transfer of information and materials from healthcare providers to patients/carers at the point of discharge. The information may include admission details, follow-up care plan, medication advice, etc. Materials commonly provided include appointment cards, discharge summaries, health education leaflets, referral letters and investigation request forms if required. The follow-up care of patients discharged from hospitals are shared among patients and their carers (government and private sectors) whose access to adequate discharge information is of paramount importance. In Malaysia, discharge communication is less than satisfactory, and this review is aimed at identifying strategies that are effective in improving discharge communication. The research question was refined with stakeholders. The reviewers consisted of clinicians, public health researchers and a nursing staff, who carried out the review from definition of key research question to creation of appropriate recommendations. PICO method was used to identify the population (P), intervention (I) to be addressed, comparison (C) and outcomes (O) to be addressed. Inclusion criteria took into account the types of studies, participants, interventions and outcome measures. Electronic searches were conducted from December 2007 until April 2008. However, cross referencing continued until April 2009. Hand-searching of non-electronic publication, namely the Malaysian quality initiative/health systems project reports in NIH libraries for studies addressing this area was also carried out. Two levels of screening were done, followed by data extraction and quality appraisal. From the initial search 333 potentially relevant studies were retrieved, of which only 18 met our inclusion criteria. From the 18 studies, only three looked at primary discharge communication outcomes, eight looked at secondary outcomes and 7 looked at both outcomes. Intervention strategies were multi-pronged. Those which significantly improved discharge communication were use of standardized/structured verbal and written information leaflet, use of discharge coordinator/ physician and/or nurse to explain, incorporation of an assessment and feedback on comprehension tool, professional instruction, educational materials, telephone instructions, home visits, post-discharge communication with patients and discharge summary. Effective discharge communication ensures smooth transition of patient from one health care setting to another to ensure continuity of care. This study demonstrated that there are effective strategies to improve discharge communication, Health care providers, both public and private could adopt, adopt and implement an effective approach for discharge communication in hospitals, as a means towards patient safety.

## Fallers and Near Fallers – Who are They?

**F S Lee\***, **S Sararak\*\***, **W K Yau\*\*\***, **A.K. Zulkarnain\*\*\*\***, **Z Mohamad Zaidan\*\*\*\*\***, **L Naing\*\*\*\*\***, **K Thillainathan\*\*\*\*\***, **A T Ng\*\*\*\*\***, **S Salimah\*\*\*\*\***, **A B Azman\*\*\*\*\***, **A H Maimunah\*\*\*\*\***, **A R Chu\*\*\*\*\***, **A Mohd Shahril\*\*\*\*\***, **S Norhayaty\*\*\*\*\***, **W V Vicneas\*\*\*\*\***, **M Sangetavani\*\*\*\*\***

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### SUMMARY

Patient falls represent the third highest reported incidents for the year 2006 to 2008. In addition, falls may lead to physical and psychological injuries. Previous studies on falls were based mainly on reporting by healthcare workers. In addition, near falls were almost always excluded. In this study, we attempt to look into the profile and consequence of the population of local fallers and near-fallers by actively querying the patients themselves. It is hoped that this study will circumvent underreporting and will lead to better understanding of fallers and near fallers so that better preventive measures could be taken in the future. This was a prospective study. All inpatients 60 years and above (except those in the intensive or high dependency care) were questioned daily by research assistants if they fell the previous day. In the event of a fall or near fall, additional information was obtained from the patient, staff and records. Instruments used include the Elderly Cognitive Questionnaire (ECAQ) and Barthel Index. Multistage random sampling of MOH Hospitals was done. Half (48.5%) of fallers were in the 60 to 69 years age group, and 57% of fallers were male. More than half (61.5%) of the fallers could not manage 75% of their basic activities of daily living as assessed using the Barthel Index of (35%) and half (47.5%) of fallers had a previous history of falls. 66% of falls occurred during the twelve hours from midnight to noon. The highest frequency of falls occurred on Sundays, and almost all falls (95%) occurred in the ward. One quarter (24.7%) of patients suffered injuries with half suffering from head. Falls in hospitals mainly occur on Sundays and during the early morning till noon hours. Most of the fallers had history of previous falls and most were functionally impaired in basic activities of daily living. Hence, inpatients with these characteristics will need special attention to prevent a fall while hospitalized.

## Wheelchairs – Give Me A Brake!

**K Thillainathan\***, **F S Lee\*\***, **M Sangetavani\*\*\***, **A R Chu\*\*\*\***, **S Norhayaty\*\*\*\*\***, **A Mohd Shahril\*\***, **W V Vicneas\*\***, **S Sararaks\*\*\*\*\***, **Z Mohamad Zaidan\*\*\*\*\***, **M H Maizatul Azwa\*\*\*\*\***, **A K Zulkarnain\*\*\*\*\***, **A H Maimunah\*\*\*\*\***, **A B Azman\*\*\*\*\***, **J Sarah\*\*\*\*\***

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### SUMMARY

The wheelchair has been in use since 17th century. Despite the safety issues related to use of wheelchairs, not many studies have been carried out. This is part of a larger study on patient safety carried out by trained occupational therapists to audit the wheelchairs used in Ministry of Health (MOH) hospitals, Malaysia. A cross-sectional study was conducted from June till July 2007. Two-stage stratified sampling was used. A total of 40 wards in 20 MOH hospitals were sampled, and all wheelchairs in these wards audited. Functional status of important components of a wheelchair, namely the seat, wheels, castors, brakes and footrests were assessed by trained occupational therapists. The data was analyzed using survey analysis in STATA version 10.0. A total of 150 wheelchairs were assessed; 82.2% in Peninsular Malaysia, 10.2% in Sarawak and 7.6% in Sabah. The most common type of wheelchair audited was the standard non-detachable wheelchair (93.4%). Overall, 58.5% of the available wheelchairs in this study were not in full functional status. When comparing the functional state of wheelchair components (i.e seat, wheels, castor, brake and footrest), the brakes showed significantly higher percentage of non-conformance to safety requirements (47.1% (34.9 – 59.6)) compared to seats (8.7% (4.1 – 17.7)), wheels (12.2% (5.4 – 25.4)) and castor (12.0% (5.1 – 26.0)). A large proportion of wheelchairs had components that did not conform to safety requirements and half of wheelchairs had non-functioning brakes.. This may be due to inadequate maintenance, improper usage and storage. Furthermore, ineffective brakes are potentially hazardous and can lead to unwanted falls. Steps need to be taken to ensure wheelchairs in hospitals are safe for patient use.



## How Safe are our Hospital Washroom Floors?

**M Sangetavani\***, **A R Chu\*\***, **F S Lee\*\*\***, **K Thillainathan\*\*\*\***, **S Norhayaty\*\*\*\*\***, **A Mohd Shahril\*\*\***, **W V Vicneas\*\*\***, **S Sararaks\*\*\*\*\***, **Z Mohamad Zaidan\*\*\*\*\***, **M H Maizatul Azwa\*\*\*\*\***, **A H Maimunah\*\*\*\*\***, **A B Azman\*\*\*\*\***, **J Sarah\*\*\*\*\***

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### SUMMARY

Most incident reports of falls in hospitals highlighted the cause to be attributed caused by the patient's physical condition and/or medications. Many do not point to the floor as the culprit. Wet floors, drop in floor level or clutters on floors all pose a risk of fall to the individual. We aimed to assess this safety aspects in MOH hospitals. A cross sectional study was conducted in mid 2007. Two-stage stratified sampling was used, and 40 wards from 20 MOH hospitals sampled. Floor safety in specified locations in the hospital was assessed in terms of whether it was wet, presence of drop in level or clutter, by trained occupational therapists. Data was analyzed using survey analysis in STATA 10.0. More than 70% of floors at toilets and bathrooms were wet. Similarly, 69.2% of floors around sinks were wet. Inside the toilets, 38.0% of floors have a drop and in the bathroom, this was 30.7%. Clutters were found in 19.2% and 11.8% of toilets and bathrooms respectively. In conclusion, most washroom floors were unsafe in at least one aspect, with wet floors, presence of clutter and drop in floor levels posing extrinsic risk for falls. There is a need to collaborate together to address this problem to make these floors safer for inpatient use.

## Hospital Beds - How Safe are They?

**A Mohd Shahril\***, **S Norhayaty\*\***, **F S Lee\***, **M Sangetavani\*\*\***, **A R Chu\*\*\*\***, **K Thillainathan\*\*\*\*\***, **W V Vicneas\***, **S Sararaks\*\*\*\*\***, **Z Mohamad Zaidan\*\*\*\*\***, **M H Maizatul Azwa\*\*\*\*\***, **A H Maimunah\*\*\*\*\***, **A B Azman\*\*\*\*\***, **J Sarah\*\*\*\*\***

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### SUMMARY

Falls commonly take place in and around the bed, with an estimated one fourth of all falls occurring around beds. Bed height, bed rails or lack of it, and the brake system of beds are external risk factors of falls. This study aimed to assess the safety of Ministry of Health hospital beds. This is part of a cross sectional study in 20 randomly selected hospitals under the Ministry of Health (MOH), Malaysia. This study was carried out by trained occupational therapists, to audit the safety of beds. Three groups comprising of two qualified occupational therapists each audited all available beds for adjustability of bed height, presence/absence of bed rail, sturdiness of rail, and the brake system, including castors. A total of 1269 bed units were assessed. Beds with non-adjustable height was 85.9% (95%CI: 66.0-95.1%) of all beds assessed. In addition, 79.3% (95%CI: 61.8-90.0) of beds either did not have any rails, had only one rail, or had rails that were not sturdy. One third of beds (30.0% (95%CI: 12.7-56.0%)) had non-functional brakes, while 13.3% (95%CI: 7.8-21.7%) had non-functional castors. Percentages differed across regions and hospital type. In conclusion, most Ministry of Health hospital beds were unsafe in one or more aspects, and this puts patients at a higher risk for falls. Non-adjustable bed height and bed rails contributed to the bulk of the problem and needs to be addressed. Proper maintenance and regular checks could improve the condition of hospital beds.

## Hospital Washrooms – Dare you go in?

**A R Chu\***, **F S Lee\*\***, **M Sangetavani\*\*\***, **K Thillainathan\*\*\*\***, **S Norhayaty\*\*\*\*\***, **A Mohd Shahril\*\***, **W V Vicneas\*\***, **S Sararaks\*\*\*\*\***, **Z Mohamad Zaidan\*\*\*\*\***, **M H Maizatul Azwa\*\*\*\*\***, **A H Maimunah\*\*\*\*\***, **A B Azman\*\*\*\*\***, **J Sarah\*\*\*\*\***

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### SUMMARY

Causative factors for inpatient falls could be intrinsic (i.e. pathological disease states and medications) or extrinsic (i.e. environmental hazards) factors. Extrinsic factors include the toilet and bathrooms (washrooms). Currently there is insufficient data on safety of washrooms in Malaysia. This study aimed to audit washrooms (sinks, toilets and bathrooms) in selected Ministry of Health (MOH) hospitals, Malaysia. This is part of a larger study conducted in 20 randomly selected MOH hospitals. Trained occupational therapists conducted the audit on condition and safety of washrooms based on the code of practice on access for disabled persons to public buildings by Department of Standards Malaysia. Washrooms adjacent to randomly selected wards were assessed in terms of sink availability, tap and tap head type, doors, toilet type, commodes, health faucet height and availability of shower chairs. In the 40 wards sampled, a total of 145 toilets, 116 bathrooms and 94 sinks were assessed. No commodes were available in 78% (CI: 56.2 – 90.7) of wards. Shower chairs could not be found in 77.9% (CI: 59.3 – 89.5) of bathrooms. In addition, of the shower chairs available, only half was safe for use. Most sinks (86.3% CI: 64.1 – 95.7) did not have a sink tap that was patient friendly. Studies show that many accidents take place in the bathroom. The presence of a shower chair will be able to improve safety in bathrooms. Hence, the absence of a shower chair was a cause for concern, with only 12 shower chairs available to 116 bathrooms. To compound this problem, half of the available shower chairs were unsafe. Another concern in this study was the lack of commodes; a toileting aid that helps to preserve a patient's dignity while hospitalized. Only 7 commodes were available in the 40 wards sampled. Furthermore, majority of sinks were not fixed with patient friendly taps and this may pose difficulty for patients with weakness or hand dysfunction. Washrooms in most hospitals were not friendly to patients. Safety components and fixtures that allow ease of use are important for patients but not available. Therefore, it is vital to ensure washrooms are designed to be user friendly and that its maintenance is continuous, to assist in improving patient's experience while in hospital.

## Walking Aids – What do we have in MOH Hospitals?

**W V Vicneas\***, **F S Lee\***, **M Sangetavani\*\***, **A R Chu\*\*\***, **K Thillainathan\*\*\*\***, **S Norhayaty\*\*\*\*\***, **A Mohd Shahril\***, **S Sararaks\*\*\*\*\***, **Z Mohamad Zaidan\*\*\*\*\***, **M H Maizatul Azwa\*\*\*\*\***, **A H Maimunah\*\*\*\*\***, **A B Azman\*\*\*\*\***, **S Shalini\*\*\*\*\***, **J Sarah\*\*\*\*\***

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### SUMMARY

The frail, elderly or disabled are more likely use walking aids, and that include canes, walking sticks, quadripods, tripods, walking frames and rollators. The aim of a walking aid is to provide more stability and confidence while ambulating. The choice of appropriate walking aids is crucial to reduce risk of falls. This study attempts to look at the safety of walking aids (cane, walking stick, quadripod, tripod, walking frame and rollator) available in selected MOH hospitals in Malaysia. A cross sectional study was conducted from June till July 2007. Two-stage stratified sampling was used to select hospital and wards. A total of 40 wards in 20 selected MOH hospitals were visited. Trained occupational therapists audited all types of walking aids available in the ward, both hospital and patient owned. There were 45 walking aids found. This consisted of 25 walking frames, 6 walking sticks, 13 quadripods and 1 tripod. Findings show that overall 51.3% of the walking aids were not safe for use. The major faults found were with the ferule for most walking aid types. There were 308 elderly admitted in the hospitals audited; extrapolated, this means that there were 15 walking aids per hundred elderly persons hospitalized, or a ratio of 0.1 walking aid per elderly inpatient (0.1:1). Overall more than half of the walking aids were not safe. They were either badly worn or loose. In addition, there was insufficient numbers of walking aids available, with a ratio of 0.1:1, compared to a ratio of 0.5:1 reported in United Kingdom. Simple regular inspection can detect problems and ensure safety of walking aids. Half of walking aids in hospitals were unsafe, and the number of aids available was not sufficient. To improve patient safety and prevent falls, there is a need to provide more walking aids. In addition, regular inspection and maintenance of available walking aids could improve the situation.

## Inpatient Preferred Footwear - Shoes or Barefoot?

**S Norhayaty\***, **F S Lee\*\***, **M Sangetavani\*\*\***, **A R Chu\*\*\*\***, **K Thillainathan\*\*\*\*\***, **A Mohd Shahril\*\***, **W V Vicneas\*\***, **S Sararaks\*\*\*\*\***, **Z Mohamad Zaidan\*\*\*\*\***, **M H Maizatul Azwa\*\*\*\*\***, **A H Maimunah\*\*\*\*\***, **A B Azman\*\*\*\*\***, **J Sarah\*\*\*\*\***

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### SUMMARY

Footwear affects stability and is a known external risk factor for falls. The aim of this study is to assess type of footwear used by inpatients and its safety in selected MOH hospitals. This is a part of a large cross sectional study in twenty randomly selected Ministry of Health hospitals Malaysia. Trained occupational therapists audited the footwear of all inpatients in randomly selected wards based on the required safety recommendations by Sherrington C et al. and Durham Region Health Department. This included assessing the footwear type and safety aspects. Of 848 patients assessed, majority wore slippers (67.8%; 95%CI: 52.5-80.0%) and 19.6% (95.3%CI: 10.4-33.9%) were barefoot. Almost all, 95.3% (95.3%CI: 86.2-98.5%), had unsafe footwear according to Australia standards, with only 4.7% (95.3%CI: 1.5-13.8%) of patients using shoes. Most inpatients do not use the footwear recommended by Australian standards. Instead, probably as a concession to the climate, and cultural influence, the commonest footwear was the slipper, a footwear type deemed to be unsafe as it has a higher risk for falls. Recommended standards for safe footwear for Malaysia currently do not exist and need to be developed.

## Safety Culture in Elective Surgery - Do Patients Participate?

**A Roslinah\***, **M H Ainul Nadziha\***, **S Shalini\***, **S Sararaks\***, **M Retneswari\*\***, **I Ruhaini\*\*\***, **B Hasnah\*\*\*\***, **M Z Rozaini\*\*\*\*\***, **A Patimah\*\*\*\*\***, **Y Narimah\*\*\*\*\***, **M Kalsom\*\*\*\*\***, **A H Maimunah\*\*\*\*\***

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### SUMMARY

Elective surgeries are expected to have better safety standards. It is often attributed to the time period that precedes the procedure which enables thorough preparation and allocation of resources to ensure better outcomes. Increasingly, patients are recognized as important allies in reducing medical errors. We sought to ascertain the level of participation among patients undergoing elective surgeries in Ministry of Health (MOH) hospitals. This study looked into patients' participation in achieving safer elective operations in MOH hospitals. All elective postoperative patients from surgical disciplines, except those from the paediatric ward and subspecialties, were randomly selected from nine similarly sampled MOH hospitals in Malaysia for this cross sectional study. Data were collected using pre-tested questionnaires administered through interviews by trained research personnel on the first post-operative day between July and December 2007. The data was analyzed using survey methods in STATA SE 10. Of the overall response rate of 81.0%, only half of the patients participated in some form of pre-operative management; 57.0% (CI 41.2-71.6) were keen to enquire about treatment options, 52.8% (CI 21.2-82.3) actively informed practitioners about existing health problems, and 48.8% (CI 36.2-61.6) asked about the procedure itself. Among those who did not actively inform their health problems, 16.2% (CI 7.4-31.9) were afraid to ask and 14.8% (CI 6.1-31.5) assumed that the doctor would have already known. About 4.9% (CI 1.9-12.2) however claimed there was no opportunity to inform their problems. The post-operative period saw lower patient participation. Only about 45.6% (CI 32.4-59.3) of the respondents enquired about results/outcome, 45.6% (CI 32.1-59.9) keen to know about the post operative care and 36.3% (CI 22.1-53.3) on the do's and don'ts. This study shows that only half of our patients did participate in their own healthcare management. Participation here was mainly in the context of keenness to ask and telling the practitioner information that could influence their management and its outcome. However, awareness and patient education on patient self-care need to be enhanced to achieve better patient participation.

# The Patient's Perception - Patient Safety and Rights

**A Roslinah\***, **M H Ainul Nadziha\***, **S Shalini\***, **S Sararaks\***, **M Retneswari\*\***, **I Ruhaini\*\*\***, **B Hasnah\*\*\*\***,  
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## SUMMARY

Surgical procedures performed electively have arguably higher safety standards. It is assumed to be due to the ample time factor which enables proper planning and allocation of resources and expertise leading to better outcomes. In order to maximize the safety of patients undertaking elective operations, there is a need to additionally understand safety cultures as patients are one of the more important allies in reducing medical errors. This study looked into patients' perception towards the role they play in achieving safer elective operations in Ministry of Health (MOH) hospitals. All elective postoperative patients from surgical disciplines, except those from the paediatric ward and subspecialties were sampled from nine randomly selected MOH hospitals in Malaysia for this cross sectional study. Data were collected using pre-tested questionnaires through structured personal interviews between July and December 2007. The data was analyzed using survey analysis methods in STATA SE 10. There was an overall response rate of 81.0%, of which 42.7% (CI 29.3-57.3) of patients perceived that being treated by a specialist was a crucial factor in increasing patient safety. Another 39.3% (CI 20.5-61.8) felt caring staff and 32.5% (CI 20.6-47.2) the experience of the doctor treating them were important. Less than one fifth felt giving full cooperation to health staff (16.9%; CI 9.7-27.6), clean and sterile environment (15.0%; CI 5.6-34.3) and good medications (0.5%; CI 0.2, 1.8) could lead to safer care. Patients also perceived that their rights mainly lay in the areas of information provision by the health staff (87.3%; CI 66.5, 96.0), in the decision-making process (80.0%; CI 63.7, 90.2) and in being allowed to have an accompanying kin during the pre- and post-operative period (79.6%; CI 59.1, 91.4). It appeared that for the Malaysian patient, overall patient safety lay with the healthcare personnel, whom patients perceived to know best. Patients also expected a caring culture among health staff during the delivery of service, and most recognised the importance of active participation in their own healthcare management.

# Improving Notification of Critical Laboratory Results

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## SUMMARY

The concept of critical values, defined as an imminent life threatening laboratory result requiring immediate physician notification, has been widely adopted as a standard of good laboratory practice worldwide and mandated by accreditation bodies. There is increased attention to the issues of effective communication among caregivers, especially for laboratory critical value reporting. The aim of the study was to evaluate the current practices and the effectiveness of an intervention package to improve notification of critical laboratory practices in selected hospitals. The study was done in three phases. The first phase was a cross sectional mailed survey to assess current practices in all 126 MOH hospitals. The second phase involved developing a list of laboratory tests with critical values and procedure for notification. Literature review and workshops with laboratory, clinicians and nursing personnel resulted in a preliminary consensus. To obtain opinion from a wider range of specialists, the Delphi survey was used. The third phase involved an interventional trial to assess the effectiveness of an intervention package to improve notification. The intervention designed included training, an audit process and materials such as reminders, flipcharts and formats to enable recording notification in laboratory and wards. The initial survey showed that the importance of critical value reporting was poorly recognized in MOH hospital laboratories. A total of 649 consultants responded to the Delphi survey. 90% of the 560 consultants agreed that laboratory critical results notification were useful in improving patient safety. Consensus was achieved for the majority of tests and critical values. Procedures were refined. A QuickGuide (version 1) that incorporated the revised values and procedures was developed to enable hospital laboratories to implement critical value reporting. The procedure incorporated covered many of the recommendations advocated in Safe Practice Recommendations from the Massachusetts Coalition for Prevention of Medical Errors. In addition, notification of critical results improved significantly with the intervention package for certain types of hospitals. Critical laboratory value reporting is still poorly recognized in MOH hospital laboratories. The QuickGuide version1 could be used by hospital laboratories for implementing critical value notification, although the procedure should be reviewed and revised as necessary according to individual hospital context. The intervention package could be implemented to improve notification.

## Prescribing Errors – How do Hospital Outpatients Fare?

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### SUMMARY

Medication errors can occur in all health care systems. They may happen at any stage in the medication process including prescribing, transcribing, dispensing, administering and monitoring. Prescribing errors can lead to unintended adverse drug events unless detected and intercepted before medications reach the patient. Internationally, prescribing error rates for outpatient settings range from 1.5% to 7.6%. In Malaysia, prescribing errors at the hospital outpatient setting is monitored under the Pharmacy Quality Assurance Programme (QAP). The objective of this study is to determine the trend and types of prescribing errors. This is a cross sectional study involving all hospitals under the Ministry of Health Malaysia (MOH). At hospital level, any error detected and intervened was documented using a daily reporting format (Form 1-OP). This data was then compiled and submitted to the state Pharmacy Division every three months using a standardized QAP 1 reporting format. Aggregated data for each hospital was reported to the Pharmaceutical Services Division, MOH, twice yearly (January-June and July-December). This data, for the years 2004 to 2008, was transferred to a data collection format in this study and analyzed. A total of 135 hospital data was obtained. The average prescribing error rate was 1.02%, with a range of 0.001% to 6.48%. More than 80% of the prescribing errors at the hospital outpatient setting were contributed by incomplete prescriptions and inappropriate regimen. Details of the errors are described. Compared with international prescribing error rates, the rate in Malaysia is low, possibly due to under-reporting. Main errors found in this study were incomplete of prescription writing and inappropriate dosage regimens. These need to be addressed to improve prescribing practices in Malaysia.

## Facilitating Equity and Efficiency in Malaysian Primary Health Care Through the Application of the ACG® Case Mix System

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### SUMMARY

The practice of financial distribution within the Ministry of Health of Malaysia has traditionally been dependent on historical information. Any additional increment has been based on arbitrary predictions of the consumer index or inflation. A more appropriate distribution would be based not only on the volume of patients, but also on the morbidity profiles of these populations. Teleprimary Care electronic system (TPC) dataset provides viable data that can be used for understanding differences in case mix and resource need by various population sub-groups. One potential area of study is to account for the differences in the health status of populations and their anticipated need for healthcare services. This was the first step in a multi-stage process to demonstrate the benefits of integrating case mix into the Malaysian healthcare system. To make full and effective use of TPC, a resource-use measure based on micro-costing information was developed and validated. This new resource-use measure enable a clearer understanding of the resource consumption based on the morbidity profile of populations across regions, as well as individual clinics. The objective of this study is to apply ACG® Case Mix System in primary care level to understand the resource consumption by measuring and validating cost and morbidity data from both public and private. The primary sources of data came from both public and private primary care clinics with electronic health information systems. The private data was mapped to the ICD 10 to enable data processing using ACG Case-Mix. Assessment of the applicability of the data was then conducted to get the morbidity and provider profiles by using unit cost as the new resource measure. Further analyses were done to validate micro-costing information. The ACG system has been proven to work with Malaysian data, and the micro-costing data works for the study population and allows us to better understand differences in resource allocation and need. The viability of a morbidity-based capitation formula was initially determined by the profiling of providers. This leads to better understanding of the differences in service delivery between public and private sectors. However, the cost data for health clinics needs to be improved before the total cost can be used to predict costs with the same predictive ability as the total visit models. This project successfully demonstrated the ability of Malaysia to apply readily available diagnostic and other clinical information to develop state-of-the-art case-mix measures relevant to medical and fiscal management activities using the TPC database. The ACG system has been proven to work with Malaysian data but the data quality needs to be improved to enable us to create more sophisticated models to help identify morbidity profiles and “high risk” patients.

# National Medical Research Registration - An Innovation

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## SUMMARY

Registration of research protocol to a public access website with searchable function allows information sharing and ensures research transparency. It provides a platform for relevant stakeholder in a country, such as the Ministry of Health to govern and monitor the conduct of medical research. The well known established research register [www.clinicaltrial.gov](http://www.clinicaltrial.gov) initiated by the United States, [www.controlled-trials.com](http://www.controlled-trials.com) in the United Kingdom and [www.who.int/ictrp/en](http://www.who.int/ictrp/en) by the World Health Organization. The National Institute of Health of Ministry of Health (MOH) of Malaysia, realising the importance of research registration, established the National Medical Research Register (NMRR) in 2007. It also initiated the development of NIH guidelines for Conducting Research in MOH Institutions and Facilities where research involving MOH personnel or being conducted in MOH facility or is funded by MOH research grant are required to register in NMRR. Registration of research protocols in NMRR is done online through its website ([www.nmrr.gov.my](http://www.nmrr.gov.my)). Information entered into the website such as study title, name of investigator and institution where the study is being conducted are accessible by public. Researchers can search for other investigators based on therapeutic areas; doctors and patients who are interested in clinical trials in particular areas can check on type and status of clinical trial of their interest. Pharmaceutical companies and Contract Research Organisations can also use the investigator directory to identify potential investigators. NMRR does not merely function as a local register; it also links to ethics approval and MOH medical research grant application. It thus facilitates researchers in its application to the Medical Research Ethical Committee (MREC) and MOH research grant. Besides, MREC committee members can review research protocol on NMRR website. By doing so much time and resources are saved. From May 2007 until December 2009, more than 3,000 people have registered as NMRR public users and more than 1000 research protocols have been uploaded in NMRR. The number of research protocol registered was increasing [231 in 2007 (May to December); 402 in 2008; and 437 in 2009]. The commonest type of research registered was clinical research (n=607), followed by public health research (n=156), biomedical research (n=78), health system research (n=66), health behavioural research (n=59) and health management research (n=34). The number of clinical trials registered has increased from 20 from 2007 (May to December), to 103 in 2008, and 71 in 2009. Among the clinical trials, the number of industrial sponsored trial registered were 9 in 2007 (May to December), 85 in 2008 and 50 in 2009. Hepatology, cardiology, oncology, diabetes and psychiatry were the top five therapeutic areas for clinical trials registered in 2008. The web based NMRR is the first research register in the world that links research protocol registration to ethical review and research grant application. Its next application is to link with publication. It is indeed an innovation that Malaysians should be proud of.

## POSTER ABSTRACTS - PUBLIC HEALTH

- PPH01** Prevalence of Iodine Deficiency Disorder Among Orang Asli in Hulu Selangor
- PPH02** Cholera Outbreak in Pantai Rombang Village, Tanjung Kling, Melaka, Malaysia, 2007
- PPH03** Sexual Behavior and Preferences Among HIV/AIDS Patients in Selangor, Malaysia
- PPH04** An Outbreak of Rubella in a National Service Training Camp, Cancun Park, Pasir Mas, Kelantan, Malaysia
- PPH05** Outbreak of *Lepidopterism* Caused by Tussock Moths, Taman Sri Serdang, Petaling District, February-April 2009
- PPH06** Food Poisoning Outbreak in Maahad Religious High School, Johor Bahru, Johor on 16 th April 2007
- PPH07** Cleanliness Status Among School Canteens of the Ministry of Education in Kelantan
- PPH08** Smoking Behavior in Type 2 Diabetic Patients in Negeri Sembilan and Pahang
- PPH09** Smoking - Identifying Status and Addressing Cessation Needs Among Oral Healthcare Personnel in Negeri Sembilan
- PPH10** Assessment of a Colorectal Cancer Screening Programme Using Faecal Occult Blood Test (FOBT) Kit in Penang State, Malaysia
- PPH11** A Study of KAP Among Food Handlers in National Service Training Camps in Kedah
- PPH12** Moderating Effect of Religiosity on Psychological Well Being of Chronically Ill Older Malay Muslims
- PPH13** Epidemiology of Traumatic Dental Injuries in Adolescents
- PPH14** Mammographer's Perspectives on Zoom Positive and Zoom Negative Digital Mammography Images in Detecting Breast Lesions at Malacca Hospital
- PPH15** Pap Smear Screening History of Women With Invasive Cervical Cancer

# Prevalence of Iodine Deficiency Disorder Among Orang Asli in Hulu Selangor

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## SUMMARY

Iodine deficiency disorder (IDD) remains a significant global public health problem. A study conducted in 1999 reported a high prevalence of goitre in three out of four Orang Asli villages in Hulu Selangor as compared to the general population. Therefore, the aim of this study was to assess the present prevalence of IDD by measuring urinary iodine concentration (UIC) among Orang Asli in Hulu Selangor. A cross sectional study was conducted in April 2006 participated by 346 children and adult women. UIC was performed in 97 (28.0%) young children between the ages of one and six years, 115 (33.2%) children aged between seven and 12 years old and 134 (38.8%) adult women ( $\geq 15$  years old). Iodine status of the studied population was determined based on median UIC categorised as excessive ( $>300$   $\mu\text{g/L}$ ), more than adequate (200-299  $\mu\text{g/L}$ ), optimal (100-199  $\mu\text{g/L}$ ), mild (50- 99  $\mu\text{g/L}$ ), moderate (20-49  $\mu\text{g/L}$ ) and severe ( $<20$   $\mu\text{g/L}$ ). The median UIC of the studied population was 45.11  $\mu\text{g/L}$  while for young children, children and adult women were 43.32  $\mu\text{g/L}$ , 50.01 $\mu\text{g/L}$  and 42.34  $\mu\text{g/L}$  respectively. In addition, moderate to severe IDD ( $<50$   $\mu\text{g/L}$ ) was present in 69.1% of young children, 49.6% of children and 61.9% of adult women. In conclusion, study areas are still threatened by moderate to severe IDD problem as compared to the World Health Organization (WHO) urinary iodine concentration levels. It is clear that level of iodine concentration is depending on the local situation such as frequency and level of seafood or goitrogen consumption. There is a need to strengthen existing intervention programs for example iodine supplementation and salt iodization to overcome this problem.

PPH02

# Cholera Outbreak in Pantai Rombang Village, Tanjung Kling, Melaka, Malaysia, 2007

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## SUMMARY

Pantai Rombang in Melaka, is a coastal village popular with tourists with a population of 1 200. There has been no record of cholera reported from this village in the last five years. However, on 28th February 2007, the Melaka Tengah District Health Office received a notification of a case of *Vibrio cholera* (Vc) serogroup 01 biotype El Tor serotype Ogawa from Pantai Rombang which was notified by the microbiologist from Melaka State Hospital. Epidemiological investigation was done to assess the extent of the outbreak, to establish the risk factors and institute control measures. Active case detection was conducted door-to-door in the neighbourhood of cases as well as work contacts and related food handlers. Passive case detection was enhanced through a network of two nearby government health clinics and eight private clinics in the area. A confirmed case was defined as a person who developed at least three episodes of watery diarrhoea and a positive stool culture for *Vibrio cholera*. A ratio case control study was done to identify the risk factor. Controls were healthy household members and neighbours with stool negative for *Vibrio cholera*. Water and food samples were taken for bacterial analysis. Control measures were immediately initiated and followed up. Eight cases of cholera were detected involving two Malay Ethnic families out of 142 contacts screened. There was no case fatality, with male preponderance of 3:1. Four of eight cases had history of eating ice condiments which were prepared in an unhygienic surrounding. Univariate analysis of a ratio case control study showed the cases were seven times more likely to consume ice condiments (95% CI= 1.11- 44.06). No other food items or water sources were implicated. Immediate control measures effectively contained the outbreak. In conclusion there was a cholera outbreak clustering around two families due to eating contaminated ice condiments served by an infected food handler. The Rapid and appropriate control measures taken, managed to control the disease.



# Sexual Behavior and Preferences Among HIV/AIDS Patients in Selangor, Malaysia

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## SUMMARY

HIV/AIDS epidemic in Malaysia has now penetrated the 'low-risk' population through sexual contact. This study aimed to explore the sexual behavior among HIV patients and their sexual behavior and preferences so as to recommend effective preventive intervention measures to high risk groups. A cross-sectional study using purposive sampling method. Three prisons, two drug rehabilitation centers, one hospital and three health clinics were chosen for the study. Respondents were those attending clinic sessions at identified premises and modified self-administered questionnaire adopted from BSS and SPSS was used. A total of 146 out of 159 (91.8%) attendees responded to the study; 84.6% were males, 13% were females and 2% were transgender. Male (53%) and transgender (71%) had more than 5 years duration of seropositivity. Being married, with less than 5 years duration of seropositivity and those with greater importance of sex ( $p < 0.05$ ) were more sexually active. Seventy five percent of the females practised unprotected sex and were 12 times more likely to engage in such practice as to transgender. Those who were under the influence of drugs were six times more likely to practice unprotected sex as compared to those who never had sex under the influence of drug (95%CI 2.5, 12.9). Those who were unmarried (63%), partner with unknown serostatus (69%), sex worker as partner (72%), buying sex (70%) were willing to disclose their HIV/AIDS status. The study showed risky sexual behavior was prevalent among HIV/AIDS patients especially women. Targeted safe sex education to high risk groups need to be incorporated into the existing HIV/AIDS counseling program.

PPH04

# An Outbreak of Rubella in a National Service Training Camp, Cancun Park, Pasir Mas, Kelantan, Malaysia

A Hasniza

Pasir Mas District Health Office, Kelantan State Health Department, Malaysia

## SUMMARY

The Cancun Park National Service Training Camp is a youth training camp to foster unity among citizens. An outbreak of Rubella was notified to Pasir Mas District Health Office on the fourth of May 2008 and a team was sent to investigate the outbreak. The case definition was any person at the camp presenting with maculo-papular rash with or without fever from the first of April 2008. A cohort study was carried out and blood samples were sent for serological test. Of the 22 cases, 94% were males. Clinically, 77% presented with fever, 41% presented with cough and 50% presented with conjunctivitis. No neck lymphadenopathy was detected. None was positive for IgM measles serology but 68% were positive for Rubella-specific IgM antibody. No history of vaccination for all confirmed cases. Epid curve showed a common source outbreak. History taking revealed a Family Day event had taken place. In conclusion, an outbreak of Rubella with a possible source occurring during a Family Day event. Trainees were isolated with different meal time and toilet use. Health talks were given which include camp trainers especially the female trainers. Vaccination were given to those unvaccinated.

## Outbreak of *Lepidopterism* Caused by Tussock Moths, Taman Sri Serdang, Petaling District, February- April 2009

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Disease Control Unit, Petaling District Health Office

### SUMMARY

Caterpillar dermatitis is an underreported skin reaction. Residents from an urban township reported acute skin reactions and irritations which attracted media and political mileage. An investigation was carried out to determine the etiology and provide control measures. A case was defined as those who exhibited rashes, skin lesions or erythema residing in Taman Sri Serdang. Water samples were analysed for contraventions and contaminants. Inter-agency collaboration involving Petaling District Health Office, the Water Quality Board, the Environmental Safety and Safety Departments were drawn in to assist in monitoring air quality, temperatures, wind directions and environmental assessment. Site inspections were carried out to identify possible environmental and contact irritants in the residential area. Face-to face interviews were conducted with affected residents. Caterpillars, tree barks and foliage were collected for analysis and identification. There were 346 residents and 82% (282) were affected. Water samples did not reveal any contraventions or contamination. Air quality monitoring showed no suspended irritants. Daily temperatures recorded were between 34-36°C and wind directions varied. Visual inspection of surrounding wooded area revealed trees heavily infested with caterpillars, identified as those of the Tussock moth (*Euproctis edwardisi*). In conclusion, the outbreak of skin dermatitis was due to lepidopterism i.e. adverse skin reactions resulting from contact with airborne caterpillar hairs or spines. Prompt insecticide spraying and destruction of affected trees significantly reduced the presence of caterpillars. Follow up examination of affected residents showed that they all had completely recovered after these interventions. The district Health Office continues to monitor this residential area in a regular basis.

PPH06

## Food Poisoning Outbreak in Maahad Religious High School, Johor Bahru, Johor on 16 th April 2007

D Shaharom

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### SUMMARY

A study was conducted to determine the epidemiological determinants of an episode of food poisoning which occurred on 16 April 2007 at Sekolah Tinggi Agama Maahad Johor Bahru. The school had previously reported food poisoning outbreak on 4 April 2007 and the hostel canteen was closed under the Communicable Disease Control ACT 1988. Since then meals were prepared in Maktab Perguruan Temengong Ismail Cafeteria by the same food handlers from the school hostel and transported by van to the school hostel to be eaten. Outbreak investigation involved case finding, environmental and laboratory investigations. A case control study was conducted amongst 137 respondents, consisting of 35 cases and 102 controls using a preformed questionnaire. Environmental investigation of food premise, bacterial sub-typing of stool samples, food and water samples were also conducted. Thirty eight (8.7%) out of 404 students reported ill. All the cases presented with abdominal pain and diarrhoea while only 2.8% presented with nausea and 14.3% with headache. The epidemic curve showed a point source infection with incubation period of 11 to 17 hours (median- 12 hours). Probable source of infection was ayam masak lemak (OR -197;  $p < 0.05$ ) infected with *Clostridium perfringens*. Contamination occurred as a result of recycling leftover food as well as poor hygiene and unsafe food preparation of food handlers. Rating of food preparation premise was 44%. All seven food handlers had not undergone any health examination or vaccinated with Ty2. Neither stool samples and hand swabs from food handlers nor food and water samples taken showed any organism growth. The outbreak was due to ingestion of leftover high risk food. Recycled food must not be allowed to be eaten by school students and the hostel supervisor is recommended to undergo training on inspection of food premises to ensure self monitoring and safety of food prepared. All the food handlers should undergo health examination and vaccination for typhoid as well as training on food safety and hygiene.

# Cleanliness Status Among School Canteens of the Ministry of Education in Kelantan

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## SUMMARY

The objective of the study was to assess the cleanliness among school canteens of the Ministry of Education in Kelantan. This was a comparative cross-sectional study involving 29 schools with past food poisoning cases (schools with cases) and 29 schools which had no past cases of food poisoning (schools without cases). Cleanliness Assessment was based on nine (9) parameters inspected by Assistant Environmental Health Officers using a checklist adapted from the Food Premise Inspection Form (KMM3P2) of the Ministry of Health (MOH). The total score assigned for each parameter was based on the standards set by the MOH. Classifications of grades based on the total score are: Satisfactory (71 – 100 marks), Average (51 – 70 marks) and Poor (50% marks or less). The study results showed that there were no significant differences in the cleanliness status between the schools with and without cases. The overall cleanliness status based on the total scores of the 58 schools was 40% Satisfactory, 41% Average and 19% Poor. Among the 58 schools, the number of schools with full/maximum scores for the individual parameters were: Flooring and interior of premise 19 schools (33%), Hand washing facility 18 schools (31%), Drainage and sullage 7 schools (12%), Refuse and food waste disposal 4 schools (7%), and 2 schools each for Food management/storage, Food Handlers, Canteen Utensils and Equipments and Overall premise. The cleanliness status of the individual parameters based on the percentage of average scores over the maximum scores were: Food management/storage (40%), Food Handlers (30%), Canteen utensils and Equipments (39%), Water supply (11%), Drainage and sullage (30%), Hand washing facility (56%), Refuse and food waste disposal (38%), Flooring and interior of premise (48%) and Overall premise (55%). In conclusion, overall less than half of the schools inspected were of satisfactory cleanliness standard. Majority of the parameters inspected scored less than 50% of the total score. The parameters that scored better were Hand washing facility and Premise overall while Water supply had the least score.

# Smoking Behavior in Type 2 Diabetic Patients in Negeri Sembilan and Pahang

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## SUMMARY

Diabetes mellitus is one of the commonest chronic non-communicable diseases globally, causing high morbidity and mortality. Worldwide prevalence of type 2 diabetes is keep increasing, including in Malaysia. Besides smoking, diabetes mellitus is another major cause of ischaemic heart disease, which explains the importance of describing the smoking behaviour in these diabetic patients. The objectives of the study are to describe the smoking behaviour of type 2 diabetic patients in terms of smoking status, the reason for quitting or failing to quit smoking among the ex- and current smokers, and its association with sex and HbA1c. A total of 697 type 2 diabetic patients from health clinics in Negeri Sembilan and Pahang participated in this cross-sectional study. Their smoking behaviour in term of smoking status, reasons for quitting and failing to quit smoking were collected using a validated questionnaire. Blood was taken and analysed for the level of HbA1c. Chi-square test was used to analyse for any association between sex and smoking status. Anova test and subsequently Ancova was used to compare the HbA1c levels between the different smoking status. From the total 697 patients included in this study, 75.3% never smoke, 13.1% still smoking and 11.6% had quit smoking. Out of 525 patients who never smoke, 78.7% were females and 21.3% were males, while among those who had stopped smoking (N=81), 88.9% were males and 11.1% were females. Among those who were still smoking (N=91), 94.5% were males and only 5.5% were females. The mean number of cigarettes smoked was 13.56 sticks per day. Seventy percent of these current smokers had tried to stop smoking. Among the reasons to stop smoking given by diabetic patients in this study included suffering from Diabetes disease itself (45.5%), strong self motivation (32.5%), high price of cigarette (9.1%), family's encouragement (6.5%) and motivation from health staffs (6.5%). On the other hand, the reasons for failure of stopping smoking were addiction (48.3%), influence from friends (16.7%), poor self motivation (15.0%) and other reasons (20.0%). Significant association was found between sex and smoking status (chi-square statistics = 272.1; df = 2; p-value < 0.001) whereby more male patients were current and ex-smokers. However, from Ancova test, there was no significant difference in the HbA1c levels between the different smoking status among the diabetic patients (F-statistics = 2.037; df = 2, 546; p-value = 0.131; adjusted for age, education level, marital status and clinic with specialist). In conclusion, majority of the diabetic patients in this study were non-smokers and majority of those who smokes were male patients. There were many reasons for these patients to quit smoking, as there were many reasons for them failing to quit smoking. However, from this study it was found that there is no difference in HbA1c levels between the different statuses of smoking in these diabetic patients.

# Smoking - Identifying Status and Addressing Cessation Needs Among Oral Healthcare Personnel in Negeri Sembilan

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## SUMMARY

Health care work force continues smoking despite efforts and aggressive promotion of healthy lifestyles to the public by Ministry of Health. Smoking impose public health burdens and warrants effective management. A cross-sectional study was conducted in April 2009 to determine the prevalence of smoking and identify smoking cessation needs among health personnel in the Oral Health division of Negeri Sembilan State Health Department. Self-administered questionnaires were distributed to all health care employees via the District Oral Health Offices in seven administrative districts. The survey questionnaire utilized items from an instrument developed and used in 'Health care Cost of Smoking' .Study conducted by National University of Malaysia (UKM) which had been pre-tested for validity and reliability. Data was processed and analysed using SPSS Version 15 software. Frequency distributions were used to describe data and bivariate analyses to measure association with statistical significance based on chi square test. Findings revealed that among 490 staffs, 12.7% were current smokers, 83.3% have never smoked and 4% ex-smokers. Smokers mainly fall in the lower income category, males, married and with family history of smoking. There were significance differences between the variables of gender and family history of smoking ( $p < 0.05$ ). The expenditure spent on cigarettes is relatively high with a maximum of RM 400 per month and average of 10.5 sticks per day. Knowledge of dangers of tobacco and smoking is found to be high among smokers and non smokers but a small percentage (4.8%) reported to be ignorant. The study found that 29% of smokers reported never having attended talks and health campaigns associated with smoking. The association between this variable and smoking is significant ( $p = 0.008$ ). About 14.5% of oral health care personnel in Negeri Sembilan who smoke reported not wanting to quit smoking and 27.4% had received treatment at quit clinics. In conclusion, the prevalence of smoking among oral health care personnel in Negeri Sembilan was 12.7% with majority (91.9%) from the lower support category group. Cessation needs are high with 85.5% reporting intention to quit. Health care workers play important roles in the projection of healthy life style and eradication of unhealthy habits. The results of this study demonstrate the need for intervention and reinforcing resources to curb the problem of smoking among health care workers. Further research is warranted to look into intervention and determine the quit ratio among health workers.

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 PPH10

# Assessment of a Colorectal Cancer Screening Programme Using Faecal Occult Blood Test (FOBT) Kit in Penang State, Malaysia

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## SUMMARY

Colorectal cancer screening programme had been held in Penang from June to November 2009. A total of 1000 FOBT kits were distributed among Penangites 50 yrs old and above, with assistance of National Cancer Society Malaysia (NCSM). Every participant collected their stool sample themselves using a FOBT kit and sent it by post for laboratory examination. Participants with positive results were advised further colonoscopy and participants with negative result were advised to repeat the FOBT annually. Five hundred and eighty six of the 1000 participants returned their kit (58.6%). Of these participants, 30 had positive results (5%). Five participants underwent colonoscopy. One case of cancer was detected, 2 polyps and 1 ulcerative colitis were treated and one case was normal. Colorectal screening is very useful in detecting early colorectal cancer and precancerous polyps. Our study showed the incidence of colorectal cancer and precancerous stage were 0.1 % and 0.3 % respectively. The compliance rate of colonoscopy was 20% among participants with positive result. Annual screening is needed to detect these cases.

# A Study of KAP Among Food Handlers in National Service Training Camps in Kedah

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## SUMMARY

Food poisoning is a persistent problem that occurs in Malaysia. This disease can cause morbidity and sometime mortality. Food handlers play an important role in ensuring food safety through chain of preparation, processing, production, storage and transportation. This study is to explore a pattern of socio-demographic distribution and to determine Knowledge Attitude and Practice (KAP) of the food handlers in National Service Training Camps (NSTC). The objective of this study was to Study the Knowledge, Attitude and Practice among Food Handlers working at NSTC in Kedah. This is a cross-sectional study involving 111 food handlers from six NSTCs in Kedah. Self-administered questionnaires were distributed to the respondents. All foods handlers from three NSTC with food poisoning and other three without cases of food poisoning were selected as samples. The result showed 91.92% respondents had mean score for Knowledge of 9.19, Attitude of 26.55 (88.5%) and practice is 13.67 (68.35%). Knowledge have significance association with food poisoning ( $p=0.05$ ). However, there was no significant association seen with food poisoning. Therefore, food handlers were recommended to undergo food handling training and practice scheduled self inspection of their food premises. There were 88.5% respondents had good attitude (mean score 26.55) and only 68.35% had good practice (mean score 13.67). The episode of food poisoning in NSTC is a major cases reported by our local media. There are significant different in the knowledge on food poisoning between food handler in NST Centre with food poisoning case and centre without the case. In this study shown knowledge is not the cause of the food poisoning. There are other factor which could cause the disease. The analysis of attitude and practice association with the food poisoning does not show any significant association.

PPH12

# Moderating Effect of Religiosity on Psychological Well Being of Chronically Ill Older Malay Muslims

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## SUMMARY

Psychological well being is one the most important indicators of successful aging. Studies have well documented that chronic medical conditions negatively affect elderly's psychological well being. Therefore, it is imperative to understand the coping mechanisms that may protect adults from the loss of psychological well being following functional decline. The present study was designed to examine moderating effect of religiosity on the relationship between chronic medical conditions and psychological well being. This study consisted of 1415 ( $n=722$  women and  $n=693$  men) community-dwelling Malay Muslims aged 60 years and over in Peninsular Malaysia. A multi-stage proportional stratified sampling procedure was used to obtain sample population. Data collection was conducted using an in-person interviewing technique. In this study, two scales namely WHO-5 Well being Index and Intrinsic-Extrinsic religiosity scale, and a checklist of 16 chronic medical conditions were utilized to measure psychological well being, religiosity and physical health status, respectively. The Cronbach's alpha coefficient for the WHO-5 Well being index and Intrinsic-Extrinsic religiosity scale was equal to .84 and .85, respectively. The Statistical Package for Social Sciences (SPSS version 13.0) and the computer program ModGraph were used in data analysis. The mean psychological well being score of the older respondents was 62.3 ( $SD=22.54$ ). Majority of the respondents (66.1%) reported good psychological well being. The mean number of chronic medical conditions was 1.3 ( $SD=1.33$ ). The eight most prevalent chronic medical conditions among older Malays were hypertension (41.1%), diabetes (21.0%), visual problem (15.4%), joint pain (15.3%), heart disease (10.0%), hearing problem (6.9%), asthma (6.0%), and hypercholesterolemia (4.0%). Bivariate correlation revealed a negative significant correlation between number of chronic medical conditions and psychological well being ( $r=-.16$ ,  $p<.01$ ). The findings from a 4-step moderated hierarchical regression analysis indicated that relationship between chronic medical conditions and psychological well being is statistically moderated by social religiosity and personal religiosity, after controlling for age, sex, and socio economic status ( $p<.01$ ). Results of ModGraph showed that when religiosity was at low levels (-1 SD), there was a strong negative relationship between chronic medical conditions and psychological well being, and that when religiosity was at high levels (+1 SD); there was a weak negative relationship between chronic medical conditions and psychological well being. In conclusion, older persons with higher levels of religiosity had higher level of psychological well being than individuals reporting low levels of religiosity, under certain levels of chronic medical conditions. In other words, religiosity statistically reduces negative effects of chronic medical conditions on the psychological well being of chronically ill older persons. It is suggested that counselors and other mental health professionals working with older persons with chronic conditions should developed interventions to strengthen religiosity as a mean to improve the psychological well being of older Malaysians.

# Epidemiology of Traumatic Dental Injuries in Adolescents

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## SUMMARY

The aim of the study was to measure the prevalence of traumatic dental injuries (TDI) to permanent anterior teeth in adolescents and to determine the causes of TDI among 13 and 16-year-old schoolchildren in Klang district. A cross-sectional study was carried out in a sample of 4602 schoolchildren and all 12 anterior teeth were clinically examined and children with TDI were given self-administered questionnaire. The prevalence of traumatic dental injury was 5.0%. The prevalence of TDI in males (6.8%) was two times higher than the females (3.0%). Indians experienced a higher TDI levels than other ethnicity. Maxillary central incisors were the most common teeth with TDI. Most of the affected children (77.2%) had trauma to 1 tooth. Enamel fracture (42.4%) was the major type of TDI. The main cause of injury reported was fall (62.7%). Most of the TDI occurred at home (52.2%). The prevalence of TDI among adolescents in Klang is low and the most of the injuries were accidental injuries.

PPH14

# Mammographer's Perspectives on Zoom Positive and Zoom Negative Digital Mammography Images in Detecting Breast Lesions at Malacca Hospital

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## SUMMARY

Women under 50 years old have more glandular breast tissue giving a denser appearance on mammogram images which potentially obscure lesions. This hinders early detection of malignancy. When the basic mammographic views inadequately demonstrate a lesion, additional views or diagnostic modalities are requested which adds to the patient's discomfort and radiation exposure. The aim of our study was to compare the accuracy of two views in determining lesion (mass and microcalcification) number, size, and shape in a dense breast based on the perspectives of mammographers. This was a retrospective study on 20 images of dense breast tissue obtained from the Malacca Hospital mammography database. Each image is inverted giving two views - a positive image, and negative (inverse) image of each breast. The images were reported as by radiologists. Some were normal and other had benign or malignant lesions. The images were then distributed to the four respondents along with a questionnaire. They were allowed to use any degree of zooming, without adjusting image density and contrast. They were blinded to the radiologist reports. Each image underwent SPSS analysis to compare between the two view modes. There was no significant difference between both views in visualizing microcalcifications and mass ( $p\text{-value} > 0.05$ ). Results also showed that the respondents preferred the non-inverted images and were able to use this view mode in determining nature of lesion. In conclusion, there was no advantage in using the inverted view mode in demonstrating breast lesion. This can be due to the glare of the white background. However, the negative view mode can be useful when the nature of the lesion is still doubtful and can be considered before requesting another diagnostic exam.

# Pap Smear Screening History of Women With Invasive Cervical Cancer

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## SUMMARY

According to the 2006 Malaysian Cancer Statistics, cervical cancer is the third leading cause of cancer-related death among Malaysian women. Cervical pap smear test is an effective screening tool and in many developed countries, it has significantly reduced the incidence and mortality rates of invasive cervical cancer. In Malaysia, the cervical cancer screening program was established by the Ministry of Health in 1969. The objectives of this study were to determine the prevalence of invasive cervical cancer cases with no previous pap smear screening history and to subsequently investigate the pap smear history in women diagnosed with invasive cervical cancer in Universiti Kebangsaan Malaysia Medical Centre (UKMMC). We performed a retrospective study on all patients diagnosed with invasive cervical cancer between 2006 and 2009. This was done by reviewing histopathological reports and the pap smear history over the previous three years, if that were available. The histopathological reports were obtained from the archives of the Department of Pathology, UKMMC and their pap smear past records were retrieved from the Integrated Laboratory Management System (ILMS). A total of 96 women had histologically-proven invasive cervical cancer, of which 75 (78.1%) had squamous cell carcinoma (SCC), 13 (13.5%) adenocarcinoma (AC), three (3.1%) adenosquamous cell carcinoma (ASC), one (1%) each of malignant mixed müllerian tumour, malignant melanoma, poorly differentiated carcinoma, synchronous squamous cell carcinoma and adenocarcinoma of the cervix and undifferentiated carcinoma, large cell type. Overall analysis showed that only 12 (12.5%) women with invasive cervical cancer had previous pap smears while 84 (87.5%) never had pap smear test prior to diagnosis. Among the 12 women who had previous pap smear screening records, 10 (83.3%) were cytologically positive for malignancy. The 10 positive-finding previous pap smears were comprised of seven (70%) SCCs, one (1%) AC, one (1%) ASC and one (1%) synchronous SCC and AC. However, the average duration between the time of positive – finding pap smear and the final histological diagnoses among the patients with positive previous pap smears was relatively short (1.9 months). Meanwhile, one case of SCC and another one of ASC had negative-finding previous pap smears taken 4 and 33 months respectively prior to diagnosis. Our findings show that the majority of women with invasive cervical cancer presented late and had never had any cervical pap screening test. Clinicians, nurses and primary health care providers should put more effort in promoting regular cervical pap smear screening test among women.

## POSTER ABSTRACTS - SURVEY

- PSV01** The National Medicines Use Survey – Identifying Research Priorities for Better Drug Utilization in Disease Management
- PSV02** The Level of Patient Satisfaction in Private Hospitals
- PSV03** Utilization of Specialist Services in Malaysia
- PSV04** Staff Perception on ICT Usage in Public Hospitals
- PSV05** Employee Job Satisfaction Survey in a Research Institute, Ministry of Health, Malaysia
- PSV06** Employee Job Stress Survey in a Research Institute, Ministry of Health, Malaysia
- PSV07** Nutritional Status of Malaysian Schoolchildren Aged 8-10 Years Old - Findings from a National Survey
- PSV08** Health Screening among Institute for Public Health, Institute for Health Management, Institute for Health Behaviour Research and Radicare Staff
- PSV09** Maternal Mortality Ratio - A Trend Analysis
- PSV10** Poliomyelitis Vaccination Status among Children in the Federal Territory of Kuala Lumpur
- PSV11** Food Factories Census in Selangor State, Malaysia 2007
- PSV12** Typhoid in Chuchuh Puteri Village, Kelantan
- PSV13** Validity of the Self-Report Adolescent Health Screening Tool
- PSV14** Clients Satisfaction In ISO Certified Health Clinic in Klinik Kesihatan Bandar Baru Bangi, Selangor and in Non-ISO Certified Health Clinic in Poliklinik Komuniti Tanglin, Kuala Lumpur and its Associated Factors
- PSV15** Prevalence of Hearing Loss in Children with Downs Syndrome



# The National Medicines Use Survey – Identifying Research Priorities for Better Drug Utilization in Disease Management

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## SUMMARY

The National Medicines Survey (NMUS) is jointly conducted by the Pharmaceutical Services Division and Clinical Research Centre, Ministry of Health Malaysia, to collect medicines utilization data in Malaysia, and to provide reference data/statistics for other purposes such evidence-based decision making, medicines policies, clinical practice guidelines and research. A cross sectional survey was conducted using secondary data from public and private hospitals (medicines procurement), private clinics (prescriptions) and private pharmacies (dispensing). Analysis on overall drug utilization based on data collected was reported in the Malaysian Statistics on Medicines (MSOM). The MSOM 2006 was reviewed and key areas of concern in medicines utilization were selected for research priorities. For 2006, anti-diabetic drugs ranked highest in utilization by therapeutic groups, followed by cardiovascular drugs, lipid modifying agents and drugs for obstructive airway diseases. Glibenclamide was the highest utilized drug and cardiovascular drugs accounted for 18 of the top 40 drugs utilized. Several areas of concern were discussed in the report. The key research priorities which are identified from the areas of concern include (1) low utilization of insulin and high utilization of sulphonylureas in diabetes management; (2) low overall utilization of anti-epileptic drugs and high usage of phenytoin among the anticonvulsants; (3) review of use drugs in management of obstetrical and gynaecological disorders in Malaysia as drugs used commonly as first line therapies have been replaced by newer drugs ; (4) appropriateness of topical steroids and topical antibiotics use in private health care practice which is relatively higher compared to that in the public sector and ; (5) adequacy and appropriateness of use of glucocorticoids versus beta agonists, oral medications versus inhaled preparations, cost benefits and affordability of inhaled preparations in treatment and management of asthma as data showed traditional treatment modalities are still entrenched. In conclusion, the NMUS survey in 2006 provides statistics on the utilization of medicines in the country. In addition it helps identify research priorities based on the pattern of use and areas of concern raised.

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 PSV02

# The Level of Patient Satisfaction in Private Hospitals

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## SUMMARY

Patient satisfaction is an important aspect of health care provision. A cross sectional study was conducted in nine private hospitals in Malaysia to determine the level of patient satisfaction and socio-demographic factors influencing them. Self-administered SERVQUAL questionnaire were distributed to in-patients and out-patients through quota sampling in nine randomly selected private hospitals from October to December 2009. A total of 893 patients responded giving a response rate of 99.2%. Overall, 90.3% of the respondents were satisfied with the services given by the private hospitals. However, only 42.3% of the respondents felt that their expectations were met. This was highest for Outcome domain (63.6%) while the lowest were for the domains of Professionalism (46.9%) and Caring (49.0%). The levels of expectations met were higher among in-patient respondents. There was no statistical difference between expectation levels met and socio-demographic characteristics of the respondents. Although there was a high level of overall satisfaction (90.3%) with services provided by private hospitals, only 42.3% felt that their expectations were met. The private hospitals need to address this mismatched by improving the domains areas where expectations were not met.

# Utilization of Specialist Services in Malaysia

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## SUMMARY

Specialists are a valuable but limited asset in the health care system of a developing country like Malaysia. It is generally perceived that specialist services in the public sector are over-utilized, while those in the private sector are under-utilized as they cater for a more limited client group. This study was aimed at assessing specialists perception on appropriateness of utilization of specialist services in Malaysia and factors influencing the public's choice of public or private sector specialists. The study involved two parts – all specialists in public and private hospitals in the country using self-administered questionnaires, and telephone interview using a structured questionnaire for the public selected through stratified and systemic sampling of fixed-line numbers by area code from the Telcom (yellow) book. Between 93.0 and 96.8% of specialists perceived that patients seeing them were appropriate to their level of expertise, with no difference between public or private sector specialists. However, they estimated that only 32.5% to 56.2% of the patients seeing specialists in government hospitals actually require specialist care. Choice of utilizing public or private sector specialists were influenced by perceived quality of care and service, affordability and who paid for the service. Utilization pattern was also influenced by ethnicity, income and education level. In conclusion, utilization of specialist services were appropriately high with no difference between types of hospitals, and whether public or private. Perceived quality of service, affordability and who bears the cost of health care are factors that influence choice of public or private sector hospitals.

PSV04

# Staff Perception on ICT Usage in Public Hospitals

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## SUMMARY

As Malaysia progress into achieving developed country status through Vision 2020, Information and Communication Technology (ICT) has been one of the main agenda to fulfil this. One of the efforts made by the government is through the Ministry of Health, in which the government has built and equipped new hospitals with sophisticated ICT application which is called Total Hospital Information System (THIS) in 1990s. The purpose of this study was to determine the perception of staff on the usage of ICT system towards improvement of delivery services in Ministry of Health's hospitals and to identify problems and issues related to it. This is a cross sectional study using a self-administered questionnaire to all staff in three hospitals equipped with THIS. A total of 4 149 staff was surveyed with 59.9% response rate. Results of the study showed that 38.0% of them felt that the system overall has accelerate treatment for patients and 40.7% of them agree that there is more effective networking within departments. The main problem faced by ICT Hospitals' staff (69.9%) was related to broken down or facing technical disturbances of the system. They felt that the response in maintenance of the system is slow (20.3%), there are insufficient facilities for the whole system (12.9) and the staff for maintenance of the ICT system in the hospital is not adequate (33.1%) to solve problems immediately. Apart from the technical issues, some of them (44.6%) felt that more time needed to key-in the patient's data compare to having interaction with patients especially among doctors and nurses respectively ( 54.1% and 47.9%). As this THIS system will be adopted in many other new hospitals in the future, training more staff on identifying and solving technical problems and provision of sufficient facilities need to be considered. The relevant ICT department for Ministry of Health have to look into improving the current system in which all hospitals will be using a same system that is user-friendly and that can be upgraded from time to time according to the needs. The system also must allow effective networking within departments and other hospitals in enhancing performance and outcomes of patients.

## Employee Job Satisfaction Survey in a Research Institute, Ministry of Health, Malaysia

**I Lasa, B Yahya, K Gurdeesh, S P Juliana, H Hazrin**

Institute for Public Health, Ministry of Health, Kuala Lumpur, Malaysia

### SUMMARY

A cross sectional study on employee job satisfaction in a research institute , Ministry of Health, Malaysia was conducted in August 2009 using a structured self-administered questionnaire. This study analyzed the level of employee job satisfaction in the institute using a scale of 1-6 (1- very disagree, 2- disagree, 3- slight disagree, 4- slight agree , 5- agree, 6- very agree). The analysis involved 67 questionnaires which represented a 84.8% return rate. In the analysis, using the Statistical Package for the Social Sciences (SPSS) version 17.0 software programme, a Cronbach alpha reliability of 0.98 was obtained and this indicated that the research instrument had a strong reliability. From this study, it showed that the level of employee job satisfaction had a difference on demographic factors and social indices. According to the analysis the highest mean score for level of employee job satisfaction stemmed from the organizational leadership (5.15) followed by preparedness by employees to receive admonition from leaders (5.08), loyalty to organization (4.97), welfare of employees (4.95), work environment (4.94) and fairness among the employees (4.93) using linear regression analysis with a p value of <0.05. Based on the percentage of average level of employee job satisfaction using multiple regression analysis, it was found that the impact of the director and heads of division (81.2%) had a significant influence on the level of employee job satisfaction followed by workplace environment (9.7%), appreciation (5.6%), co-worker (1.1%) legislation and work ethics (0.6%) and work procedure (0.4%). Therefore, we concluded from the study that the impact of the director and heads of division played vital roles in determining the level of employee job satisfaction in a research institute, Ministry of Health, Malaysia.

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 PSV06

## Employee Job Stress Survey in a Research Institute, Ministry of Health, Malaysia

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### SUMMARY

A cross sectional study on employee job stress in a research institute was conducted in August 2009 using a structured self-administered questionnaire. This study analyzed the level of employee job stress experienced by employees in the institute using a scale with six responses (1- completely disagree, 2- strongly disagree, 3- somewhat disagree, 4- somewhat agree, 5- strongly agree, 6- completely agree). The analysis involved 67 questionnaires which represented a 84.8% return rate. In the data was analyzed using the Statistical Package for the Social Sciences (SPSS) version 17.0 software programme. A Cronbach alpha reliability of 0.98 was obtained indicating that this research instrument was very reliable. This study showed job tenure had significant affected the level of employee job stress. Based on the percentage of average level of employee job stress using multiple regression analysis, it was found that the impact of the co-worker (31.1%) had a significant influence on the level of job stress followed by organization (11.9%), job post (6.5%) and work procedure (5.9%). Job satisfaction was significantly associated with with job stress with a p value of 0.0001. We conclude that increasing job has a negative impact on job satisfaction among the employees in the research institute, Ministry of Health, Malaysia.

# Nutritional Status of Malaysian Schoolchildren Aged 8-10 Years Old - Findings from a National Survey

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## SUMMARY

A nationwide survey was conducted in schools as part of the National Iodine Deficiency Disorders (IDD) survey in 2008 to determine the current nutritional status of children aged between eight and ten years old. 18078 children from 445 primary schools participated. All the three z-scores for nutritional status [(weight for age (WAZ), height for age (HAZ) and Body Mass Index (BMI) for age) were calculated based on World Health Organization (WHO) 2007 reference using software WHO AnthroPlus for Personal Computers. WAZ, HAZ and BMI for age were obtained from 16738, 18053 and 18015 school children respectively. Overall, the incidence of poor nutritional status and stunted growth among school children were 13.6% and 10.9% respectively. Around 2.3% were severely underweight and 11.3% were moderately underweight. The incidence of poor nutritional status and stunted growth were almost double in rural school children. As for thinness, the national prevalence was 7.8% (CI: 7.2, 8.4). The survey found that 70.1% had normal BMI for age. Only 7.6% of these children were overweight. Although the nutritional status of most children were within the normal range, we can conclude that there is still a significant incidence of poor nutritional status and stunted growth, especially among the rural children. There were higher percentages of overweight children in urban compared to rural areas. The findings of the study have suggested that concerted efforts need to be taken in dealing with the double burden of nutritional problems.

PSV08

# Health Screening among Institute for Public Health, Institute for Health Management, Institute for Health Behaviour Research and Radicare Staff

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## SUMMARY

Health screening activity was conducted by the Community Health Development Division of IPH from the 19th to the 26th October 2009 in conjunction with the Annual Health Promotion Week. This activity involved the staff from all divisions of IPH, IHM, IHBR and Radicare. The objective of this study was to determine the health status of staff and their socio-demographic profile. The study design was a cross sectional study. Data from 273 staff of IPH, IHM, IHBR and Radicare was collected by individual face to face interview, physical examination including dental screening and fitness test. Blood test and electrocardiography (ECG) were done for those who were 35 years and above. The targeted and high risk female staff were given opportunity to do Pap Smear at Tanglin Community Health Clinic and mammogram at Sungai Buloh Hospital. Data was analyzed using Statistical Packages for Sciences Software (SPSS) version 17.0. The results showed that unhealthy lifestyle still exist among health staff as shown by percentages of staff who are still smoking (prevalence 13.5% compared to 21.5% for Malaysian population from National Health Morbidity Data) and not doing physical activity (70.1% informal exercise; 88% formal exercise compared to 43.7% physical inactivity for Malaysian population from National Health Morbidity Data). Health staff still do not fully utilise the health services offered to them as reflected by the poor dental hygiene status (54% abnormal result) and pap smear screening offered to them (54% had pap smear before compared to 43.7% for Malaysian population from National Health Morbidity Data). Hypertension (22.6% compared to 32.2% for Malaysian) remain the main medical conditions among health staff while overweight (40.7% compared to 29.1% for Malaysian), hyperuricemia (93.3% of those with abnormal renal profile) and high cholesterol level (71.2% compared to 20.7% hypercholesterolemia for Malaysian) were the main findings among staff. The study showed that screening programme is beneficial in highlighting the health status of the staff as it enables us to detect a few undiagnosed conditions such as diabetes, hyperuricemia, dyslipidemia and even abnormality of liver function.

# Maternal Mortality Ratio - A Trend Analysis

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## SUMMARY

Maternal mortality ratio (MMR) is the number of women who die from any cause related to pregnancy or its management within 42 days of termination of pregnancy, per 100,000 live births. MMR reflects the quality of care received during the pregnancy. Advances in health, socioeconomic status, education and empowerment of women have had a major impact on reducing maternal mortality. Maternal mortality ratio returns compiled by MOH, Report on Confidential Enquiry on Maternal Deaths 2001 – 2005, MOH and other relevant reports were reviewed to conduct a trend analysis of MMR from 1990 to 2008 or to the latest year, subject to availability of data. The results of this study showed that the MMR has declined dramatically from 44 per 100,000 live births in 1991 to 27.6 per 100,000 live births in 2008. About half of the deaths were due to direct causes example, obstetric embolism, postpartum hemorrhage and hypertensive disorders of pregnancy Sabah had a higher MMR and Sarawak a lower MMR than the national figure. Age specific live births showed that MMR increased with the 2 extremes of the reproductive age group. By ethnicity, MMR was highest among Malays (60%) and lowest among Indians (4%). Although "other Bumiputra" contributed to less than 15% of MMR, trend analysis of ethnic group specific MMR showed high MMR among Bajau and Ibans. All states showed an increasing trend in safe deliveries, as seen in proportion of births attended by skilled health personnel. However, Sabah had the lowest proportion of births attended by skilled health personnel. In conclusion, Malaysia has done well in declining its MMR, similar to the pattern of most developed countries. Maternal mortality ratio in Malaysia has reached a plateau over the last few years. There are many successful factors leading to the reduction of national MMR. However, there are pockets of vulnerable groups with higher MMR than the national figure. The best practices should be scaled up to be implemented among the vulnerable groups. Further areas for exploration would be to review the contraceptive prevalence rate and address the issue of abortion and unwanted babies. Strengthening a Gender and Rights approach in maternal and reproductive health would ensure equality and non discrimination of the health services.

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PSV10

# Poliomyelitis Vaccination Status among Children in the Federal Territory of Kuala Lumpur

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## SUMMARY

Despite achieving a polio-free country status since 2000, there were still areas where polio vaccination coverage was low in Malaysia. In 2005, the reported polio vaccination coverage in the Federal Territory of Kuala Lumpur (FTKL) was only 29.3%, but with improved reporting from the private general practitioners, it increased to 61.2% the following year. The targeted polio vaccination coverage is 95%. A descriptive, cross sectional household survey was carried out in June-July 2007 to assess the actual polio vaccination status of children in the FTKL. The study population consisted of all children aged 9-24 months as of 1.6.2007, i.e those born from 1.6.2005 until 31.8.2006, living in the Federal Territory of Kuala Lumpur at the time of the survey. The study was carried out from the first of June until the 15th of July 2007. A minimum sample size of 1644 was calculated based on an estimated 80% coverage, with a 95% confidence interval and a desired precision of two percent. This sample was then proportionately divided into the 11 parliamentary constituencies (based on the population of each parliamentary constituency). The population in each Parliamentary constituency was grouped into clusters, enumerated and then randomly selected for the study. All living quarters in the selected clusters were surveyed. A total of 1842 children between the ages of nine and 24 months (born between 1.6.2005 and 31.8.2006) were successfully surveyed. One thousand eight hundred and eight (1808) children (98.2 %) had completed their polio immunization; 25 children did not complete their immunization and ; nine children were not immunized at all for polio. The Federal Territory of Kuala Lumpur had 20 430 live births in 2006 (estimated based on 11 months data) while the estimated live births by the Statistics Department was 28 400 for the same year. The vaccine coverage reported for 2006 was 61.2% when the estimated live births of 28 400 was used as the denominator, while the coverage was 85% when the denominator of 20 430 was used. The differences in vaccination coverage obtained for the year 2006 is largely due to the denominator used in the method of calculation of the vaccination coverage. The FTKL Health Department used estimated live births by the Statistics Department, while our study was based on the total number of respondents. When actual number of live births for the FTKL from the Federal Registration Department for 2006 was used as the denominator, the coverage improved to 85%, but was still short of the targeted 95% vaccine coverage. The main reason for this gap is due to under-reporting by the private practitioners. It is recommended that the estimation of live births by the Statistics Department be reviewed to match the actual live births, and enhance the reporting by the private general practitioners.

# Food Factories Census in Selangor State, Malaysia 2007

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## SUMMARY

Food Factories Census was conducted to develop a database of food factories in Selangor, Malaysia. The objective of this study was to determine the baseline data of food factories in Selangor for the purpose of surveillance and monitoring, enforcement and research in food safety. A total of 1256 factories were identified as food processing premises from the Registrar of Companies and Health District Offices databases. 488 were completely interviewed while others were not eligible as respondent. The data collection was done by face to face interview based on guided questionnaire and phone calls for follow up. The data were collected based on demographic profile, types of product, quality assurance system, quality control, workers, waste management and food safety management system. From the census, Petaling District had shown the highest population of food factories in Selangor. This study shown that 30% of the factories were producing grain & bread products meanwhile 35% of the company has been certified with Food Safety Management System. Majority of the food producers were supplied with tap water and using self waste management system. As a conclusion, Food Factories Census 2007 was important to establish baseline data and accommodate the development of Food Safety S Food Safety System in Malaysia.

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 PSV12

# Typhoid in Chuchuh Puteri Village, Kelantan

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## SUMMARY

Chuchuh Puteri Village is a village in Kelantan. Typhoid is one of the food borne diseases resulting from ingestion of contaminated food or water. The incidence of typhoid in Kelantan has always been higher compared to the other states in Malaysia. The aim of this paper was to describe the outbreak by time, place and person and to determine the source of pathogen. We defined an outbreak associated case of typhoid as a person from Chuchuh Puteri Village and adjacent village presenting with fever for more than three days associated with constitutional symptoms (headache/malaise/loss of appetite) from the third of April 2008 and Salmonella typhi was isolated from their blood or stool sample. We interviewed the patients in the ward, conducted house-to-house active case detection and ascertained environmental status. We also reviewed laboratory records; Accident and Emergency records for suspected cases of typhoid and treated as outpatient. A structured questionnaire survey was done on typhoid cases and randomly selected controls. The questionnaire included sex, occupation, symptoms, night market/food premises and type of foods. A total number of 64 cases were notified, 26 (40.6%) confirmed cases, 31(48.3%) suspected cases and 7(1.0%) probable case. The first case was notified on the third of May 2008. Chuchuh Puteri Village had the highest typhoid cases among three other villages. All typhoid cases were equal in gender, Malay (95.3%) was the major ethnic group and 15-24 age group registered highest typhoid cases of 32.8%. Two water samples from Lata Kesedar River were positive for Salmonella abony and one positive for Salmonella typhii. There were 24 typhoid cases and 48 controls involved in this survey. There were no significant associated factors or food related to typhoid cases. The study showed that typhoid outbreak in Chuchuh Puteri involved those with a history of taking foods from night markets.

# Validity of the Self-Report Adolescent Health Screening Tool

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## SUMMARY

This study was done to validate Adolescent Health Screening Form (Borang Saringan Kesihatan Remaja, BSSK/R/1/2008). This Adolescent Health Screening Tool was found to be very sensitive (100%) and specific (79.0%) in detecting anxiety disorders, and very specific (98.8%) but less to moderate sensitivity (28.6% and 54.5% respectively) in detecting depression and suicidal risk. The aim of this study was to determine the sensitivity and specificity of the Adolescent Health Screening tool by validating the mental health components of the form using specific validated tools. Sample size was calculated based on the prevalence of mental health problems noted in the 3rd National Health and Morbidity Survey (NHMS III).<sup>10</sup> Based on "Sample Size Calculation for Sensitivity and Specificity Studies, by Dr Lin Naing or Mohd Ayub Sadiq, School of Dental Sciences, USM" to ensure a 90% sensitivity and specificity, with an expected prevalence of psychiatric morbidity of 20%, desired precision of 5.0% and Confidence Interval of 95%, expected sample size was 65. Based on the prevalence of acute suicidal ideation among 16-19 years (NHMS III) of 11.4%, for a 90% sensitivity and specificity, with desired precision of 5.0% and Confidence Interval of 95%, expected sample size was 107. Considering of possibility of 10% no-response rate, required sample size was 120 respondents. Sample was selected using quota sampling where all respondents who were eligible to be included in the study based on the inclusion criteria and agreed to involve in the study were selected. Sampling frame was adolescents who attended Adolescent Health Programme at the selected clinics. The inclusion criteria for the respondents were; adolescent aged between 10 to 19 years old, new case (new case to the Adolescent Health Programme of the clinic) and able to understand, and read and write in Bahasa Malaysia and English (scored minimum of 90% of both languages tests). Fluency in both language was a requirement as our screening tool was in Bahasa Malaysia, while the validated tools were in English. Respondents with history of mental health problem or under treatment for mental health problems were excluded. Research teams members decided to only focus on validation of mental health component (C6) as other parts of the screening tool were not suitable for sensitivity and specificity test. The group had selected several validated tools to be used in the validation process namely: six-item Kutcher Adolescent Depression Scale: KADS11, Beck Anxiety Inventory<sup>12,13</sup> and Tool for Assessment of Suicide Risk: Adolescent Version (TASRS-A)<sup>14</sup>. The respondents who were recruited from the four identified clinics (KK Tangling, KK Jinjang, KK Putrajaya, KK Bandar Baru Bangi) were screened by the four Family Medicine Specialists who also act as Co-Investigators cum Data Collectors. To ensure standardization of data collection, Manual for Data Collectors was developed and adhered to. Data collectors also underwent specific training given by the Principal Investigator and technical advisors. Validation process involved several steps; filling-up of the self-administered Adolescent Health Screening Forms; followed by self-administered validated screening tools (6-item Kutcher Adolescent Depression Scale: KADS and Beck Anxiety Inventory); followed by interview by Family Medicine Specialist to validate suicide risk using Tool for Assessment of Suicide Risk: Adolescent Version (TASR-A). Ethical issues were handled by protection of respondents' right to privacy and assurance of confidentiality and anonymity of responses. Any medical problems or risk factors identified were managed accordingly. Adolescents with suspected depression and suicidal ideation were referred to Child and Adolescent Psychiatrist for further management. Research Proposal was approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia. Data quality control was ensured through development of Manual for Data Collectors and ensuring that all data collectors underwent specific training. Findings from the screening form and validated tools were entered into SPSS database manually. Double entry and consistency check was done followed by data cleaning. Syntax for diagnosis based on agreed criteria was done and data analysis was done using SPSS Version 16.0 to look for sensitivity and specificity of the BSSK/R/1/2008. A total of 106 adolescents were noted as eligible and agreed to involve in this study. By sex, almost equal distribution was noted with 57% females and 43% males. Most of the adolescents (71.7%) were in their mid-adolescence, with 15.5% in early adolescence and the remaining 13.2% were in late adolescence stage.

More than three quarter of the respondents was Malays (77.4%), with 21.7% Chinese and 0.9% Indian. A small percentage (2.8%) of the respondents had not completed their primary education at the time of the interview. Majority of them (84.0%) had completed their primary education, with 11.3% had completed secondary education, and 1.9% had completed tertiary education. Based on Borang Saringan Kesihatan Remaja, BSSK/R/1/2008, (Adolescent Health Screening Form) 23 respondents (21.7%) were noted as having anxiety problems, 7 respondents (6.6%) had depression and another 9 respondents (8.5%) were at risk for suicide. Problems detected using Borang Saringan Kesihatan Remaja, BSSK/R/1/2008, (Adolescent Health Screening Form), by sociodemographic profiles were shown in Table I. By sex, anxiety, depression and suicidal risk were noted as higher among females. By stage of adolescence, anxiety disorders were higher during mid-adolescence. Depression and suicidal risk were noted as directly related to age. By ethnicity, depression and suicidal risk were higher among Malays compared to other ethnics. Table II shows comparison between problems detected using Borang Saringan Kesihatan Remaja, BSSK/R/1/2008, (Adolescent Health Screening Form) and problem detected using validated tools. Percentages on respondents with anxiety were noted as lower by using validated tools compared to BSSK. However, validated tools revealed a higher percentage of respondents with depression and suicidal risk. Based on the above findings, sensitivity, Specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV) of Adolescent Health Screening Tool was tabulated in Table III. Adolescent Health Screening Tool was noted as very sensitive but low PPV in the screening of anxiety disorders, but less sensitive but very specific and has high PPV, in detecting depression and suicidal risks. In conclusion, this validity study using identified validated tools had noted that this Adolescent Health Screening Tool to be very sensitive and specific in detecting anxiety disorders, and very specific but less sensitive in detecting depression and suicidal. However, this tool was noted as able to correctly identify adolescents who did not have the screened problems (high NPV). Based on these findings, this screening tool was unable to correctly identified adolescents with either anxiety, depression or suicidal ideation. It is advisable to revise the mentioned components in order to increase their sensitivity as a screening tool.

# Clients Satisfactions in ISO Certified Health Clinic in Klinik Kesihatan Bandar Baru Bangi, Selangor and in Non-ISO Certified Health Clinic in Poliklinik Komuniti Tanglin, Kuala Lumpur and its Associated Factors

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## SUMMARY

All health care services are moving towards quality management system including ISO 9000 due to pressure from various stakeholders involves and also to improve health care quality. The objective of this study was to measure the satisfaction level among the outpatients in ISO Certified Klinik Kesihatan Bandar Baru Bangi, Selangor and in Non – ISO certified clinic in Poliklinik Komuniti Tanglin, Kuala Lumpur. Also to identify to identify the relations of patient's satisfaction with the socio-demographic factors and service dimensions such as general satisfactions, technical quality of clinic staffs, interpersonal aspect of clinic staffs, time with doctors, communications with clinic staffs and availability/accessibility of clinic. A cross sectional study was carried out from February to Jun 2008 and a total of 240 respondents in each clinic were selected using universal sampling. Only those who are Malaysians aged 18 and above and complied with the inclusions criteria's were selected as the respondents. The study found that the respondents in Non – ISO certified clinic were more satisfied compared to respondents in ISO certified clinic with 91.7% and 78.8% respectively. It has been shown that the predictor factors of total patient's satisfaction were general satisfaction (AOR=5.22, CI= 2.06-13.24), technical quality of clinic staff (AOR = 7.73, CI= 3.35-17.32), interpersonal aspect of clinic staff (AOR = 4.21, CI= 1.92-9.24), availability/accessibility of clinic (AOR = 26.42, CI= 11.27-61.96) , housewife (AOR= 7.76, CI= 1.13-53.21) and also the status of non-ISO certified clinic ( AOR = 2.47, CI= 1.05-5.81). In conclusion, respondents in Non-ISO certified clinic were more satisfied than respondents in ISO clinic. The study concluded that the ISO certified clinic should improve the service dimensions in order to increase patient's satisfaction.

# Prevalence of Hearing Loss in Children with Downs Syndrome

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## SUMMARY

Hearing loss is one of the most common disabilities in children with Down syndrome (DS). Speech impairment, upper airway obstruction and otorhinolaryngology infections often lead to increased handicap in these children. Previous studies had reported 38 -78% incidence of hearing loss in children with DS. The objective of this study was to provide an updated local data on the prevalence, type of hearing loss, hearing threshold, type of ear surgeries performed and hearing rehabilitation used in children with DS. This was a one year cross sectional study performed in the Universiti Kebangsaan Malaysia Medical Center. All DS patients aged less than 12 years old were invited to participate in this study. The study period was from December 2008 to November 2009. An interview, clinical examination and hearing assessment which included an audiogram, tympanometry and brainstem evoke response test (BSER) were used to evaluate these patients. Two hundred and twenty four children with DS were recruited for this study. All patients had BSER and tympanometry performed but only 93 patients were co-operative for pure tone audiometry. The tympanometry was type B in 156 patients (69.6%) and type C in 44 patients (19.6%) whilst the other 24 patients (10.8%) had type A. The prevalence of hearing loss was 90.2% (202 out of 224 patients). The commonest type of hearing loss were conductive hearing loss in 160 patients (79.2%), followed by sensorineural hearing loss in 36 patients (17.8%) and mixed hearing loss in six patients (3.0%). Most of them had mild to moderate level of hearing loss. Myringotomy and grommet was the most common surgical procedure performed, indicated for middle ear effusion. Only 32 patients were prescribed with hearing aids and the compliance was moderate with 65.6% wearing it between three to five hours daily. The study demonstrates that there is a high prevalence hearing loss in children with DS with conductive hearing loss being the most common. However efforts at hearing rehabilitation are still inadequate. Therefore the physician should be vigilant in identifying and treating all reversible causes of hearing loss and to prescribe hearing aids early when necessary. This could help to lessen the handicap and thus promote better learning abilities and intellectual development in children with DS.



## POSTER ABSTRACTS - OTHERS

- POT01** Benchmark to Improve Health-Related Quality of Life (HRQOL) in Malaysia
- POT02** Exploring Dark Chocolate's Effect on Mood and HRQOL in Palliative Care
- POT03** Spatial Distribution of Breast and Colorectal Cancer Cases in Penang, Malaysia
- POT04** Diagnostic Value of Vestibular Evoked Myogenic Potentials (VEMPS) Test Among Peripheral Vestibular Disorders Patients
- POT05** Refined Palm Oil's Potential as Transdermal Drug Delivery Enhancer
- POT06** Simultaneous Determination of Ofloxacin and Ornidazole in Pharmaceutical Formulations by Capillary Electrophoresis
- POT07** Accuracy of Pre-Necropsy Screening Test in the Department of Forensic Medicine Hospital Kuala Lumpur (HKL)
- POT08** Development of Emergency Response Model for Ambulance Services
- POT09** The Development of Special Needs Dentistry – A Situational Analysis (Based on New Zealand Experience)
- POT10** Enoxaparin and Bleeding Complications
- POT11** Level of Understanding and Compliance on Drug Stability Profile of Reconstituted Drugs Among Nurses of Pediatric Ward at Hospital Raja Perempuan Zainab II
- POT12** Optimization of Feature Selection for Classification of Infant Cries With Asphyxia Using Orthogonal Least Square Analysis
- POT13** Development And Validation Study of Malay Language Version Brief Treatment Outcome Measure (BTOM) for the Purpose of Outcome Monitoring in Drug Addiction Under Methadone Maintained Programme
- POT14** Costs Associated With Different Methods of Treatment in Mandibular Fractures – A Prospective Evaluation
- POT15** Characteristics of Drug Wastage at Hospital Tuanku Jaafar, Seremban - A Descriptive Study
- POT16** Development of a Computerized Objective Assessment of Area and Erythema for PASI Scoring Of Severity of Psoriasis, and Comparing with the Conventional Visual Assessment of PASI by Dermatologists
- POT17** A Comparison Between Dental Aesthetic Index (DAI) and Index of Orthodontic Treatment Need (IOTN)
- POT18** Prospective Study of Antibiotic Use in Hospital Raja Perempuan Zainab II Surgical Wards
- POT19** Cost Analysis of Antibiotic Therapy in Patients with Dosages Adjusted for Renal Function in ICU Hospital Raja Perempuan Zainab (HRPZ) II
- POT20** Attitudes and Experience of General Dentists in Providing Oral Health Care for Children With Special Needs (CSN)
- POT21** The Effect of Duration of Using Injectable Contraceptives on Bone Mineral Density
- POT22** Comparison of HRQOL Between Patient Receiving Methadone Maintenance Therapy (MMT) and Rehabilitation Program
- POT23** Effects of Nicotine Administration Duration and Nicotine Cessation on Bone Histomorphometry in Sprague-Dawley Male Rats
- POT24** The Regeneration of Dental Hard Tissues from Cultured Rat Tooth Bud Cells
- POT25** The Automatic Dysphonic Voice Diagnostic System Based on Dysphonic Severity Index

- POT26** Fast Detection of Hearing Loss Based on Time Frequency Representation of ABR Signal
- POT27** Evaluation of the Tolerance and Acceptability of Oral Caffeine for the Treatment of Apnoea of Prematurity
- POT28** Detection of MDR1 Haplotypes (C1236t, G2667t/A and C3435t) Using an Allele Specific PCR Method
- POT29** Correlation Between Body Mass Index (BMI) and Image Evaluation Criteria in Mediolateral Oblique (MLO) Mammography Images With Different Tube Angulations
- POT30** Economic Evaluation of Vaccination Against Human Papillomavirus (HPV) Infections In the Prevention of Cervical Cancer
- POT31** Novel Feeders of Mesenchymal Stromal Cells Obtained from Human Foreskin Facilitates Long Term Propagation of Human Embryonic Stem Cells
- POT32** An Analysis of Socioeconomic Inequalities in Health Care Utilization in Malaysia

# Benchmark to Improve Health-Related Quality of Life (HRQOL) in Malaysia

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## SUMMARY

Rates of reported health problems in different demographic groups in Malaysia were evaluated and the results were compared with that of a United Kingdom National Survey to set a national benchmark. A hundred and fifty heterogeneous respondents were conveniently chosen from Klang Valley. Chi-Square test was conducted to compare the population subgroups. The demographic background of the respondents, their self-rated health on a three-point scale and self-rated health status on the visual analogue scale (VAS) in EQ-5D were summarized using descriptive statistics. The Mann-Whitney or Kruskal-Wallis non-parametric test was used to assess whether the median VAS score was significantly different among different demographic measures. Analysis of variance (ANOVA) was used to investigate the collective influence of demographic factors. The results from Chi-Square test revealed that none of the demographic factors were significant and this can be attributed to small sample size. Surprisingly, the outcome of the dimensions showed prominent results. Both populations presented consistent findings with higher problems reported in dimensions such as pain/discomfort and anxiety/depression. Results from the ANOVA reflected only age group significant contributed to VAS score (p-value of 0.02). An increased level of EQ VAS was seen in Malaysians after 59 years of age while United Kingdom presented decreasing levels. Generally the female Malaysian population had better health status compared with the male population except at 50-59 years of age. In conclusion, the EQ-5D has demonstrated to be an ideal HRQOL tool as part of the National Morbidity Survey to assess the quality of life among the Malaysian population.

POT02

# Exploring Dark Chocolate's Effect on Mood and HRQOL in Palliative Care

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## SUMMARY

Most people believe that chocolate consumption can produce pleasurable sensation. The psycho-active ingredients in dark chocolate (DC) are perceived to be the main contributor of mood regulation. Anxiety and depression (AD) occurs to varying degrees in oncology patients and may heighten as the disease progresses. These disorders can generate adverse impacts on the disease outcomes as well as health-related quality of life (HRQoL). We investigated the effect of a three-day DC consumption intervention on AD and HRQoL in palliative cancer patients. The intervention study was based on parallel, prospective and open-labelled design. This was a 3-day follow-up experimental study involving two groups, one of which was the intervention group (IG; N = 28) that included patients receiving DC consumption and the other group was the control group (CG, N = 18) consisting patients assessed with mineral water ingestion. The Malay versions of Hospital Anxiety and Depression Scales (HADS) (domain score  $\geq 8$  = case) was utilised to screen AD levels. Additionally, the Malay McGill Quality of Life Questionnaire (MMQoL) was administered to assess patient's HRQoL. Data were analysed descriptively and the scores within groups and between groups were compared with non-parametric tests. The value of  $p < 0.05$  was considered significant. Out of 168 available patients, only 46 were eligible to participate (response rate = 27.3%). They were randomly assigned into IG or CG (mean age = 46.9 years, age range 23 - 68 years, chocolate consumption per week  $\approx 1.25 \times 50g$ , extent of chocolate - loving = 58.5%). No significant differences in AD levels and Total MMQoL Score were detected at baseline between IG and CG ( $p > 0.05$ ). Significant reduction of AD scores were demonstrated in both IG and CG between baseline and follow-up ( $p < 0.01$ ). Nonetheless, the decrease of AD scores was significantly greater for IG compared to CG (HADS-A: IG mean difference = 4.67, CG mean difference = 2.00,  $p < 0.001$ ; HADS-D: IG mean difference = 6.03, CG mean difference = 1.31,  $p < 0.001$ ). The Total MMQoL Score was significantly increased greater in IG at post-consumption compared to CG (IG mean difference = 1.42, CG mean difference = 0.18,  $p < 0.001$ ). The findings demonstrated that AD levels and HRQoL significantly improved for patients who received DC as intervening food, compared to patients in the CG. Findings suggest that DC consumption for 3 consecutive days may contribute to the alleviation of poor mood state which could also enhance HRQoL among palliative patients. Extensive interventional studies with one or more different types of chocolate and with longer consumption time of DC are further warranted.

# Spatial Distribution of Breast and Colorectal Cancer Cases in Penang, Malaysia

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## SUMMARY

Geographical Information Systems (GIS) have been widely used in many developed countries to map health related events. The results are used for planning of health services (e.g screening) and assessing clusters of cases to look for possible aetiological factors. In the United States, cancer case addresses are routinely entered into GIS and trends can be monitored over time. In Penang, Penang Cancer Registry (PCR) collects data on all cancer patients diagnosed in Penang or have Penang home addresses. Reports are generated on cancer cases with home address in Penang. The mapping of cases using information from PCR will give a fairly complete picture of the spatial distribution of cancer cases from that state and case clustering can be readily assessed. This study demonstrates the potential application of GIS in mapping and evaluating the spatial distribution of Breast and Colorectal Cancer cases in Penang. Point pattern analysis was used to evaluate the spatial clustering of cancer cases. In addition, the study evaluates patients' accessibility to health facilities here. Once more detailed demographics are entered into GIS, we will be able to carry out other forms of analyses.

POT04

# Diagnostic Value of Vestibular Evoked Myogenic Potentials (VEMPS) Test Among Peripheral Vestibular Disorders Patients

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## SUMMARY

High diagnostic value test are able to detect whether the disease is present or not, the severity of the disease and the site of lesion. Having an accurate clinical diagnosis is obviously important for effective management. Therefore, this study was conducted to elicit the sensitivity and specificity value of the VEMP test in peripheral vestibular disorders patients. Vestibular evoked myogenic potential (VEMP) is one of the recent vestibular tools that specifically investigates the status of saccule, inferior vestibular nerve and central vestibular tests. It is rapid, non-invasive and can be recorded using the existing auditory evoked potential device. This test can actually evaluate other organs of the vestibular system that cannot be assessed by typical clinical tests such as the caloric or rotational chair test. In this study, 40 normal participants and 65 PVD subjects participated. While sitting, VEMPs were recorded with active electrode on sternocleidomastoid muscle and negative electrode on upper forehead. Normal and PVD subjects were found to be statistically different by VEMP test. Sensitivity and specificity of VEMP test was then determined using Receiver Operating Characteristic (ROC) method. By considering the Youden Index, the N1 amplitude of 750 Hz was found to be most ideal parameter of VEMP. Its sensitivity was reasonably high, i.e., 64.6% on the right side and 63.1% on the left side. Its specificity was also high, i.e., 85% on the right side and 77.5% on the left side. This study demonstrated the VEMP is one vestibular assessment tools that showed high sensitivity and specificity value among the PVD patients. In this situation, having VEMP is useful to appropriately diagnose patients with PVD as well as to reduce the number of false negative cases. Further, early and accurate diagnosis may also improve and enhance the rapid recovery of the patient's balance symptoms. Indirectly, improved and enhanced recovery may prevent the psychological impacts or other associated symptoms related to the recovery. Ultimately, this may improve the patient's quality of life. This improvement will be able to help the community in terms of socially, economically and psychologically. In future, it is also of interest to compare the diagnostic values of VEMP using different intensity levels and clicks tone burst on PVD patients to be compared with the findings in the present study.

# Refined Palm Oil's Potential as Transdermal Drug Delivery Enhancer

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## SUMMARY

Transdermal drug delivery (TDD) is defined as the systemic delivery of drugs across the skin. This method of drug delivery can overcome several significant limitations associated with other routes such as gastro-intestinal tract (GIT) and hepatic first-pass metabolism and complex dosage regimens. However, the major drawback of TDD is that it is often difficult to attain sufficient drug flux to achieve clinically effective plasma drug concentrations as the skin forms an excellent barrier. In our current study we have chosen to evaluate the ability of refined palm oil as a penetration enhancer. The rationale of selecting palm oil is due to the fact that fatty acids, which are present in palm oil in both the free form and (largely) as triacylglycerols, have been shown to act as permeation enhancers in previous studies. Moreover, some components within palm oil, such as squalene and the tocotrienols, possess anti-inflammatory properties. Inflammation at the site of transdermal formulation (patch) application is sometimes cited as a drawback of TDD. Refined palm oil is also generally regarded as safe (GRAS), being widely used in the cosmetic and pharmaceutical industries. Ibuprofen was selected as a model drug in this experiment and three additional vehicles (propylene glycol, 2-pyrrolidone and oleic acid) were used as controls. The vehicles propylene glycol, 2-pyrrolidone and oleic acid were employed as a high enhancement positive control, modest enhancement positive control and negative control, respectively. Simple single phase drug in vehicle formulations were used to assess the permeation of ibuprofen, across full thickness human skin *in vitro*. In each formulation, ibuprofen was present a concentration in excess of its saturated solubility in that specific vehicle. Samples were assayed using HPLC and permeation profiles were constructed. The highest flux was observed when the vehicle was 2-pyrrolidone, this was followed by propylene glycol, refined palm oil and then the negative control, oleic acid. The significance of these results was analyzed using Student's T-test with significance of  $p < 0.05$ . It was found that only the flux of ibuprofen from 2-pyrrolidone flux was significantly different from the negative control. Hence, refined palm oil did not exert a significant effect on the percutaneous permeation of ibuprofen across human skin. However, these results were only true for drugs with Log P of about 3, where drugs with slightly lower and higher Log P may vary in their respond. This holds true as some chemical enhancer are polarity specific enhancers, such as the hydrophobic terpenes which enhances the non-polar drugs only. Furthermore, there remains a possibility that refined palm oil may be a concentration dependent enhancer such as oleic acid, which only exerts its effect at lower concentrations. Further work is being planned by the authors to investigate the possibilities discussed above.

POT06

# Simultaneous Determination of Ofloxacin and Ornidazole in Pharmaceutical Formulations by Capillary Electrophoresis

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## SUMMARY

A simple, rapid and specific capillary electrophoresis (CE) method has been developed for the separation and determination of ofloxacin and ornidazole in pharmaceutical formulations using photo diode array (PDA) detection at 230 nm. Optimal conditions for the quantitative separations were investigated. Analysis time, shorter than four minutes were found using a background electrolyte solution (BGE) consisting of 25 mmol L<sup>-1</sup> phosphate buffer, adjusted by 1 M TRIS to pH 8.5, with hydrodynamic injection of five seconds and 20.0 kV separation voltage were used. Main aspects of the validation method criteria for the accuracy, precision, linearity, limit of detection and quantitation were examined and discussed. Excellent linearity was obtained in concentration ranging of 25 – 250 µg mL<sup>-1</sup>. The detection limits for ofloxacin and ornidazole were  $1.03 \pm 0.11$  µg mL<sup>-1</sup> and  $1.80 \pm 0.06$  µg mL<sup>-1</sup>, respectively. The proposed method has been applied to the analysis of commercial formulations of ofloxacin and ornidazole in a combined dosage form. To the best of our knowledge, this method is the first to report on the simultaneous determination of ofloxacin and ornidazole concentrations in pharmaceutical preparation using CE. Recoveries between 96.16% and 105.23 percent over the nominal contents were obtained.

# Accuracy of Pre-Necropsy Screening Test in the Department of Forensic Medicine Hospital Kuala Lumpur (HKL)

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## SUMMARY

A six month descriptive, prospective study was carried out from the 18th of January 18th until the 18th of July 2009 on the pre-necropsy test conducted on cases received by the Department of Forensic Medicine, Hospital Kuala Lumpur (HKL). The study was aimed at assessing the accuracy of the pre-necropsy screening test conducted on all post mortem cases received by the Department of Forensic Medicine HKL. The pre-necropsy test consists of three basic rapid tests, which are Human Immunodeficiency Virus (HIV) test, Hepatitis B and Hepatitis C test, which are purchased from True Bioscience. A total of 110 cases were analyzed in this study which consisted of police cases with various causes of deaths. The data was retrieved by comparing rapid screening test results for each case with the results obtained from the Virology Unit, Department of Pathology, HKL. The data collected included the number of cases, results for the three screening tests conducted in the Department of Forensic Medicine and results for the three screening tests obtained from Virology Unit, Department of Pathology, HKL. This study reflected the accuracy of the rapid test kits purchased from True Bioscience and thus assisting mortuary staff involved in performing the cases to assess risk of infection including proper protection needed to handle each case respectively. The outcome of the study showed that more than 90% of the pre-necropsy rapid tests were accurate rendering the test useful as a tool in prevention of infection among mortuary staff.

# Development of Emergency Response Model for Ambulance Services

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## SUMMARY

Immediate emergency medical care can minimize the consequences of serious injury including long term morbidity and mortality. One of the key indicators to evaluate the efficiency of the emergency service is ambulance response time. Therefore, it is essential to generate a model that considers factors affecting current emergency response time for strategic planning of efficient ambulance services. Four hospitals (two state and two district) were selected for the study. Data on the ambulance response time was obtained via Global Position System (GPS) and hospital records. Data recorded by GPS included name of the hospital; date and time of ambulance dispatch; date and time of arrival at the emergency location; name of the location; GPS coordinates of the location, travel time, average ambulance speed to the call, maximum recorded ambulance speed, and distance travelled. Time of call and case type were obtained from the hospital record. Ambulance movement for emergency cases were identified by cross-checking GPS and hospital records. Multiple linear regression analysis was performed to develop statistical model in predicting response times. 1153 ambulance responses were analyzed. Around 17.5% of responses were made to motor vehicle (MVC) crash sites. The overall mean ambulance response time was 18.4 minutes with 50%, 90% and 95% of the cases were responded to within 17.0, 28.0 and 32.3 minutes respectively. The response time was slightly better for MVC cases with the mean of 15.8 minutes. Three variables significantly associated with the response time were distance, activation time and average speed of the ambulance. Specifically for MVC cases, the model predicted that the response time increases by 1.40 (95% CI: 1.29, 1.52) minutes for every one km increase in distance. In order to achieve a response time  $\leq 12$  minutes, the distance should not exceed 4.2 km when the activation time is 5.0 minutes. The results highlight the need for improved activation and travelling time in order to enhance response time. The model generated could be used for strategic planning of ambulance services especially in deciding maximum coverage of a dispatch centre. This is to ensure early response time to medical emergencies.

# The Development of Special Needs Dentistry – A Situational Analysis (Based on New Zealand Experience)

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## SUMMARY

The aim of this project was to understand the expectations of the Malaysian population for future development of SND service in Malaysia. Along with the current recognition of the specialty by the Malaysian Ministry of Health, the Ministry has identified New Zealand as an appropriate nation to provide information on service developments and lesson learnt from an established service. Fifty five participants who represented the major stakeholders in the service were interviewed, encompassing people with special needs, caregivers, policy makers, dentists and disability support group representatives. The qualitative data were analysed using applied grounded theory. Data collection is expected to be completed in April 2010. Five major areas which need to be considered in the development of SND service in Malaysia have been identified. These are (a) access to information and education; (b) access to dental facilities; (c) screening and referral system required for people with special needs; (d) involvement of other organizations apart from oral health care providers in the system and; (e) increasing knowledge and exposure to special needs individuals by general practitioners during undergraduate training. In addition to the five areas of deficiency identified above, the absence of a clear referral pathway and lack of involvement of the community increased the risk of poor oral health in this vulnerable group of population.

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 POT10

# Enoxaparin and Bleeding Complications

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## SUMMARY

Bleeding is one of the commonest complications of enoxaparin use. Determining the predictors of bleeding will assist in the safety of low molecular weight heparin administration. The study was carried out to identify the incidence of bleeding, to compare the bleeding complication among patient with and without renal insufficiency and to determine other co-predictors which can influence bleeding. Data was collected retrospectively from patients who were admitted to medical wards, Hospital Melaka in between July and December 2008. A total of 166 patients who received enoxaparin were included in the study. The mean age of this study was  $59.9 \pm 12.5$  years. There were 10 bleeding events (6%), of which 0.6% was classified as major. Around 63.9% of the total patients were having renal insufficiency. There was no significant difference in incidence of bleeding among patient with and without renal insufficiency. Age, serum creatinine, creatinine clearance, amount of enoxaparin given, number of doses given, gender, smoking and concomitant antiplatelet therapy did not significantly affect the incidence of bleeding. In conclusion, the prevalence of bleeding in this study were 6%. There was no difference of incidence of bleeding among patient with and without renal insufficiency. The co-predictors tested were not found to influence the bleeding.

# Level of Understanding and Compliance on Drug Stability Profile of Reconstituted Drugs Among Nurses of Pediatric Ward at Hospital Raja Perempuan Zainab II

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## SUMMARY

Stability is defined as the capacity of a drug product to maintain its identity, strength, quality, and purity until the expiration date. This study was done to access the level of understanding and compliance on drug stability profile among nurses of the pediatric ward at Hospital Raja Perempuan Zainab II (HRPZ II). Collection data was done through self-administered questionnaires (n = 50) and observation from the 20th of February 2008 to the 4th of March 2008. From these questionnaires, we found that 20% of the staff (N=10) scored 81-100%, 50% (N=25) scored 71-80% and 30% (N=15) scored <70%. From observation, reconstituted drugs that had been marked date of open were 96.8%, 84.2%, 83.6%, 63.1%, 60% and 22% respectively in Ward 2, 5, NICU, PHDW, 4 and 1. Multi-use drugs stored in fridge after opened were 96.7%, 94.7%, 90.9%, 81.6%, 80.6% and 47.2% respectively in Ward 4, 5, 3, PHDW, 2 and 1. Number of opened single use drugs that still remained on the medication trolley were 26, 23, 18, 1, 7 and 2 respectively for Ward 2, 3, 1, PHDW, 4 and 5. Date of open was important as a tool to ensure drugs were still stable at the time of administration. Typically, a small increase in temperature results in drug decay. Therefore, all reconstituted drugs should be stored in the fridge to prevent further deterioration. Single use drugs do not contain any preservative hence should be discarded immediately after reconstitution. In conclusion, level of understanding among nurses were still low. In addition, compliance to drug stability profile was not at acceptable level. Therefore, ongoing observation and education should be done to ensure only stable and potent drugs were administered to patients.

POT12

# Optimization of Feature Selection for Classification of Infant Cries With Asphyxia Using Orthogonal Least Square Analysis

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## SUMMARY

Asphyxia occurs in infants with injury to the central nervous system, as a result of drop in the maternal blood pressure, interruption of blood flow to the newborn's brain etc during delivery. Previous works have shown that the asphyxiated cry signals exhibit distinct pattern, which can be recognized with intelligent pattern classifier such as Artificial Neural Network. Most of these works adopted the Mel Frequency Cepstral (MFC) analysis, with filter banks to mimic the human auditory system, hence the most appropriate for voice recognition, to represent the infant cry signals. A major drawback with MFC transform was generation of a massive volume of coefficients. This will incur a heavy penalty on the computation load and thus impede the efficiency of post-processing. Our work investigated the performance of a three-layer structured Multi-Layer Perceptron (MLP) classifier in differentiating between the healthy and asphyxiated infants of age zero to seven months, and uniquely the effectiveness of orthogonal least square (OLS) analysis in enhancing the accuracy of the MLP classifier with an optimized input feature vector. The OLS, developed originally to select the model order for system identification, is adapted to rank the significance of each MFC coefficient according to their error reduction ratio (ERR). The infant cry waveform was first transformed into MFC coefficients, which are then ranked and trimmed, according to their ERR before input to the MLP classifier. Then, performance of the MLP classifier was examined with different network structures, varying in number of coefficients, filter banks and hidden nodes. It was found that the OLS analysis was effective in enhancing the accuracy of the MLP classifier while reducing the computation load, with a ranked and reduced order input feature vector. Both the average and highest MLP classification accuracies with coefficients being ranked by the OLS algorithm have consistently displayed better score than those with full order input feature vector. This was because the lowly ranked MFC coefficients have been proven to make minimal contribution towards the performance of MLP classifier. The highest MLP classification accuracy of 94% was obtained with 40 filter banks, 12 highly ranked MFC coefficients and 15 hidden nodes.



# Development and Validation Study of Malay Language Version Brief Treatment Outcome Measure (BTOM) for the Purpose of Outcome Monitoring in Drug Addiction Under Methadone Maintained Programme

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## SUMMARY

Substitution therapy of methadone among opioid addiction has been put into practice for more than 30 years. However, in Malaysia, it has been introduced as maintenance therapy in the year 2005 until now in a controlled environment by a trained practitioners. Various tools have been used to assess response and outcomes such as Opioid Treatment Index (OTI) and WHO-BREF-QOL. Our aim in this study was to produce a validated Malay version of another assessment tool, Brief Treatment Outcome Measure (BTOM) for the purpose of outcome monitoring in methadone maintained patients. Two sets of translation from English to Malay language were prepared by two independent individuals who were fluent in both languages. The translated versions were next translated back to English by another two individuals and both sets were reviewed to produce a pre-final Malay version. The individuals involved in translation were the researcher herself and also from the Centre for language and translation Universiti Sains Malaysia. They are totally independent from each other, hence no discussion was allowed. Furthermore, they were unfamiliar with the questionnaire thus preventing any bias. The pre-final version was further reviewed, comments and face validated by five independent viewers (n=5) and some amendments has been made. Pre-test of amended version of the pre-final BTOM Malay version was done to the target group of population (n=25). The results were analyzed by using SPSS version 14 and review to produce the validated final Malay version of BTOM. After few steps of translation, face-validation and reviews followed by amendments, a pre-test was conducted directly to the target group in Drug Intervention Community (DIC) – a drop in centre for drug addiction. Twenty-five patients were participating in the study and all of them (100%) were male addicts. The mean administration time was 14.7 minutes. The researcher faced no difficulties in interviewing the patients with a good response and understanding. The Cronbach's alpha value for reliability test of scale type questions was 0.7 which is acceptable and reliable. BTOM was chosen for several reasons. It is an upgraded version of opioid treatment index (OTI) which has undergoes four steps of review consuming almost 10 years of study by National Drug and Alcohol Research Centre, University of New South Wales. The latest version (Version 4) was chosen for this study. It can be easily administer in any setting for routine assessment with comparable score-based system. It will investigate the characteristics of persons entering treatment, capture the disability of the client population, document treatment outcomes, informed the planning and development of treatment services and to act as a quality assurance measure. Key considerations in the design of the BTOM were that it place minimal time demands on clinical staff and clients, be acceptable, easy to administer and interpret and have good psychometric properties, such that it is a reliable and valid instrument. With 14.7 minutes mean time needed for administration and 0.70 for reliability test makes BTOM-Malay a validated instrument to be used as an outcome assessment tool in methadone maintained patients in Malaysia's clinical setting.

# Costs Associated With Different Methods of Treatment in Mandibular Fractures – A Prospective Evaluation

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## SUMMARY

The treatment of mandibular fractures has evolved over time. Numerous studies have shown that the use of semi-rigid mini plated gives a very good surgical outcome in treatment of mandibular fractures. However, there have been only a few studies examining other outcomes in mandibular fracture treatment such as cost of treatment and benefits from societal perspective. In Malaysia, the economic factor is an important determinant of the method of mandibular fracture. Therefore, the objective of this study was to investigate the importance of this factor. This prospective study was carried out to investigate and compare costs incurred for three common methods of treatment of isolated mandibular fractures. Patients with isolated mandibular fractures in Oral Surgery Units in ten selected Ministry of Health hospitals were admitted into one of the three groups after an informed decision was made by the patient, which were (1) patients treated with closed reduction only (IMF); (2) patients treated with open reduction only (ORIF) and ; (3) patients treated with open reduction and a short period of intermaxillary fixation (ORIM). Trained research staff administered cost charge questionnaires at discharge and three subsequent recall visits through interviews. One hundred and twenty-two patients met the study criteria. The mean number of hospitalization days for the IMF group was the lowest with a mean of 1.93 and the ORIM group the highest. The ORIM group had the highest mean of RM 1126.68 ± 1057.60 for treatment charges and the IMF group the lowest. The total cost spent on a special diet was again highest among the ORIM group (RM202.86 ± 294.50) and the lowest in the ORIF group (RM159.05 ± 205.55). The total days taken off from duty by the patient were highest in the ORIM group -mean of 5.57 ± 11.48 and the lowest was the ORIF group with a mean of 2.64 ± 6.47 and it was the same for the caregivers where the ORIM group had the highest mean of 4.06 ± 9.51 and the ORIF group had the lowest with a mean of 0.90 ± 1.93. Among the unemployed patients, the mean days that these patients were unable to carry out their usual daily duties were almost similar in all three groups. For caregivers who were unemployed, the mean days that they were unable to carry out their usual daily duties was again highest in the ORIM followed by the IMF and the ORIF group. In conclusion, our study shows that in terms of cost and benefits from societal perspective, ORIM treatment for all mandibular fractures is not justified given the substantive costs. Contrary to most common trepidation, IMF should be considered a viable alternative when patients cannot afford the more expensive treatment of ORIM or are anxious of undergoing a surgical procedure.

# Characteristics of Drug Wastage at Hospital Tuanku Jaafar, Seremban - A Descriptive Study

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## SUMMARY

Adherence with chronic medication therapy was not adequately achieved because a high percentage of patients discontinued treatment. A study done in Penang showed that the trend of use is more towards wastage because consumers are not fully aware of the types of medication used or how to use them properly. Common pressures on the provision of health care have contributed to increase in spending on medications. Datuk Dr. Chua Soi Lek, former Health Minister of Malaysia said that the ministry could not afford current practices anymore because of the increasing cost of subsidizing expenditure for medications. He also said the prescription of medications for patients in government hospital should have to be reviewed to prevent abuse and wastage. The objective of this study was to determine the characteristic of drug wastage at Hospital Tuanku Jaafar Seremban (HTJS). Two methods were used to get the amount of medication wastage; (i) excessive medication from patients' houses and (ii) returned medication by patients to pharmacy counter. In the first method, 103 patient houses (convenient sampling from Medical Specialist Clinic HTJS) were visited from April to November 2007 to collect all the previous excessive stock of medications (minus the currently supplied). The second method involved putting an empty box at the pharmacy counter HTJS used for volunteers to return their unwanted medicine. All returned medication was collected from June to November 2007. All excessive and unwanted medications were listed and costing was done by using cost price from Integrated Store HTJS. Total cost of collected excessive medications from patients' house was RM 4,869.91 with average cost RM 47.28 per patient. Total cost of volunteer medications returned was RM 60,386.37 and average for each month was RM 10,064.40. The medicine in the top six of quantities medication wasted for both methods were metformin, potassium chloride, isosorbide dinitrate and captopril. These were maintenance doses taken three times daily; frusemide has an inconvenient side-effect especially diuresis and lovastatin which should be taken at night before sleep. In conclusion, pharmacists should play an active role in reviewing prescribed medicines, counsel and educate patients regarding treatment and medication regime.

# Development of a Computerized Objective Assessment of Area and Erythema for PASI Scoring of Severity of Psoriasis, and Comparing with the Conventional Visual Assessment of PASI by Dermatologists

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## SUMMARY

Psoriasis Area and Severity Index (PASI) is the gold standard method used in clinical trials for evaluating the severity of psoriasis. However, PASI is not frequently used in daily practice, due to the complexity of the assessments and calculations. Furthermore, it is subjective, and has marked inter-individual variations. Therefore, an objective method is needed, which is reliable, valid and consistent from investigator to investigator. The aim of this study was to develop an objective and computerized image analysis system to assess the surface area and erythema of psoriasis for use in PASI scoring. We also want to compare the scores from the computerized image analysis with the conventional visual assessment of PASI by dermatologists. Forty patients with plaque psoriasis participated in this study. Photographs of the patients (head, upper limbs, trunk and lower limbs) were taken using a digital camera and Konica Minolta Non Contact 3D Digitizer VIVID-910. The colour of the normal skin and representative plaques were assessed using Konica Minolta Chroma Meter CR-400. Two dermatologists evaluated independently the surface area and erythema for PASI score by visual inspection. There were moderate agreements in PASI score for area in the head region between Dermatologists 1 and Computerized Image Analysis (Kappa 0.54) and Dermatologist 2 and Computerized Image Analysis (Kappa 0.69). For the upper limb, trunk and lower limb, there were no agreement in the surface area scores given between Dermatologist 1 & 2 and Computerized Image Analysis. There were moderate agreements in PASI scores between Dermatologist 1 and Computerized Image Analysis for the assessment of erythema in both the head and trunk regions (Kappa 0.56 and 0.53 respectively). However, there were minimal agreements in the erythema scores between Dermatologist 1 and Computerized Image Analysis in the upper and lower limbs regions. There was substantial agreement in PASI scores for erythema between Dermatologist 2 and Computerized Image Analysis in the head region (Kappa 0.79). For the upper limb, trunk and lower limbs, there was no agreement in the erythema scores between Dermatologist 2 and Computerized Image Analysis. There were more agreements between the two dermatologists in the assessments of surface area. For erythema assessment, apart from the head and lower limb regions, there were minimal agreements between the two dermatologists. In this study, we have developed an objective assessment of the surface area and erythema of psoriasis using a computerized image analysis system. There were marked variations in the PASI area and erythema scores obtained using the newly developed computerized method, compared to the conventional visual assessment of PASI by dermatologists. There was more inter-rater variability noted between the two dermatologists in the assessment of erythema, compared to area of psoriasis involvement. Work is currently in progress to evaluate the thickness and scaliness scores objectively.

# A Comparison Between Dental Aesthetic Index (DAI) and Index of Orthodontic Treatment Need (IOTN)

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## SUMMARY

Currently there are two indices which have incorporated the dental and aesthetic component namely the Index of Orthodontic Treatment Need (IOTN) and the Dental Aesthetic Index (DAI). The objectives of this study are to determine the relationship between the two indices in terms of assessing the prevalence of malocclusion. A cross sectional study was carried out using a multistage and clustered random sampling procedure. The sample involved 723 participants aged 13-14 years, attending four government schools in urban and rural area in Muar district. A clinical examination for occlusal status using IOTN and DAI was performed for each participant to assess for their orthodontic treatment need. The results revealed that the prevalence of malocclusion according to DAI was 44.4% with the mean score was 26.6 (95%CI: 26.08, 27.13). The prevalence of malocclusion was 36.2% according to the Aesthetic Component of IOTN and 38.7% according to the Dental Health Component of IOTN. There was a positive relationship between DAI and IOTN. The Spearman correlation coefficient were  $r = 0.71$  between DAI and the AC of IOTN and  $r = 0.72$  between the DAI and DHC of IOTN ( $p < 0.01$ ). The Kappa value for Aesthetic Component of IOTN and Dental Aesthetic Index in agreement of assessing treatment need was 0.61 ( $p < 0.05$ ). Similarly, the Kappa value for Dental Health Component of IOTN and Dental Aesthetic Index was 0.61 ( $p < 0.05$ ). The findings indicate that the DAI records a higher prevalence of malocclusion than either the Aesthetic Component or the Dental Health Component of IOTN. Hence it is recommended that the DAI be used as a screening tool by dental nurses in the school dental service as it can act as a safety net and ensure that students in need of orthodontic treatment are not left out. Dental officers can be trained to use the IOTN as the next level of referral to re-check the students using the DHC of the IOTN before referring them to the orthodontists.

# Prospective Study of Antibiotic Use in Hospital Raja Perempuan Zainab II Surgical Wards

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## SUMMARY

Antibiotic misuse in hospitals has led to bacterial resistance. Excessive use of antibiotics is a known risk factor for the selection of resistant bacteria. In general, there is close association between the antimicrobial quantity and resistance rate. This study looks at factors determining antibiotic selection in our surgical wards. To assess the pattern of antibiotic use in surgical wards in Hospital Raja Perempuan Zainab II. This is a prospective study conducted on 31 randomly selected surgical patients over one month (April 2008) looking at antibiotic type, method/route of administration, dosage, dose frequency; patient demographics; diagnosis, microbiological results; and indication for use. Antibiotic use was divided into 2 categories: treatment (empirical or specific based on culture results) and prophylaxis (empirical based on clinical evidence). Data was analyzed using Microsoft Excel. Cefoperazone injections were the commonest antibiotic prescribed followed by metronidazole injections. 54% and 46% of all antibiotics were given as part of infection treatment and surgical prophylaxis respectively. In conclusion, antibiotics were used widely in surgical ward according to prescriber's preferences, guideline, patient's condition (lab result and vital signs) and patient's diagnosis.

# Cost Analysis of Antibiotic Therapy in Patients with Dosages Adjusted for Renal Function in ICU Hospital Raja Perempuan Zainab (HRPZ) II

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## SUMMARY

Patients admitted to the Intensive Care Unit (ICU) are frequently treated with antibiotics. The most common complication in those patients is renal failure. Several antibiotics such as penicillins, aminoglycosides, cephalosporins, carbapenems, glycopeptides, aminoglycosides, cephalosporins, carbapenem and fluconazoles need proper dosage adjustment based on renal function. Prescribing inappropriate dosage is associated with increased costs and increases the overall costs of medical care due to failure of treatment and adverse drug reactions. Dose adjustment in renal failure can easily be accomplished by estimating the creatinine clearance based on serum creatinine, age, weight, and gender; calculating the individual elimination capacity for a given drug; and adjusting dose and/or dosing interval. As a general rule, severely infected patients with poor renal function and patients who are dialysis dependent should receive normal antibiotic doses given less frequently. Using an optimal course of antibiotics can have economic as well as clinical advantages, including a faster return to normal daily routine and earlier return to work. We conducted the research with aim to see the need for appropriate dose reductions in patients with renal failure. The main objectives are (1) to study the cost saved when a patient's antibiotic dosage was adjusted according to his/her renal function, (2) to analyze the overall cost saved after dosage adjustment and (3) to identify which antibiotics commonly used in ICU that need dosage adjustment. A prospective cross sectional study was done in the Intensive Care Unit (ICU) from January to June 2009. The renal impaired patients (153 patients) who were prescribed with antibiotic were selected as our subject in the study. Out of 153 patients, 37 patients were evaluated for their antibiotic/s dosage adjustment. The informations collected were the patient's creatinine clearance, initial antibiotic prescribed including dose, frequency and duration and any dosing adjustments made as according to the renal function. Those who had at least one estimated clearance value of 50 mL/min or less were included in the study. Data were collected using data collection form. A paired t-test with 95% CI was done using Minitab. Thirty-seven patients were included in the study and their renally eliminated antibiotics were adjusted according to renal function which involved 7 types of antibiotics. The most adjusted antibiotic was Meropenem (44%), followed by Piperacillin/Tazobactam (14.6%) and Fluconazole (14.6%). The total cost saved for Meropenem was RM 2618.73, Piperacillin/Tazobactam RM 466.70 and Fluconazole RM 429.93. Whereas the total cost saved were RM4234, which is 50.78% of overall cost of antibiotics. This study clearly documented that an immediate concurrent feedback strategy implemented directly on the ward may result in a substantial reduction of inappropriate drug regimens. A beneficial effect of having a clinical pharmacist involved in patient care in the intensive care unit was observed in this study, based on the number of acceptance of pharmacist interventions and the potential cost avoidance of over fifty percents.

POT20

# Attitudes and Experience of General Dentists in Providing Oral Healthcare for Children With Special Needs (CSN)

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## SUMMARY

Oral health care is the most prevalent unmet health care need for children with special needs. Obtaining comprehensive health care for this group, however, may prove difficult due to an inadequate number of health care professionals who are trained, experienced, and willing to provide treatment. It would be expected that with adequate training, experience and exposure in dealing with these children, it will lead to a positive behaviour and motivate dentist to provide care for them. The aim of this study is to determine the attitudes and experience of general dentists in providing oral health care for children with special needs. A descriptive cross-sectional study was carried out among all general dentists in Selangor and Kuala Lumpur. Self-administered questionnaire was used for data collection. The final sample comprised of 385 participants, with a response rate of 82.1% (n=165) for public dentists and 34.1% (n=220) for private dentists. The results showed that the majority (90%) reported experience and willingness in providing care for CSN with a significantly higher proportion among the public dentists, younger age groups (40 and below) and those with less than 10 years of practice (p<0.05). The most frequent care provided was extraction (77.7%), examination only (76.8%) and restorative (74.8%). Perceived barriers to providing care were mainly patient factors; lack of cooperation (92.7%), difficult communication (90.1%) and time factor (81.3%) as well as dentist factors; lack of experience (77.9%) and lack of knowledge (63.4%). Their undergraduate training (79%) and knowledge (40%) were perceived to be inadequate. About half (51%) reported not confident in the management of CSN. The majority (93%) perceived the need for after-graduate training. However, only a few (35.3%) received additional training. Willingness to provide care for CSN were significantly higher among those with prior experience, those with after-graduate training, those who rated their knowledge as adequate and those who claimed to be confident (p<0.05). It is concluded that the dental undergraduate training as well as on the job training for general dentists need to emphasize on soft skills as well as technical competency in the management and preventive care for CSN to improve the knowledge and confidence of general dentists in the provision of a comprehensive care for CSN.

# The Effect of Duration of Using Injectable Contraceptives on Bone Mineral Density

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## SUMMARY

Injectable contraceptives are one of the most effective and convenient form of birth control means as more than 30 million women are using it throughout the world. There are two main choices of progesteron only injectable methods include depot-medroxyprogesterone acetate (DMPA) used 90-day intervals and norethisterone enantate (NET-EN) used at 60-day intervals which only less than 1 million women use this type and it is used as Unidepo in Malaysia since 1976. It contains a synthetic hormonal progesteron, like the natural female progesterone and its annual pregnancy rates is less than one per 100 users. Although birth control injections have a number of advantages, but like all other medications, have some potential side effects. One of the most worrying complications is bone density reduction. Bone loss and in turn osteoporosis as a systemic multi factorial skeletal disease is a growing public health concern especially in elderly people particularly in postmenopausal women that is reaching an epidemic proportion because the elderly population is the most rapidly growing segment of any population although it occurs in both sexes and all race/ethnicities and age groups. Several studies have reported lower bone mass in long-term injectable users, however, few studies have investigated the effect of hormonal contraceptives on BMD in premenopausal long-term users of injectables in their 40s, and there is very limited investigations related to the effect of NET-EN on BMD and no data on recovery of BMD on cessation of NET-EN use have been reported so far. The purpose of this study was to investigate the effect of duration of using Unidepo on Bone Mineral Density in postmenopausal women. This is a quasi-experimental study in menopause clinics in Kuala Lumpur where 133 postmenopausal women were interviewed for information on Injectable contraceptive use history and risk factors for decreased bone mineral density and ultrasound measurements of the left calcaneous were taken. Also, Height and weight were measured and BMI was calculated. All ethical aspects were considered. A two step hierarchical regression analysis was employed to examine effect of duration of Unidepo using on bone mineral density. Results revealed that use duration of Unidepo significantly was associated with BUA (broad band ultrasound attenuation) over and beyond of some socio demographic and reproductive factors, BMI, family history of osteoporosis, physical activity and calcium intake ( $\Delta F(1, 109) = 18.69$ ,  $p < 0.001$ ). This study suggest that bone density reduction in long term users is not completely reversible as when the duration of use increased the bone mineral density is decreased.

POT22

# Comparison of HRQOL Between Patient Receiving Methadone Maintenance Therapy (MMT) and Rehabilitation Program

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## SUMMARY

This study aims to compare the health related quality of life (HRQoL) between patients receiving methadone maintenance therapy (MMT) program with those in the rehabilitation program. This was a cross-sectional study involving 400 randomly selected patients from two primary and secondary hospitals and one rehabilitation centre (PUSPEN) in northern part of Malaysia. Consented patient was interviewed to collect their socio-demography, drug consumption and quality of life information. The quality of life was measured by using EQ-5D and EQ-VAS questionnaires. Their quality of life scores were then compared using independent t-test. Majority of the participants were male with mean age 38.49 (SD=9.6) in MMT group and 34.77 (SD=8.6) in rehabilitation group. Mean duration of treatment for MMT group was 17.5 months (SD=15.74) and rehabilitation group was 7.8 months (SD=3.52). EQ-5D score was significantly ( $P = 0.01$ ) higher among MMT participants (mean=0.783, SD=0.190) compared to those in rehabilitation program (mean=0.707, SD=0.227). Participants receiving MMT treatment also had lesser problems in mobility (10.5% versus 21%;  $p < 0.01$ ), normal activity (6.5% versus 15%;  $p < 0.05$ ) and anxiety (54.5% versus 71%;  $p < 0.001$ ). There was no statistically difference found between the groups in self care activity and pain dimensions. However, EQ-VAS score was significantly lower in MMT group compared to rehabilitation group [65.5 (SD=17.9) versus 73.5 (SD=17.6),  $p < 0.001$ ]. This study shows that treatment for patient with substance use disorder with MMT program can provide a better quality of life compared to rehabilitation program (PUSPEN). Variation seen between EQ-5D and EQ-VAS scores suggest that patients might perceived their health worst than the general population value.

# Effects of Nicotine Administration Duration and Nicotine Cessation on Bone Histomorphometry in Sprague-Dawley Male Rats

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## SUMMARY

Nicotine is a major alkaloid of tobacco which can increase free radical formation leading to osteoporosis. Histomorphometric analysis is the recognized standard for the quantification of the structural properties of bone. The effects of nicotine administration duration and nicotine cessation on bone histomorphometry were studied in 28 Sprague-Dawley male rats. Rats aged 3 months and weighing between 250-300 g were divided into 4 groups. Group 1 was the control (C) group, which was given normal saline for 4 months. The other 3 groups were the nicotine administrated-groups (N2 and N4), and nicotine cessation (NC) group. The N2 group was administrated with nicotine (7 mg/kg) for 2 months, whereas, the N4 group was administrated with nicotine (7 mg/kg) for 4 months. The NC group was given nicotine (7mg/kg) for the first 2 months and then allowed to recover for the following 2 months without nicotine. Nicotine and normal saline was given by intraperitoneal injection, six days a week for a period of 4 months (except for N2 group). Histomorphometric analysis was done on the metaphyseal region of the trabecular bone of the left femur by using an image analyzer. All the N2, N4 and NC groups showed a significant decrease in the trabecular bone volume (BV/TV), osteoblast surface (Ob.S/BS), double labeled surface (dLS/BS), mineral appositional rate (MAR) and bone formation rate (BFR/BS), and an increase in the single labeled surface (sLS/BS) as compared to the C group. No significant differences were observed in all bone histomorphometric parameters analyzed among the N2, N4 and NC groups, except for the MAR and BFR/BS. In conclusion, nicotine administration at a dose of 7 mg/kg for 2 months and 4 months has detrimental effects on bone histomorphometric parameters. Furthermore, nicotine administration at 7 mg/kg for 2 months is sufficient to produce significant effects on bone histomorphometric parameters and prolonging the treatment for another 2 months did not show any significant differences. Cessation of nicotine for 2 months did not result in recovery of damage or in reversion of the histomorphometric parameters to control levels.

POT24

# The Regeneration of Dental Hard Tissues from Cultured Rat Tooth Bud Cells

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## SUMMARY

The incidence of children with missing primary and/or adult teeth is high (Nunn et al., 2003), and tooth loss in the older population is also a prevailing health problem. Absence of teeth will cause problems related to masticatory efficiency, language function, facial aesthetics and psychological health. Dental hard tissue regeneration was shown by Duailibi et al (2008). In this study, we are utilizing collagen scaffold as a medium for in vivo expansion of epithelial and mesenchymal cells. Sumita et al (2006) showed that the performance of a collagen scaffold were better compared to polyglycolate (PGA) scaffold in the adhesion and differentiation of dental hard tissue cells. The general objective of this study was to produce bioengineered dental hard tissue from cultured rat tooth bud cells. The specific objectives were to 1) isolate and culture the epithelial and mesenchymal cells from rat tooth bud cells and to expand them in vitro; 2) characterize dental hard tissue via tissue engineering technology; and 3) establish collagen scaffold as a medium in in vivo expansion of epithelial and mesenchymal cells. Molar tooth buds were isolated from 3- to 7- dpn Lewis rat pups and minced into <1-mm-pieces. Tooth bud tissues were digested with type I collagenase and dispase I. The cells were re-suspended in Dulbecco's Modified Eagle medium / F12 (DMEM/F12), plated into 6-well plate. The cells were harvested by trypsinization for 10 min at 37°C, washed twice with the same medium, recounted, split into equal portions, and seeded onto (PGA), poly-l-lactate-co-glycolate (PLGA) and collagen scaffolds for 1 hour prior to implantation into the omenta of syngeneic Lewis rat hosts. The characterization of the tooth bud cell was carried out using RT-PCR. The result showed that both primers Dentin Sialophosphoprotein(DSPP) and Amelogenin Precursor was positively expressed. Histological analysis showed that there was extracellular matrix produced by cell. Dentin Sialophosphoprotein(DSPP) is responsible for production of dentin, while Amelogenin precursor produced by is responsible for production of enamel. Implantation of Lewis rat tooth bud cells into syngeneic adult Lewis rat hosts demonstrates successful use of autografts for tooth-tissue engineering. Further studies are now need to identify the underlying mechanisms responsible for differentiation of dental tissue and factors promoting eruption.

# The Automatic Dysphonic Voice Diagnostic System Based on Dysphonic Severity Index

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## SUMMARY

Voice diseases are dramatically increasing due to the unhealthy social habits such as smoking and alcohol consumption, voice abuse, and the most importantly the lack of awareness among the general public and from the health care provider. Until today, most of the acoustic analysis systems are owned by the speech pathology clinics and by speech therapists. General public do not have the access to these system and are unable to self monitor their rehabilitation progress at home. This situation has lead to the development of an automatic system to diagnose voice disorders that is meant to be patient-friendly. The automatic approach in diagnosing voice requires a non-invasive and objective technique so that the patient can use it with ease at home during rehabilitation. An effective and objective diagnostic technique is still needed in the speech therapy and rehabilitation field. Dysphonic Severity Index (DSI) has been introduced in the literature as one of the approaches for objective measurement for voice disorders. But this approach still requires speech therapists to use the voice diagnostic software manually. This study looks at the accuracy of using an automatic system for DSI calculation for self-monitoring purposes. As the DSI calculation needs parameters such as the highest fundamental frequency or pitch, the value for jitter, the maximum perturbation time, and the lowest intensity in decibel, an efficient pitch detection algorithm (PDA), an automatic vocal intensity measurement, automatic start/end detection for speech are all incorporated into the system. The accuracy test for the PDA is presented in the project to show that the PDA used is the efficient to be applied to dysphonic voices. The start/end detection for the system is based on the short-time energy proven in the literature to be effective in detecting the beginning and the end point of an utterance. The system is going to be able to present the DSI value, either approaches or exceeds +5 (normal voice) or -5 (dysphonic voice) to the patients so that they can see how much they improve. In conclusion, the overall system is accurate in calculating simulated dysphonic voice based on the DSI parameters and may be useful as part of a home voice rehabilitation tool.

# Fast Detection of Hearing Loss Based on Time Frequency Representation of ABR Signal

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## SUMMARY

Congenital hearing loss is a common and important health problem. According to Joint Committee on Infant Hearing (JCIH) and Centers for Disease Control and Prevention (CDC), audiologic evaluation should be done in infants before they are three months old. In addition, children who are treated before the age of six months develop significantly better language skills. Auditory brainstem response (ABR) is currently the gold standard for physiologic testing in infancy and the most accurate method available for determining hearing function. The auditory brainstem response (ABR) is an electrophysiological response in the electroencephalogram (EEG) reading generated by the brainstem in response to auditory signals. Standard algorithms being used to extract the ABR signals relies on band pass filter, which will filter the EEG captured, followed by averaging the EEG by frames in a synchronous manner. However, in currently available setups and devices, a large number of sweeps have to be averaged to obtain a meaningful signal at low stimulation levels due to a poor signal-to-noise ratio (SNR) making the procedure time-consuming. This measurement time requires the infant be in a state of spontaneous sleep or narcosis or on a strong sedative for the measurements to be reliable. A recent excellent implementation of a three stage NHS program in Malaysia recently (Abdullah *et al.* 2006) resulted in an overall lost to follow-up rate of more than 50%. The objective of this study was to reduce screening time of ABR testing. This project utilizes the quadratic (bilinear) time frequency B-distribution technique to extract the ABR signals for fast detection of wave V. The experiment has been tested on 13 adult's samples with no hearing problem and one adult sample with right side ear problem, where the ABR signal is collected using commercial ABR machine (G-tec). Chirp signal is used as a stimulus to evoke electrophysiological responses in the brainstem. 2000 sweeps are recorded from each sample. The duration of the stimulus is 40 ms., Wave V occurs in normal individuals within 20 to 30 ms after stimulus is sent. The analysis was conducted by varying the number of averaging sweeps from 2000 to 50 sweeps. The results shows that the normal averaging technique fails to detect the V wave when the sweeps are less than 500. By using time frequency B-distribution analysis, wave V still can be seen even the average number of sweeps reduced to 200. Implementations of time-frequency B-Distribution analysis technique on the ABR signal interpretation gives reliable result where hearing threshold can be determine with lower number of sweeps. This technique can be used as part of mass hearing screening of newborns in Malaysia.

# Evaluation of the Tolerance and Acceptability of Oral Caffeine for the Treatment of Apnoea of Prematurity

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## SUMMARY

Apnoea of prematurity occurs in about 70% of premature infants. Methylxanthines remain the mainstay of pharmacotherapy. Caffeine is the preferred drug and is currently used in many developed nations because of its wider therapeutic index and safer profile. We sourced hard for caffeine and first used it in the Neonatal Intensive Care Unit of UKM Medical Centre to replace aminophylline, an inferior sole alternative available to neonatal intensive care units in Malaysia. To evaluate patient tolerance and caregiver acceptance of the use and administration of oral caffeine. To achieve therapeutic efficacy, a loading dose of caffeine is normally given intravenously. However, intravenous caffeine is expensive and not as readily available. Our study monitored the outcome of a novel method we devised to administer a loading dose of caffeine in an oral solution, which we know is readily absorbed. Oral caffeine was prepared using Caffeine Anhydrous Powder USP (Medisca, USA). A 10mg/mL concentration solution was prepared using 600mg of caffeine powder diluted in 60mL of sterile water. The solution was kept in an amber bottle to protect it from light and if kept refrigerated at 4°C, is stable for use up to 28 days. To ensure dosing accuracy and reduce medication error, a pre-printed prescription order sheet was prepared. The caffeine dose was administered via an orogastric tube before the first enteral feeding. The loading dose of 20mg/kg birthweight was pump-infused at one mL/hr (Graseby Medical MF 16A). We routinely monitored patient intolerance such as increased gastric residuals, coffee-ground aspirates, vomiting or abdominal distension. Between August 2009 and March 2010, 22 male and 24 female premature infants, received oral caffeine. The mean gestation and birthweight of the group were 30 wks and 1300 g respectively. The mean time of the first dose administered was at 3.5 hours of life and the average volume of caffeine was 1.5 mL. There were no reports of intolerance. There were no increase in apnoea cases detected requiring infants to be re-loaded with intravenous aminophylline. Furthermore, evaluation carried out among nurses and medical staff showed that the majority preferred caffeine to aminophylline because of it is easy to administer, only requires a once daily dose without the need for therapeutic drug monitoring. We are currently monitoring reports of side-effects in premature infants on longer term oral caffeine. We described a novel method of loading and the use of oral caffeine to replace aminophylline. This preparation is easily administered, with reliable efficacy and not associated with significant patient intolerance. Monitoring the side-effects of oral caffeine and cost effectiveness of oral caffeine in the long term will help register this drug as the primary pharmacotherapy for apnoea of prematurity in Malaysia.

POT28

# Detection of MDR1 Haplotypes (C1236t, G2667t/A and C3435t) Using an Allele Specific PCR Method

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## SUMMARY

Tacrolimus (FK506) is a calcineurin inhibitor that has been used as an immunosuppressive agent in patients undergoing organ transplantation. Its clinical use is complicated due to wide inter-individual variation in responses. In-vivo and in-vitro studies have shown that P-glycoprotein (P-gp) acts as an efflux pump and reduce the intracellular concentrations of many drugs including tacrolimus (Saeki et al., 1993). This protein is encoded by the MDR1 gene and single nucleotide polymorphisms (SNPs) have been associated with variations in protein expression and function. This study aim was to investigate the frequency of MDR1 haplotypes of polymorphic C1236T (Exon 12), G2677T/A (Exon 21) and C3435T (Exon 26) among healthy volunteers and patients treated with tacrolimus. DNA was extracted from five ml of blood using standard salting-out method. Primers specific to 3' end that amplify the variants of C1236T, G2677T/A and C3435T were designed. The optimized method was validated by direct sequencing. Ninety-eight of Malay healthy blood donors and fifteen kidney-transplant patients who are on tacrolimus therapy were recruited and DNA subjected to genotyping of MDR1. Reproducible allele-specific polymerase chain reaction (AS-PCR) methods for detection of MDR1 variants were successfully developed. The genotyping result using the AS-PCR methods were in accordance with direct sequencing. Twenty haplotypes were detected among the ninety-eight healthy Malay volunteers; while eleven different haplotypes were observed among the fifteen patients. However, two haplotypes (CAC/CAC & TTC/TTC) were observed in patients but not in the healthy volunteers. We successfully developed a fast and economical AS-PCR method for detection of genetic variants. The MDR1 haplotypes were heterogenous among both the healthy and patients which may have different expression level and function of P-gp. We are conducting an on-going study with a larger sample size of the patients to understand the impact of haplotypes difference and drug responses as well as cost-effectiveness of pharmacodiagnosics of MDR1 in patients treated with tacrolimus.



# Correlation Between Body Mass Index (BMI) and Image Evaluation Criteria in Mediolateral Oblique (MLO) Mammography Images With Different Tube Angulations

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## SUMMARY

A study on the correlation between mediolateral oblique (MLO) projection using different tube angulations and body mass index (BMI) with has been done. This study was carried out to observe changes in the parameters of the MLO image evaluation criteria as different tube angulations were applied. The purpose of our study is to establish a reference range of parameters used in the image evaluation criteria for MLO images which further improves mammographic image quality. 60 women who underwent mammographic screening at the National Cancer Society (NCS) had their BMI calculated. They were then divided into 2 groups; Group 1 will be positioned with a 450 tube angulation for MLO while Group 2 will be positioned with a 600 tube angulation. Craniocaudal (CC) views were not included in the data sampling. From the MLO images produced, the parameters: width and length of pectoralis muscle; posterior nipple line (PNL); and nipple line (NL) were measured using workstation in NCS. Only MLO images from the right breast were used. The data consists of 60 right MLO images obtained from 60 women. The mean width, length, PNL and NL for Group 1 were 50.37 mm, 134.93 mm, 115.43 mm and 112.87 mm respectively. The mean width, length, PNL and NL for Group 2 were 44.57 mm, 123.77 mm, 110.83 mm and 113.23 mm respectively. The r-value for correlation between BMI and width, length, PNL and NL for Group 1 were 0.098, 0.101, 0.711 and 0.722 respectively. The r-value for correlation between BMI and width, length, PNL and NL for Group 2 were -0.056, 0.080, 0.589 and 0.683 respectively. This study showed that there were poor correlation between BMI and pectoralis muscle width and length for both groups. This poor relationship might be due to the nature build of the pectoralis muscle. The mean of width and length of pectoralis muscle for both groups were found to be more and lower compared to mean of width and length of pectoralis muscle in a study by Bentley et al (2008). This study found that the mean width and length of pectoralis muscle were comparable to other studies. It was found that there were positive relationships between BMI and PNL and NL and the relationships were stronger for Group 1. These results might be due to better breast positioning for 450 tube angulation compared to 600 tube angulation as 600 tube angulation was rarely used and the mammographer might have difficulty in positioning the breast as this was her first time with 600 tube angulation. The length of PNL and NL also might be due to the natural mobility of the breast as it measured based on the position of the nipple. Further studies on patient and tube positioning techniques are needed to further improve mammography image quality.

# Economic Evaluation of Vaccination Against Human Papillomavirus (HPV) Infections In the Prevention of Cervical Cancer

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## SUMMARY

Cervical cancer is the second most common cancer affecting females in Malaysia. The resulting cost of chronic management not only affects patient quality of life but also has a negative impact on our nation's economy. This can be avoided by better screening and Human Papillomavirus (HPV) vaccination. This is a cross sectional study done from 2006 until 2009 and respondents from six public Gynecology-Oncology hospitals were interviewed. Methods include experts' panel discussions to estimate treatment costs by severity and direct interviews with respondents using costing and SF-36 quality of life (QOL) questionnaires. Three programs options were compared i.e. screening via Pap smear; quadrivalent HPV vaccination and combined strategy (screening plus vaccination). Scenario based sensitivity analysis using screening population coverage (40-80%) and costs of vaccine (RM 300-400/dose) were calculated. 502 cervical pre-invasive and invasive cancer patients participated in the study. The mean age was 53.3 ± 11.21 years, educated till secondary level (39.4%), Malays (44.2%) and married for 27.73 ± 12.12 years. Life expectancy gained from vaccination is 13.04 years and average Quality Adjusted Life Years saved (QALYs) is 24.40 in vaccinated vs 6.29 in unvaccinated women. Cost/QALYs for Pap smear at base case is RM 1,214.96/QALYs and RM 1,100.01/QALYs at increased screening coverage. In HPV vaccination, base case is at RM 35,346.79/QALYs and RM 46,530.08/QALYs when vaccination price is increased. In combined strategy, cost/QALYs at base case is RM 11,289.58/QALYs; RM 7,712.74/QALYs at best case and RM 14,590.37/QALYs at worst case scenario. Incremental cost-effectiveness ratio (ICER) showed that screening at 70% coverage or higher is highly cost effective at RM 946.74 per QALYs saved and this is followed by combined strategy at RM 35,346.67 per QALYs saved. Budget impact analysis indicated that it costs the government RM 180.4 million per year and 2.5% of the national health budget. Vaccination increases life expectancy with better QOL of women when cancer can be avoided. Cost effective strategies will include increasing the Pap smear coverage to 70% or higher. Since feasibility and long term screening adherence is doubtful among Malaysian women; vaccination of young women is a more cost effective strategy against cervical cancers.

# Novel Feeders of Mesenchymal Stromal Cells Obtained from Human Foreskin Facilitates Long Term Propagation of Human Embryonic Stem Cells

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## SUMMARY

Feeder layers are commonly used for the derivation and culture of human embryonic stem cell (hESC) lines. Different types of feeder cells are able to support the growth of hESC, although mouse embryonic fibroblasts (MEFs) are more favorable for the proliferation. Human feeders in form of human mesenchymal stromal cells (hMSCs) and human foreskin fibroblasts (HFFs) lay the foundation for eradication of animal-derived hESC culture system. In this study we explored the potential of human foreskin derived mesenchymal stromal cells to support self renewal and pluripotency of hESC in a similar fashion to that observed in normal in vivo scenario of bone marrow haematopoietic stem cells and stromal niche. The MSCs isolated from human foreskin were found to be resistant to standard concentrations and duration of mitomycin-C treatment similar to bone marrow mesenchymal stromal cells (BM-MSC). Characterization of these MSCs for cell surface antigens demonstrated positivity to CD105, CD166, CD73, CD44, CD90, SSEA-4 and negativity to CD34, CD45, HLA-DR which is similar to the immunological properties of BM-MSC. Population doubling time, growth kinetics, gene profiling (Oct-4, Nanog, Sox-2, Rex-1), cytoskeletal protein expression (vimentin, nestin) and tri-lineage differentiation potential into adipocytes, chondrocytes and osteocytes further confirmed their mesenchymal stromal cell status. hESC lines cultured on these feeders showed enhanced expression of pluripotent transcription factors Oct-4, Nanog, Sox-2, GDF-3, Rex-1, STELLAR, ABCG2, Dppa5, hTERT and surface markers SSEA-3, SSEA-4, TRA-1-60, TRA-1-81 during long term passaging. These novel feeders also ameliorate the formation of embryoid bodies (EBs) from hESC which differentiated in vitro into cell types representing ecto-, meso- and endo-derm germ layers. Foreskin can serve as a valuable source of alternative MSCs coupled with the advantages of their easy access, isolation, propagation and might be of potential use in future studies on stem cell differentiation and therapeutic applications. hESC cocultured with these cells are not only free of murine feeders but also retain their plasticity which may enable us in establishing tailor-made cell types for drug screening and toxicity testing.

# An Analysis of Socioeconomic Inequalities in Health Care Utilization in Malaysia

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## SUMMARY

Escalating expenditures on health care in Malaysia has made health care utilization an important area for research. Although it has been long debated, there is a lack of review on socioeconomic inequalities in health care utilization in Malaysia. Hence the aim of this paper is to measure and compare socioeconomic inequalities in health care utilization in Malaysia over ten years and to identify the contributions of different subpopulations to these inequalities. Socioeconomic inequalities in health care utilization can be defined as differences in the prevalence of seeking care between people of lower and higher socioeconomic status such as income, education and occupation. The health care utilization variable is observed by looking at the prevalence of outpatient and inpatient treatment in public and private health facilities in Malaysia using data from the National Health and Morbidity Survey in 1996 and 2006. The inequalities are explored using concentration curves and concentration index whereas the factors that contribute to the inequalities are identified using logistic regression that incorporates the complex sampling design of the survey data. The analysis on income per household member reveals that in public health care facilities, inequalities in outpatient attendances exist to be clearly in favor of the lower income groups for both periods 1996 and 2006 with concentration index of -0.1639 and -0.1530 respectively. However, there appears to be a slight shift towards becoming less pro-poor which shows that more people from the higher income groups are utilizing public health care facilities that are in fact targeted towards vulnerable groups in the society. As for hospitalization at public health care facilities, the concentration index changed from -0.0757 to -0.0887 indicating a more pro-poor utilization pattern over the years. Although still pro-poor, the smaller magnitude of inequality for hospitalization compared to outpatient attendance in public health care facilities indicate even more visits by the richer households. This raises an issue of concern because if this trend continues, the government will have to increase its' expenditure on health to cater even for the rich segment of the society. Clearly, more concerted efforts should be taken to increase inequalities in the utilization of public health care facilities to be more in favor of the poor. On the other hand, as expected, inequalities in outpatient and inpatient treatment in private sectors are highly in favor of the higher income groups with concentration index values indicating a more pro-rich pattern over the span of ten years. This finding coincides with the mushrooming of private health care facilities in Malaysia accommodating higher demand for care from private health facilities. In the same way, the analysis on the education level and occupational ranking of the heads of households produce a somewhat similar finding as the socioeconomic variable of income. Odds ratios from the logistic regression analyses of both periods show a higher utilization pattern of public health care facilities by the least advantaged groups. This indicates a higher need for health care by the least advantaged group, thus urging the need to maintain, better yet increase inequalities in public health care facilities to be in favor of the least advantaged.

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# The Validation of the EQ-5D in Malaysian Dialysis Patients

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## SUMMARY

The EQ-5D is a quality of life instrument that measures five dimensions of health. This study investigated the reliability and validity of its use in the Malaysian dialysis population. Test-retest reliability, convergent and discriminant validity were assessed. Responses of 86 subjects who completed both surveys were used in analysis. Test-retest reliability using Cohen's kappa was acceptable in four out of five dimensions, with the exception of self-care. Convergent validity was present. Discriminant validity was found in only two out of six hypotheses tested. In conclusion, the EQ-5D has potential in this population but further study is required.

## KEY WORDS:

*Validation, Quality of Life, EQ-5D, Haemodialysis, Continuous ambulatory peritoneal dialysis.*

## INTRODUCTION

Health Related Quality of Life (HRQoL) research has been extensively studied and utilised in healthcare decision making in many developed countries. As escalating costs place greater pressure on limited budget resources, developing countries such as Malaysia, have made progress in this field of research. The last decade has seen a small but increasing number of studies that quantify improvements in patient outcomes and costs in following different treatment options among various conditions, both acute and chronic<sup>1-9</sup>. One of the conditions considered resource intensive is chronic renal failure, and this has generated studies investigating the cost-effectiveness of dialysis modalities in Malaysia<sup>1,2</sup>. Quality of life can be measured using existing instruments such as, the SF-36, SF-12, HRQoL-20, the Nottingham Health Profile (NHP) or the Quality of Well-being (QWB) Scale<sup>10</sup>. However, for the purposes of economic evaluation, the quality of life should be measured using a preference based utility measure such as the EQ-5D or the Health Utilities Index Mark III (HUI)<sup>11</sup>. The EQ-5D has an advantage where the questionnaire is relatively short and therefore simpler to administer while information obtained can be converted into a single utility index. The instrument has thus been used in many studies around the world<sup>12-21</sup>.

Prior to formal usage in economic evaluation studies, methodological rigor requires that validity and reliability is established in the specific study population. To the best of our knowledge, this has not yet been performed in Malaysia. In neighbouring Singapore, the EQ-5D has been validated

among English and Chinese-speaking rheumatic disease patient populations and used in other patient populations such as knee osteoarthritis and cancer<sup>22-25</sup>. These studies are of interest because Singapore and Malaysia share social, historical and demographic similarities such that the languages spoken in both countries are very similar, including English, Malay and Chinese<sup>26</sup>. From a practical standpoint, the languages spoken in these two countries cannot be differentiated easily. We had utilised a composite version of the EQ-5D, available in three languages; Malaysian Malay, Singaporean English and Singaporean Chinese as these were the closest approximation in terms of language requirements available at the time of the study. However, after the conduct of our study, the EuroQol group made available a Malaysian Chinese and Malaysian English versions of the instrument.

This study was undertaken with a view to conduct an economic evaluation using the EQ-5D in the near future. The objective of this study was to validate the use of EQ-5D in Malaysian dialysis patients. This study looked into the

- 1) Reliability of the EQ-5D as measured through test-retest reliability.
- 2) Convergent validity of the EQ-5D.
- 3) Discriminant validity of the EQ-5D.

## MATERIALS AND METHODS

### *Subjects and data collection*

Patients undergoing dialysis at selected dialysis centers in Ministry of Health hospitals were recruited (Table I). Those included were patients undergoing both haemodialysis (HD) or Continuous Ambulatory Peritoneal Dialysis (CAPD). Convenience sampling was conducted at selected study sites. During visits by the study team, patients who were present were approached and recruited, if they agreed. Eligibility criteria were defined as clinically stable patients receiving dialysis, HD or CAPD for more than 12 months, aged 18 years and above, the ability to read and willingness to participate.

The data used in this study were collected in two concurrent surveys administered to patients at the selected centres from December 2004 to April 2005. The surveys were conducted as part of a study on the cost-effectiveness of erythropoietin therapy in the dialysis programme which was funded by a research grant from the Ministry of Health. The first survey was conducted from December 2004 to April 2005 to obtain data on quality of life. Responses were obtained from 686 dialysis patients through self-administration or nurse-assisted

administration. The second survey was conducted during the same time period intended to obtain health preference data from dialysis patients, carers and dialysis staff at the same hospitals. A total of 153 face-to-face interviews were conducted with dialysis patients, their carers and staff. During these two separate surveys, a total of 86 dialysis patients were independently recruited into both surveys and were used to assess test-retest reliability.

Study procedures and instruments were subjected to an ethical review process by the Malaysian Ethics Review Committee and approval was obtained. Verbal consent was obtained from subjects prior to administration of the questionnaire. Most subjects independently completed questionnaires while those who had difficulty, reading, writing or understanding, were assisted by dialysis centre nurses.

#### *Health status measurement*

The study utilised a trilingual questionnaire which was a combination of three different validated versions of EQ5D, namely Malaysian Malay, Singaporean Chinese and Singaporean English. The Singapore Chinese and Singapore English versions were used as Malaysian versions were not yet available from Euroqol at the time the study. Subjects completed the EQ-5D questionnaire in any one of the three languages. Linguistic validation was not part of the current study.

The EQ-5D includes an assessment of five dimensions of health which are mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D uses a three-level scale for each dimension that describes whether a patient reports difficulty ranging from none, some, to extreme levels of problems. These represent a score of 1, 2, or 3 respectively. A higher score describes a greater level of impairment. The health states can be described as numeric codes with one digit representing each of the five dimensions. Thus, code 11111 represents no problem in all dimensions, and 33333 represent severe problems in all dimensions. As an example, 11231 represents no problem in mobility or self care, some problems in usual activity, severe problems in pain/discomfort and no problems with anxiety/depression. A total of 243 different health state permutations are possible.

The thermometer line on the second page is the Visual Analog Scale (EQ-VAS) which is to be marked by the subject to reflect his or her health status on that particular day. The subject grades their answer by drawing a line from the box labeled "Your own health state today" to a point on the scale between 0 as "Worst imaginable health state" and 100 which describes "Best imaginable health state". Thus the health status of each patient is associated with a EQ-VAS score with a higher score indicating a better health status.

#### *Statistical analysis*

Reliability was tested through demonstration of test-retest reliability. This was performed by calculating Cohen's Kappa comparing the results of the first survey administration with the results of the second survey. We hypothesized that results of the first and second test would correlate well with each other. The higher the Kappa value, the better the correlation. Kappa values that range from 0.21 to 0.40 are considered fair,

0.41 to 0.60 moderate, 0.61 or more are considered substantial correlation<sup>27</sup>.

Validity testing was performed by assessing convergent and discriminant validity. Convergent validity was assessed using EQ-VAS values from the study population compared to health state valuations obtained from the UK general population known as the York Utility Index. Since general population utility values are not available for the Malaysian population, this was considered as a reasonable alternative<sup>14</sup>. We hypothesized that the utility values obtained from Malaysian renal dialysis population would be correlated with the UK general population. The relationship between the Malaysian EQ-VAS and the UK general population was examined using Spearman's correlation coefficient. A correlation between 0.3 and 0.5 is considered a moderate correlation while a correlation of greater than 0.5 is considered strong<sup>28</sup>.

Discriminant validity was assessed by comparing the following groups: (i) Age groups and mobility (ii) Gender and anxiety/depression (iii) Modality and usual activity (iv) Age groups and EQ-VAS scores (v) Gender and EQ-VAS scores (vi) Modality and EQ-VAS scores.

Statistical analysis was conducted using Stata version 9.0. The results of respondents who completed the EQ-5D were included in the analysis. Descriptive statistics was used to summarise demographic, clinical and health status characteristics. All possible permutations of health status were ranked by frequency. The mean and standard deviation for EQ-VAS scores for each health status was calculated. The numerical and ordinal scale comparisons were made using the Kruskal-Wallis test while the categorical data was compared using the Chi-square test. A p-value of less than 0.05 was considered significant.

## **RESULTS**

### *Subject characteristics*

A total of 686 completed questionnaires were obtained. Of these, 32 subjects were excluded from analysis due to incomplete responses. The results of 654 subjects were available for analysis, 311 on CAPD and 343 on HD. Eighty-six subjects completed the second survey to enable assessment of test-retest reliability.

The population studied consisted of 354 male and 300 female subjects, aged between 18 to 86 years old. The mean age of patients was 47.8 years old (SD=14.1), (Table II). As shown in Table III, the majority of subjects reported no problems with their health in terms of mobility (80.12%), self-care (95.11%), usual activities (82.42%), pain/discomfort (64.53%) and anxiety/depression (77.22%). The domain which was most disruptive was pain/discomfort with a third of subjects (34.71%) reporting "moderate problems", followed by a fifth (21.41%) of subjects reporting "moderate problems" with anxiety/depression. Very few subjects reported "extreme problems" in any of the domains mobility, self-care, usual activity and pain/discomfort as reported by approximately 1% or less of subjects. Relative to the other dimensions, the dimension of anxiety/depression had the most reports of extreme problems (1.38%).

**Table I: Participating Hospitals**

Hospital	N
Hospital Putrajaya	19
Hospital Kajang	17
Hospital Seremban	91
Hospital Pulau Pinang	113
Hospital Kota Bharu	59
Hospital Tuanku Ampuan Rahimah	82
Hospital Kuala Lumpur	165
Hospital Ipoh	29
Hospital Selayang	79
Total	654

**Table II: Participant demographics**

	N (%)
Mean age (SD, range)	47.8 (14.1, 18-86)
Female	300 (45.9)
<b>Ethnicity:</b>	
Malay	403 (61.6)
Chinese	167 (25.5)
Indian	77 (11.8)
Iban	1 (0.2)
Other Malaysian	5 (0.8)
Foreigner	1 (0.2)
<b>Education level:</b>	
No schooling	33 (5.1)
Primary	200 (30.6)
Secondary	318 (48.6)
University/College	103 (15.8)
<b>Dialysis modality:</b>	
HD	343 (52.4)
CAPD	311 (47.6)

**Table III: Distribution of responses**

EQ-5D dimension	Response (%)			Kappa value	p-value
	No problems	Moderate	Extreme		
Mobility	80.12	19.42	0.46	0.30	0.00*
Self-care	95.11	4.28	0.61	-0.02	0.59
Usual activities	82.42	16.51	1.07	0.18	0.03*
Pain/discomfort	64.53	34.71	0.76	0.43	0.00*
Anxiety/depression	77.22	21.41	1.38	0.38	0.00*

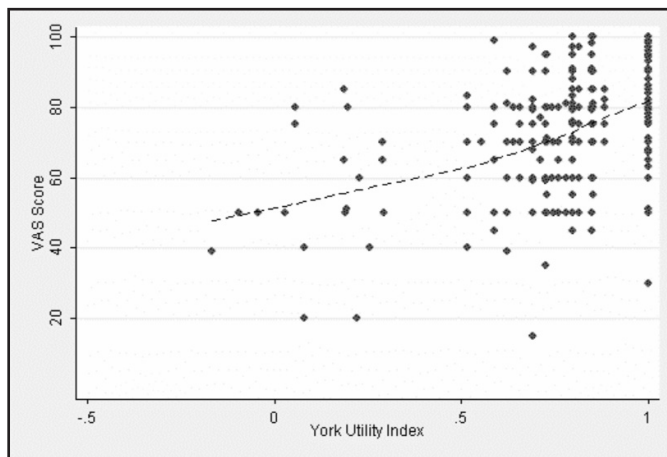
\*significant at p<0.05

**Table IV: Top 10 Most commonly reported Health Status and Mean Vas Score**

Rank	Health Status	Mean VAS Score	Std. Dev.	Freq.
1	11111	81.8	11.9	325
2	11121	74.3	12.8	85
3	11112	75.6	13.4	45
4	11122	68.7	13.1	35
5	21111	75.8	12.1	21
6	21221	64.5	15.3	19
7	21121	73.3	11.4	17
8	21222	59.4	13.2	17
9	11211	77.9	5.8	11
10	11222	72.4	15.8	10

**Table V: Discriminant validity among known group**

EQ-5D dimension vs. other variable	N			p-value
Age group vs. mobility	<50	50-65	>65	
Percentage reporting some problem	12.8	24.5	42.9	0.00*
Gender vs. anxiety and depression	Male	Female		
Percentage reporting some problem	20.6	25.3		0.15
Modality vs. Usual Activity	HD	CAPD		
Percentage reporting some problem	21.3	13.5		0.01*
Age group vs. VAS	<50	50-65	>65	
Mean VAS score (N)	76.8 (358)	75.5 (233)	73.0 (63)	0.09
Gender vs. VAS	Male	Female		
Mean VAS score (N)	74.91 (354)	77.24 (300)		0.07
Modality vs. VAS	HD	CAPD		
Mean VAS score (N)	74.86 (343)	77.21 (311)		0.06



**Fig. 1:** Correlation between EQ-VAS score of Malaysian dialysis patients and UK general population utility tariff, the York Utility index

In terms of each respondents overall experience, most reported no problems in any of the dimensions, thus the health status code 11111 was reported by 325 respondents. The mean EQ-VAS score associated with this code was 81.8 with a standard deviation of 11.9. A description of the top 10 most commonly reported health status is shown in Table IV.

*Reliability and Validity*

In terms of test-retest reliability, the results varied with agreement in all but one dimension. Dimensions of mobility, pain/discomfort and anxiety/depression demonstrated fair agreement between the two tests ( $\kappa=0.30$ ,  $p<0.05$ ;  $\kappa=0.43$ ,  $p<0.05$ ,  $\kappa=0.38$ ,  $p<0.05$ , respectively) while the usual activities dimension demonstrated a smaller agreement ( $\kappa=0.18$ ,  $p<0.05$ ). The self-care dimension was the exception showing no agreement between the two tests ( $\kappa= -0.02$ ,  $p=0.59$ ) (Table III).

The EQ-5D was able to demonstrate moderate convergent validity between the study population’s EQ-VAS score and the York Utility Index with a Spearman’s rho of 0.45 ( $p <0.05$ ) (Figure 1). Discriminant validity was demonstrated with differences found between known groups in two out of six of the stated hypotheses. Age groups vs mobility was found to be statistically significant at the  $p<0.05$  level. Similarly a statistically significant difference was found comparing modality vs usual activity,  $p<0.05$ . The remaining four comparisons were not found to be statistically significant (Table V).

**DISCUSSION**

The results of our study showed that the EQ-5D has acceptable psychometric properties in the Malaysian dialysis patient population. Test-retest reliability showed that the instrument is moderately reliable for almost all dimensions. There was fair agreement between test and re-test results in four out of five dimensions. The only exception to this was the self-care dimension, where there was absence of agreement in the two tests. This rather unexpected result may have been caused by an actual change in subjects’ ability

to “self-care” in that time period. The kappa values obtained in this study were not as high as in other studies<sup>24,25</sup> perhaps due to the stability of the health status of dialysis patients compared to rheumatic disease and other patient groups. Reliability, as measured by internal consistency of the instrument, was not tested in this study as there is only one item in the EQ-5D per dimension. Hence comparing internal consistency to items within dimensions would not be helpful.

Convergent validity of the EQ-5D instrument has been shown to be high in prior studies<sup>12, 13, 29</sup>. This study also demonstrated good correlation through a comparison between the EQ-VAS scores of the study population compared to the York Utility Index from the UK population. However, discriminant validity of the instrument was present in only two out of the six hypotheses tested, which were age group vs. mobility and modality vs. usual activity. These were perhaps the strongest known discriminators for this patient population. As age increases, for most people, difficulty with mobility also increases due to aches and pains resulting from wear and tear of the joints. Dialysis patients are not an exception, and are at greater risk of impaired mobility due to likelihood of fracture and loss of bone mass<sup>30, 31</sup>. Thus, the instrument was able to show changes in mobility status with varying age. Differences between subjects on HD or CAPD treatment were also shown with regard to satisfaction with health status, similar to a previous study<sup>15</sup>. Those on CAPD tended to report higher VAS scores than those on HD. This may have been due to the convenience of CAPD for the patient compared to HD, as CAPD patients have a higher degree of autonomy in their treatment and may undergo dialysis at home. Unlike CAPD patients, those on HD require regular and frequent visits to dialysis centres several times a week. Severity of their condition may also have had an influence on patients’ perception of their health status. Since HD patients are usually more severely ill than CAPD patients, their perception of health may consequently be less optimistic.

The study was unable to conclude the other four hypotheses tested. This is inconsistent with the findings of prior studies that showed good discriminant validity of the EQ-5D in other populations<sup>12, 24, 25, 29</sup>. Regarding the influence of gender on health status reporting, some previous studies demonstrated differences in anxiety/depression among males vs females using the EQ-5D, such as in a population health study in the UK which showed women reporting higher rates in the anxiety/depression dimension than men<sup>14</sup>. However, a study in Malaysia among the mobility impaired found the opposite effect<sup>32</sup>. Yet other studies have shown no differences found between women and men. In particular, the Quality of Life study using EQ-5D conducted among Swiss dialysis patients did not show gender differences<sup>15, 16</sup>.

We had also expected to see differences in EQ-VAS scores comparing age groups<sup>33</sup>, men and women<sup>34</sup> as well as modality. However, none of these comparisons successfully showed differences between the groups. As the EQ-VAS score is intended to measure the subjects’ perception of their own health, we attribute this to subjects having a positive view of their own overall health, despite possible limitations in any specific dimension. Adaptation to change in lifestyle is

especially true of dialysis patients who have been undergoing treatment for longer than 12 months compared to those who have been on dialysis for six months or less.

As mentioned earlier, since the completion of this study, Malaysian English and Malaysian Chinese versions of the EQ-5D have been made available by the EuroQol group. The differences between the phrases used in these two Malaysian versions compared to the Singapore English and Singapore Chinese version that we used in our composite questionnaire are relatively minor and are not thought by the authors to have had significant impact on the results of this validation study. Nonetheless future studies utilising the EQ-5D in Malaysia should use the Malaysian language versions since it is now available.

For more than a decade, EQ-5D has established its usefulness as a HRQoL instrument in many developed countries. However, in Malaysia and the region, interest in the instrument has begun to take-off in recent years due to new focus on cost-effectiveness research. Thus far, in Singapore, the EQ-5D has been validated in the target patient populations with rheumatic disease<sup>24, 25</sup>. This study adds to the existing literature by providing some evidence for the usefulness of this instrument in Malaysian renal dialysis patients. Strengths of this study are the high total number of subjects and the diverse geographical locations involved. The study was able to demonstrate overall test-retest reliability in almost all dimensions and convergent validity. The study was also able to partially demonstrate known-groups validity.

Recommendations for future study include further demonstration of the ability of EQ-5D to show known-groups validity. Despite its limitations, given the paucity of primary data establishing base-line HRQoL of the Malaysian population, as well as lack of research particularly using the EQ-5D in the region, this study offers limited but useful additional insight into the characteristics and health status perception within this population.

## CONCLUSION

This preliminary study tentatively establishes that the EQ-5D is a valid and reliable tool to be used assessing HRQoL in the Malaysian renal dialysis population. Acceptable level of reliability was shown with respect to test-retest reliability. Validity as shown through convergent validity was good, and discriminant validity was narrowly demonstrated. Although the study has limitations, it forms a basis for recommending the use of EQ-5D in Malaysian dialysis patients. Further research into test-retest validity and linguistic equivalence is warranted to strengthen the findings of this study.

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# Contact Lens - Related Corneal Ulcer: A Two-Year Review

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## SUMMARY

To create a national registry of contact-lens related corneal ulcers (CLRCU) patients in Malaysia with the aim of detecting outbreaks, identifying pattern of causative organisms, determining patient demography, risk factors, wearing patterns and monitoring outcome of treatment. The CLRCU registry is an ongoing patient registry established in 2007 as a surveillance tool used by Malaysian Ministry of Health ophthalmology departments. Notification of patients clinically suspected of CLRCU was performed online through the National Eye Database (NED). Data collected included patient demography, contact lens type, causative organism and treatment outcome. During 2007-2008, a total of 202 patients were notified to the CLRCU registry with a mean age of 26.7 years (71.8% female). All registered patients wore soft contact lens and monthly disposable lenses were the most popular (83.5%). The majority of patients had bacterial CLRCU and the most common causative organism was *Pseudomonas* (79.7% of bacterial cases). No epidemics were identified during the period of data examination. Use of contact lenses, which is increasing during modern times, may lead to CLRCU as a severe complication. The CLRCU registry is an effective tool which uses a web-based notification system that allows quick and up to date reports of CLRCU cases. This provides the ability to monitor outbreaks of disease and identify important causative and associated factors of the disease which may be used to reduce future incidence.

## KEY WORDS:

*Contact lens related corneal ulcer, Infectious corneal ulcer*

## INTRODUCTION

Widespread use of soft contact lens is associated with increasing number of ocular complication in young adults, the most severe being corneal ulceration. Without early intervention, it may lead to permanent visual loss<sup>1</sup>. Common risk factors include overnight wear, non-compliance with advised lens care and contaminated cleaning solution/case. The 2006 *Fusarium* outbreak reported in Singapore, Hong Kong and the United States of America (USA) lead to the beginning of web surveillance of local cases for the purpose of overcoming delayed reporting and efficient disease trend monitoring. The contact lens-related corneal ulcer (CLRCU) registry was established in 2007 and ophthalmologists from 35 MOH tertiary hospitals participated. This article presents data from the first two years.

## MATERIALS AND METHODS

This is an active surveillance of patients with CLRCU. All doctors at MOH Ophthalmology departments would notify any patient with clinically suspected CLRCU. A total of 36 hospitals took part in this surveillance. Data was entered online through a web application at [www.acrm.org.my/ned](http://www.acrm.org.my/ned) according to patient demography, contact lens type, wearing pattern, cleansing solution used, cultured organisms and vision one month post-treatment. Real time reports are available online.

## RESULTS

Review of 202 cases of clinically diagnosed CLRCU over two years (103 cases in 2007 and 99 cases in 2008; Figure 1, Table I) showed bilateral involvement in 7.9% (six cases in 2007 and ten cases in 2008; Table I). A third of the patients were females (71.3%) and the mean age was 26 years (Table I). All patients wore soft contact lens, the most popular was the monthly disposable type (79.6%) (Table II). In terms of wearing pattern, most of the patients removed their contact lens daily (67%) (Table III).

A significant number of patients could not recall the brand name of cleansing solution used (22.9% in 2007 and 24.7% in 2008). Table IV shows the type of contact lens cleaning solution used by patients. The commonest was Bausch & Lomb, followed by Allergan (AMO) and normal saline. Six patients used tap water to clean their contact lens. In most cases, corneal scraping cultures grew *Pseudomonas* (84.6%). Snellen acuity was performed on a total of 218 eyes of which six eyes met the criteria for legal blindness ( $\leq 3/60$ ) at the time of presentation. Only eight of the total 202 patients gave a history of ocular trauma (3.7%). Epidemiological curve constructed from the available data on the registry did not suggest an outbreak.

More than 80% of cases were treated empirically for a bacterial corneal ulcer while 7.0% were presumed to have acanthamoeba and 5.9% were suspected to have fungal corneal ulcer (Table V). Corneal scrapings of 175 eyes (83 (49.5%)) had no yield. Of the 69 culture-proven cases, 65 were bacterial, three fungal and one Acanthamoeba. The commonest causative organism was *pseudomonas* (55/69=79.7 %) (Table VI).

Snellen acuity was scored on presentation. Seventy-six eyes (34.9%) were able to read lines down to 6/12, 56 eyes (25.7%) read between 6/18 to 4/60 and 36 eyes (16.5%) did not even score 3/60. Vision in 50 eyes (22.9%) could not be obtained.

A month later, 36 eyes (16.5%) scored better than 6/12, 18 eyes (8.3%) read from lines 6/18 to 4/60 and six eyes (2.8%) had visual acuity worse than 3/60. Visual outcome in 158 eyes (72.4%) could not be obtained.

**Table I: Demographic Characteristics**

	Year 2007		Year 2008		Total	
	No.	%	No.	%	No.	%
Total number of patients	103		99		202	
Mean Age (SD) (years)	26.1(8.1)		26.5(8.8)		26.3(8.4)	
Min (years)	10		15		10	
Max (years)	51		68		68	
<b>Distribution of age group, years</b>	<b>No.</b>	<b>%</b>	<b>No.</b>	<b>%</b>	<b>No.</b>	<b>%</b>
0-<10	0	0	0	0	0	0
10-<20	22	21.4	18	18.2	40	19.8
20-<30	51	49.5	53	53.5	104	51.5
30-<40	24	23.3	21	21.2	45	22.3
40-<50	5	4.9	5	5.1	10	5
50-<60	1	1	0	0	1	0.5
70-<80	0	0	2	2	2	1
Gender						
Male	29	28.2	29	29.3	58	28.7
Female	74	71.8	70	70.7	144	71.3

**Table II: Types of contact lens worn at diagnosis**

Types of contact lens	Year 2007		Year 2008		Total	
	No.	%	No.	%	No.	%
Daily disposable	6	5.5	4	3.7	10	4.5
Weekly disposable	1	0.9	1	0.9	2	0.9
2 weekly disposable	3	2.8	2	1.8	5	2.3
Monthly disposable	92	84.4	84	77.1	176	79.6
Extended wear	3	2.8	5	4.6	8	3.6
Rigid gas permeable	0	0	0	0	0	0
Others	5	4.6	6	5.5	11	5
Missing	1	0.9	8	7.3	9	4.1

\*multiple checks were allowed for types of contact lens.

**Table III: Contact lens wearing pattern at diagnosis**

Wearing pattern	Year 2007		Year 2008		Total	
	No.	%	No.	%	No.	%
Remove daily	70	64.2	76	69.7	146	67.0
Extended wear	32	29.4	26	23.9	58	26.6
Missing	7	6.4	7	6.4	14	6.4

**Table IV: Types of cleaning solution used at diagnosis**

Types of cleaning solution	Year 2007		Year 2008		Total	
	No.	%	No.	%	No.	%
Alcon	4	3.7	4	3.7	8	3.5
Bausch and Lomb	24	22	17	15.6	41	18.1
Allergan (AMO)	12	11	4	3.7	16	7
Ciba Vision	0	0	4	3.7	4	1.8
Opto-medic	0	0	1	0.9	1	0.4
Freskon	3	2.8	2	1.8	5	2.2
Sauflon	2	1.8	7	6.4	9	4
Multisoft	1	0.9	2	1.8	3	1.3
I-Gel	4	3.7	3	2.8	7	3.1
Medivue	0	0	1	0.9	1	0.4
Normal Saline	4	3.7	8	7.3	12	5.3
Simvue	0	0	0	0	0	0
Multimate	1	0.9	1	0.9	2	0.9
Pharmasafe Multipurpose solution	3	2.8	1	0.9	4	1.8
Tap water	3	2.8	0	0	3	1.3
Do not use because of daily wear	1	0.9	1	0.9	2	0.9
Not known	25	22.9	31	28.4	56	24.7
Others	24	22	15	13.8	39	17.2
Missing	4	3.7	10	9.2	14	6.2

\*multiple checks with allowed for cleaning solution.

Table V: Presumptive causative organism

Presumptive causative organism	Year 2007		Year 2008		Total	
	No.	%	No.	%	No.	%
Bacteria	86	78.9	75	68.8	161	87
Fungus	2	1.8	9	8.3	11	5.9
Acanthamoeba	5	4.6	8	7.3	13	7.0
Others	4	3.7	2	1.8	6	3.2
Missing	14	12.8	19	17.4	33	17.8

\*multiple checks to the presumptive causative organism were allowed.

Table VI: Bacteria specify for each types of lab investigation

Bacteria	Year 2007		Year 2008		Total	
	No.	%	No.	%	No.	%
Corneal scraping (n)	34		31		65	
Pseudomonas	27	79.4	28	90.3	55	84.6
Enterobacter	3	8.8	0	0	3	1.3
Staph. epidermidis	1	2.9	0	0	1	1.5
Acinetobacter	1	2.9	0	0	1	1.5
Serratia Marcescens	1	2.9	0	0	1	1.5
Missing	1	2.9	3	9.7	4	6.2
Contact lens (n)	26		16		42	
Pseudomonas	20	76.9	16	100	36	85.7
Enterobacter	3	11.5	0	0	3	7.1
Klebsiella	1	3.8	0	0	1	2.4
Burkholderia cepacia	1	3.8	0	0	1	2.4
Serratia Marcescens	1	3.8	0	0	1	2.4
Contact lens solution (n)	16		12		28	
Pseudomonas	13	81.3	12	100	25	89.3
Enterobacter	1	6.3	0	0	1	3.6
Klebsiella	1	6.3	0	0	1	3.6
Coagulase negative Staphylococcal	1	6.3	0	0	1	3.6
Serratia Marcescens	0	0	0	0	0	0

\*Multiple checks were allowed for corneal scraping, contact lens and contact lens solution.

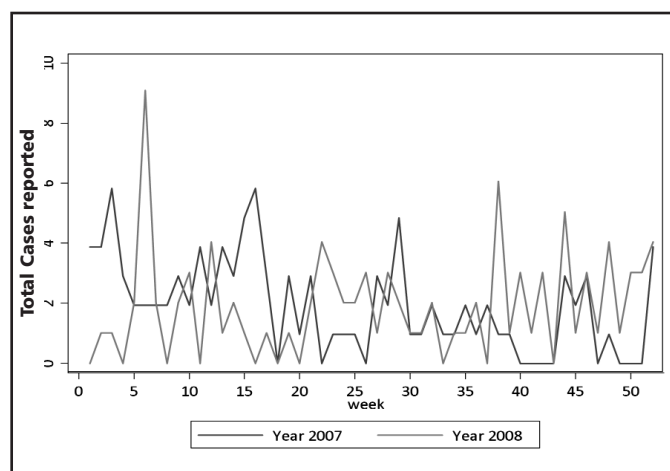


Fig. 1: Epidemiologic curve – notification of CLRCU by week in 2007-2008

**DISCUSSION**

Corneal ulcers are undoubtedly the most devastating complication of soft contact lens use. Evidence suggests that history of corneal ulcers is a predisposing factor for further corneal inflammation in contact lens wearers. Improper lens wear and care as well as lack of awareness of the importance of aftercare visits have been identified as risk factors for

corneal ulcer among contact lens wearer<sup>3</sup>. Our findings where females are predominant and pseudomonas is the most frequently isolated organism were similar to those from larger population surveys done in Australia & New Zealand<sup>3</sup> and the United Kingdom (UK)<sup>4</sup>.

Antibiotic resistance is an important issue associated with pseudomonas infection<sup>5</sup>. Pseudomonas is less sensitive to chloramphenicol, a common antibiotic prescribed by general practitioners. This finding suggests the importance of referral of all contact lens wearers with suspected corneal infection to ophthalmologists for further treatment and culture of the corneal scraping and contact lens solution should be done to guide antibiotic therapy.

Overwear and improper lens care and replacement schedules<sup>6</sup> are important modifiable risk factors of CLRCU. Thus, eye care providers should educate prospective contact lens users on proper lens care and wear duration. Importance of lens fitting and regular after – care visits should be stressed. The use of daily-disposable lenses should be encouraged as it has been suggested to reduce the risk of developing ulcer if introduced at the disinfectant stage<sup>7</sup>. Regular re-enforcement on proper lens care, compliance monitoring and regular aftercare visits with eye health providers is crucial.

Web based notification and prompt dissemination of reports make the CLRCU registry a useful monitoring tool. However,

there is a significantly large number of patients who seek private medical care only once the registry receives more participants from the private sector can the surveillance data reflect the actual incidence in our population and help the registry achieve its objectives.

#### ACKNOWLEDGEMENT

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# The National Medical Research Register - A Vital Link Between Current and Future Research

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## SUMMARY

Registration of research proposal to a publicly accessible website with searchable function allows information sharing and ensures research transparency. The National Institutes of Health Malaysia, realising the importance of research registration, established the National Medical Research Register (NMRR) in 2007. The NMRR functions more than just a local register: it also links to ethics approval and MOH medical research grant application. It thus facilitates researchers in their application to the Ministry of Health Research and Ethics Committee (MREC) and for Ministry of Health research grant. In addition, MREC committee members can review research protocol on NMRR website, thus saving much time and resources. From May 2007 till December 2009, more than 3000 people have registered as NMRR public users and more than 1000 research proposals have been uploaded in NMRR. The number of registration of research proposals, clinical trials and industrial sponsored trials steadily increased from year 2007 to year 2009. The web-based NMRR is the first research register in the world that links research proposal registration to ethical review and research grant application. Its future plan is to be linked with publication. Therefore, it is indeed an innovation that Malaysians should be proud of.

## KEY WORDS:

*National Medical Research Register, Ethical review, Transparency, Malaysia*

## INTRODUCTION

The WHO's development of a common set of rules for registering clinical trials was done in response to calls for new standards and rules for the registration of studies involving human participants. Its goal is to increase transparency and accountability on the part of companies and institutions that do clinical research, and, in turn, boost public trust and confidence in that research<sup>1</sup>. Transparency in medical research also minimises publication bias as well as maintains ethical principles of scientific communication. In addition, the Food and Drug Administration Amendments Act of 2007 (FDAA) introduced a new international public law enforcing the increase of clinical trials information that is publicly available through the database<sup>2</sup>.

In Malaysia, the National Medical Research Register (NMRR), which was designed to correspond with international guidelines that require medical research, particularly clinical

research to be registered in publicly accessible research registers, was set up in accordance to the National Institutes of Health (NIH)'s guideline on the conduct of research in the Ministry of Health Malaysia (MOH)<sup>3</sup>. In addition to being a publicly accessible register, NMRR functions as a tool to assist online registration of research and online submission to appropriate authority for approval, review and subsequent publication. NMRR also aims to convey information to physicians and prospective volunteers who wish to participate in a particular research. With this register, NIH hopes to reduce review time and enable investigators to track the status of their research online. It also would enable the MOH management to document the level of research activity in its premises and to track the progress of the research that it approves and/or supported.

This paper reviews NMRR registration, the data it generates as well the register's role in current research practices and its future potential.

## *Research registration with the National Medical Research Register*

Registration of research protocols in NMRR is done online through its website ([www.nmrr.gov.my](http://www.nmrr.gov.my)); and basic information such as name of investigator and name of their institution and study title may be viewed by the public. Researchers interested to find collaborators can also search according to therapeutic areas; and doctors and patients seeking for clinical trials can check to see whether a trial is ongoing based on its recruitment status. Pharmaceutical companies and Contract Research Organisations can also use the directory to identify potential Malaysian investigators, especially as NMRR now identifies researchers who are Good Clinical Practice (GCP) certified.

The current NMRR version has three main stages; 1) submission screening by NMRR secretariat; 2) submission forwarded to relevant authority for processing and 3) amendment after approval by relevant authority. The first stage i.e. screening, is when all registrations and submissions will be vetted and verified by the secretariat. During the first stage, an NMRR identification number will only be provided when submission is adequate. In the second stage, the proposal is submitted to the respective authorities for review and rating. Reviewers, as always, can assess the documents by specifying their comments and recommendations. Updates and amendments in research will also be reported to the NIH who will oversee all ongoing research and ensure compliance. This is definitely one of the benefits of having a computerised

system for research documents and information as the regimented process will enable proper research audit.

*Comparing the National Medical Research Register to UK and US registers*

The UK clinical trials register (<http://www.controlled-trials.com>), the Current Controlled Trials was launched in the late 90s as a response to the growing body of opinion in favour of prospective registration of controlled trials to increase the availability, and promote the exchange of information about ongoing randomised controlled trials worldwide. The US counterpart (<http://www.clinicaltrials.gov>) is also a web-based information portal which provides general information on clinical research, especially clinical trials. Although the NMRR provides a myriad of functions to assist researchers during the initial start-up of a research it does not have some of the features exhibited by the US and UK

registers.

Compared with the Clinical Trials.gov, the NMRR does not categorise clinical trials according to condition, drug intervention, sponsor and location. Likewise, the UK also differentiates the studies according to ISRCTN (International Standard Randomised Controlled Trial Number Register) register, metaRegister (metaRegister of Controlled Trials-active registers) and UKCTG (UK Clinical Trials Gateway), which the Malaysian NMRR does not. Similarly, the World Health Organization's International Clinical Trials Registry Platform (ICTRP) also has a way to unambiguously identify a trial, even though it may have appeared on more than one registry database, by providing special trial identifiers that include the Universal Trial Number (UTN), criteria for WHO registries and linking related records on the ICTRP Search Portal (<http://www.who.int/ictcp/en>; Table I).

**Table I: Comparing the National Medical Research Register with the WHO trial registration data set**

Item	Does NMRR collect this data? (yes /no)	Does NMRR publicly display this data? (yes /no)
1 Primary Registry and Trial Identifying Number	Yes	Yes (Research ID)
2 Date of Registration in Primary Registry	Yes	Yes
3 Secondary Identifying Numbers	Yes	No
4 Source(s) of Monetary or Material Support	Yes	No
5 Primary Sponsor	Yes	No
6 Secondary Sponsor(s)	No	No
7 Contact for Public Queries	Yes	No
8 Contact for Scientific Queries	Yes	No
9 Public Title	Yes	Yes
10 Scientific Title	Yes	No
11 Countries of Recruitment	Yes	No
12 Health Condition(s) or Problem(s) Studied	Yes	Yes
13 Intervention(s)	Yes	No
14 Key Inclusion and Exclusion Criteria	Yes	No
15 Study Type	Yes	Yes(only research types)
16 Date of First Enrollment	No	No
17 Target Sample Size	Yes	No
18 Recruitment Status	Yes	Yes
19 Primary Outcome(s)	Yes	No
20 Key Secondary Outcomes	Yes	No

**Table II: Distribution of research protocols registered by states**

State	2007	%	2008	%	2009	%	2010	%
1. Johor	12	2.4	54	3.0	70	3.9	6	1.7
2. Kedah	3	0.6	26	1.5	27	1.5	13	3.2
3. Kelantan	7	1.4	29	1.6	27	1.6	1	0.3
4. Melaka	4	0.8	14	0.8	15	0.8	3	0.8
5. Negeri Sembilan	16	3.3	92	5.2	86	4.8	16	4.3
6. Pahang	2	0.4	72	4.1	63	3.5	8	2.1
7. Perak	62	12.6	167	9.4	139	7.7	25	6.7
8. Perlis	0	0	8	0.5	6	0.3	4	1.1
9. Pulau Pinang	38	7.7	187	10.6	219	12.1	54	14.4
10. Sabah	19	3.9	115	6.5	84	4.7	13	3.5
11. Sarawak	146	29.7	177	9.9	139	7.7	32	8.5
12. Selangor	61	12.4	306	17.3	288	15.9	62	16.5
13. Terengganu	6	1.2	62	3.5	46	2.5	9	2.4
14. Wilayah Persekutuan	114	23.2	386	21.8	475	26.3	101	26.9
15. Putrajaya	2	0.4	76	4.3	121	6.7	28	7.6
All	492	100	1771	100	1805	100	375	100

Figures as of 29 March 2010

\*All students' research is excluded from this report. Total exceeds total number of research registered as one research may be conducted in more than one state.

**Table III: New clinical trials registered in the National Medical Research Register (mainly involving Ministry of Health sites)**

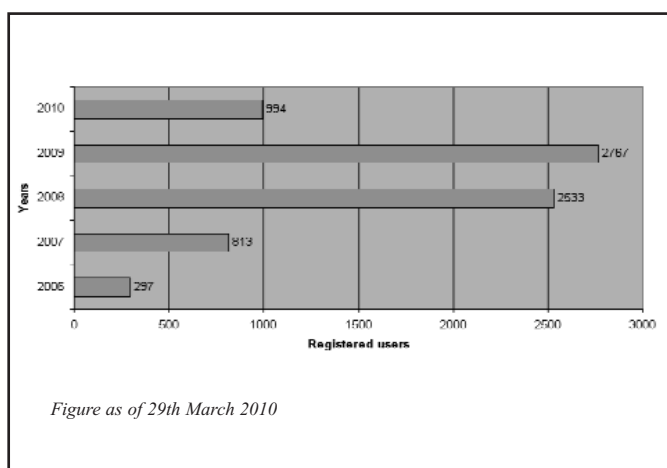
Year	2007 (May-Dec)	2008	2009
All types of clinical trials	20	103	71
Industry Sponsored Research (ISR) Clinical trial only	9	88	50
ISR: Number of sites	17	353	182
ISR: Enrolment target	251	5036	4804

\*All students' research is excluded from this report

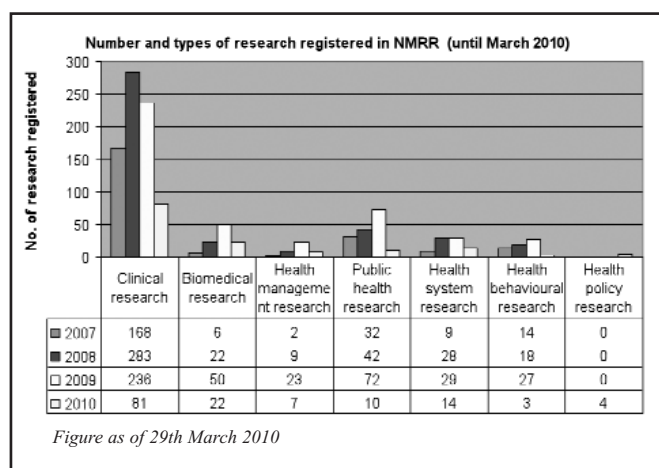
**Table IV: Top Ten sponsored trials registered on the NMRR by therapeutic areas by years**

#	Therapeutic area	2008		2009		
		No	%	Therapeutic area	No	%
1	Hepatology	20	12.6	Psychiatry	17	20.2
2	Cardiology	17	10.7	Cardiology	12	14.3
3	Oncology	17	10.7	Diabetes mellitus	12	14.3
4	Diabetes mellitus	14	8.8	Oncology	10	11.9
5	Psychiatry	14	8.8	Infectious Disease	7	8.3
6	Nephrology	11	6.9	Respiratology	7	8.3
7	Haematology	10	6.3	Rheumatology	6	7.1
8	Infectious disease	8	5.0	Endocrine/Metabolic	5	6.0
9	Gastroenterology	6	3.8	Anaesthesiology	4	4.8
10	Medicine	6	3.8	Haematology	4	4.8

\*All students' research is excluded from this report.



**Fig. 1:** Number of registered users in NMRR



**Fig. 2:** Number and types of research registered in NMRR (2007-2009)

*Key findings from the NMRR*

From May 2007 till December 2009, more than 3000 people have registered as NMRR public users (Figure 1) and more than 1000 research proposals uploaded in NMRR (Table II). We see upward trends in all types of research registered in NMRR (Figure 2). Clinical research had the highest number of protocols submitted but despite this lead, there was a drop in the number of clinical trials in 2009 (n=71) compared to 2008 (103; Table III). As these trials were mostly industry sponsored ones, we can attribute the decrease to the global economic recession that caused pharmaceutical companies to cut back on the number of research projects in 2009. Another factor is stiff competition from other ASEAN countries such as Thailand, the Philippines and Singapore. Nevertheless as a whole, we see that research registration has slowly but surely caught on. For example, Putrajaya merely recorded two protocols in year 2007 but this grew to 76 in the following year and 121 in 2009 (Table II). This is in tandem with

growing levels of appreciation and awareness for research registration among researchers across the globe<sup>4</sup>. In Table IV's list of top therapeutic areas for 2008 and 2009, we see a good range of clinical disciplines; with no single discipline dominating the rest. This indicates that we have equally good researchers in various fields.

*The NMRR's uniqueness outshines its limitations*

The system was originally set up to manage and coordinate research activities of various NIH Network (i.e. Clinical Research Centre, Institute for Medical Research, Institute for Public Health, Institute for Health Management, Institute for Health Systems Research and Institute for Health Behavioral Research) since 2007. This system is still in progress and is expected to bring some welcome relief to the long process of research proposal management which is costly and require a lot of manpower.



Finally, it is a research directory and investigator directory available in real-time, thus enabling prospective investigators to search for other potential investigators and also potential clinical trial sites. With an ever-updating record of research activities in Malaysia, prospective researchers are able to constantly make reference to the NMRR data in real time, in order to decide on what research they would embark on, how to proceed with application for approval by ethics committee and to seek for medical research grant from the MOH, as well as to seek potential investigators who are GCP-certified.

Despite it being the first research register in the world that links research proposal registration to ethical review and research grant application, the utility of NMRR may not be fully assimilated by all potential and actual users. This is mainly due to the lack of hands-on training experience to familiarise users with its functions. Apart from that, many potential investigators from the private sector may not use NMRR if there is no collaboration with the MOH. Therefore, the database does not reflect the actual number of research that is conducted in Malaysia.

#### *The way forward*

With the NMRR, researchers can save time, cost and energy. Security and confidentiality of document data are also more intact. As the development of NMRR continues, so will the avenues of providing a greater range of services to all registered users. The next phase would have NMRR generate

post-trial reports, assist in safety reporting to regulatory authorities, act as a coordinating body with the review boards and get involved in keeping an archived set of publication of trial reports. All these additional services will require sufficient groundwork to be laid out before the actual implementation. As the NMRR gradually develops its functionality, a better and more representative depiction of Malaysia's clinical research performance will be generated.

#### **ACKNOWLEDGEMENT**

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# Retinoblastoma Registry Report – Hospital Kuala Lumpur Experience

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## SUMMARY

**Retinoblastoma is a childhood ocular cancer. The aim of this paper is to describe the clinical and epidemiological characteristics of patients with retinoblastoma in a major paediatric ophthalmology center in the country. Retrospective information was collected through the retinoblastoma registry. Late presentation with advanced staging is a major problem.**

## INTRODUCTION

Retinoblastoma is the most common ocular cancer in children. It usually occurs in children under 5 years of age. It is an aggressive tumour that can lead to loss of vision and, in extreme cases, death. Prognosis for vision and survival has significantly improved due to timely diagnosis and improved treatment methods. In developing countries, however, most of the case are detected at advanced stages<sup>1-7</sup>.

There is no exact information regarding the frequency and clinical characteristics of retinoblastoma in Malaysia. The purpose of this paper is to report the result of the Retinoblastoma Registry, which was part of the Malaysia National Eye Database (NED). NED is a web-based surveillance, online data collection system on eye diseases and clinical performance in ophthalmology service<sup>8</sup>.

## MATERIALS AND METHODS

This is a retrospective review of patients with retinoblastoma which was collected through the retinoblastoma registry. We evaluated records of patients diagnosed between 1 January 2004 till 31 December 2009, who were managed in Hospital Kuala Lumpur, the main referral center for retinoblastoma.

Patients were examined under general anaesthesia, including indirect ophthalmoscopy, fundus imaging (Retcam) and ultrasonography. Tumours were characterised using the International Intraocular Retinoblastoma Classification, IIRC (ABC Classification, Group A to E, Table I). Earlier data with Reese-Ellsworth Classification were reassigned with the ABC classification.

Patients were jointly managed by a team of paediatric ophthalmologists and oncologist. We enucleated eyes with advanced tumor with no visual potential, classified as Group E or Group D (in unilateral RB). Enucleated eyes were sent for pathological examination. Patients with tumors requiring

shrinkage (Group B to D) were treated with systemic chemotherapy (Vincristine, Etoposide and Carboplatin), with focal consolidation using 810nm diode laser and cryotherapy. Adjuvant systemic chemotherapy was also given to patients which enucleated eye showed extraocular infiltration in histopathological studies. Small tumors (Group A) received local laser or cryotherapy. Radiotherapy was given to extraocular RB and to tumors which were resistant to other treatment.

Data collected in the registry were demographic and clinical presentation at registration, modes of treatment, outcome (remissions and recurrences) and complication. Descriptive statistics for each variable were obtained.

## RESULTS

Between January 2004 and December 2009, a total of 87 patients (117 eyes), diagnosed with retinoblastoma were seen in Hospital Kuala Lumpur. Figure 1 presents the number of patients per year. On average 14.5 new cases were seen per year. Fifty-four patients (62.1%) were male and 33 (37.9%) females with M:F ratio of 1.6:1.0. Majority of the patients were of Malay ethnicity (50 patients, 57.5%) followed by Chinese (16 patients, 18.4%) and Indians (eight patients, 9.2%).

The age at presentation range from 3 weeks to 122 months (mean of 24 months). Ten patients (11.5%) presented above 5 years of age. The disease was unilateral in 57 (65.5%) and bilateral in 30 (34.5%) patients. Only one patient has a family history of Retinoblastoma. Figure 2 showed the ocular presentation of the disease.

The mean duration of symptoms before presentation was 4 months, with the range of 1 day to 36 months. Seventy-five percent (65 patients) presented within 6 months, 10.3% (nine patients) between 7 to 12 months while 6.9% (six patients) had the symptoms for more than 12 months before being seen at the referred center. Staging of the disease at diagnosis is presented in Table II. Six patients had orbital retinoblastoma while two patients had intracranial metastases at presentation.

Enucleation was performed in 85.1% of patients. Of the 74 enucleated eyes, 24 eyes (32.2%) showed 'high risk factors predictive of metastases' evident on histopathological examination. 51 (58.6%) patients had systemic chemotherapy whereas six (6.9%) patients had external beam radiotherapy.

**Table I: International Intraocular Retinoblastoma Classification (IIRC)<sup>9</sup>**

- Group A** - Small intraretinal tumours away from foveola and disc.
- All tumours are 3 mm or smaller in greatest dimension, confined to the retina and
  - All tumours are located further than 3 mm from the foveola and 1.5 mm from the optic disc.
- Group B** - All remaining discrete tumours confined to the retina.
- All other tumours confined to the retina not in Group A.
  - Tumour-associated subretinal fluid less than 3 mm from the tumour with no subretinal seeding.
- Group C** - Discrete local disease with minimal subretinal or vitreous seeding.
- Tumour(s) are discrete.
  - Subretinal fluid, present or past, without seeding involving up to one-fourth of the retina.
  - Local fine vitreous seeding may be present close to discrete tumour.
  - Local subretinal seeding less than 3 mm (2 DD) from the tumour.
- Group D** - Diffuse disease with significant vitreous or subretinal seeding.
- Tumour(s) may be massive or diffuse.
  - Subretinal fluid present or past without seeding, involving up to total retinal detachment.
  - Diffuse or massive vitreous disease may include "greasy" seeds or avascular tumour masses.
  - Diffuse subretinal seeding may include subretinal plaques or tumour nodules.
- Group E** - Presence of any one or more of these poor prognosis features.
- Tumour touching the lens.
  - Tumour anterior to anterior vitreous face involving ciliary body or anterior segment.
  - Diffuse infiltrating retinoblastoma.
  - Neovascular glaucoma.
  - Opaque media from hemorrhage.
  - Tumour necrosis with aseptic orbital cellulites.
  - Phthisis bulbi.

**Table II: Classification of Retinoblastoma (IIRC)**

	Number of eyes	%
Group A	5	4.3
Group B	5	4.3
Group C	10	8.5
Group D	18	15.4
Group E	73	62.4
Not Available	6	5.1
Total eyes	117	100

Recurrences of tumour were seen in seven eyes at the average of 15 months after diagnosis. The earliest recurrences were at five months and the latest at 24 months. Four patients eventually had bilateral enucleation after treatment failure in the one remaining eye. Fourteen patients (16.1%) were lost to follow-up. Death was reported in three patients, two of them had intracranial metastases at presentation and one had associated 13q deletion syndrome.

**DISCUSSION**

Retinoblastoma affects between one in 15,000 and 20,000 livebirths depending on the country. As only children developed retinoblastoma, the birth rate and infant mortality rate of a country are important to estimate the number of children that may be affected. In the United States it is estimated about 250-300 new cases diagnosed per year<sup>10</sup>. In Malaysia the exact incidence is unknown. Based on the 2009 census data for annual births in Malaysia, approximately 27 to 36 new cases are expected to be diagnosed each year. Hospital Kuala Lumpur, being the main tertiary center for Retinoblastoma in Malaysia, sees an average of 14.5 new cases per year.

Our findings showed that the spectrum of the presenting symptoms were similar to those reported elsewhere in which leucocoria was the most common presentation followed by strabismus (68.4% and 12.0% respectively). The disease was unilateral in 65.5% and bilateral in 34.5% of patients. Late presentation seems to be common in developing countries. This is observed in this study where diagnosis are made at older age with majority of patients presented in advanced stage of classification.

Chemotherapy with adjuvant local treatment are now an integral part of the current management of retinoblastoma. Two-thirds of our patients had systemic chemotherapy either as primary chemoreduction or as adjuvant therapy following enucleation. Given the late presentation of patients, enucleation still plays a major role in treatment of retinoblastoma with an enucleation rate of 85% of patients in this study.

Sixteen percent of the patients were lost to follow-up at various levels. Although there was no exact data on the cause of this, experience at this centre showed that most of them are at the initial phase due to refusal and inability to accept enucleation as a form of treatment. Some patients are lost in the middle of treatment because parents are unable to cope with the intensive treatment and frequency of the follow-ups. In most instances the issues are more of parental motivations rather than financial constraints as treatment for this childhood cancer are highly subsidised by the government and National Cancer Council (MAKNA).

There are limitations to this registry. Presently the data from this registry were only collected from a single treatment center. The data was analysed to give an overall view of

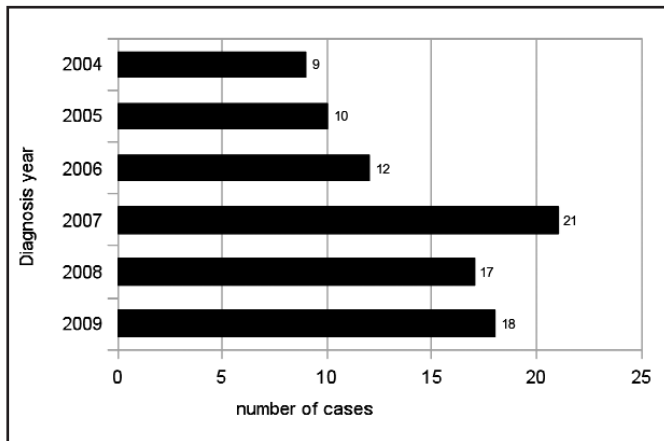


Fig. 1: Frequency of new patients per year

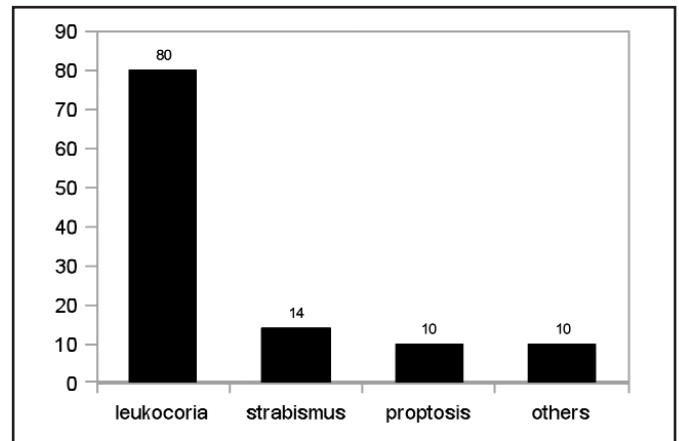


Fig. 2: Clinical presentation

retinoblastoma without differentiating the unilateral (non-hereditary) and bilateral (hereditary) disease. This study is relevant because the data obtained were from the country's national reference center. These preliminary findings reflected the retinoblastoma situation of the country. The problem of late diagnosis and presentation has to be tackled to improve prognosis and quality of life for these patients. These data demonstrated the need to develop an awareness programme for early detection, to decrease the number of patients with advanced extraocular disease and offer less aggressive treatment with better outcomes.

This registry will be open to other centres that manage retinoblastoma nationwide. These centres are the university hospitals (Pusat Perubatan Universiti Malaya, Pusat Perubatan Universiti Kebangsaan Malaysia and Hospital Universiti Sains Malaysia), Hospital Umum Sarawak in Kuching, Sarawak and Hospital Queen Elizabeth in Kota Kinabalu, Sabah. With participation of these centers, the actual impact of retinoblastoma to the country will be better understood.

It is our hope that with the development of this registry, and collaboration with all these centres, we can develop a national treatment protocol to enhance medical care to retinoblastoma patients. Treatment can be standardised so that every centre can offer the best available treatment and patients can be treated at the nearest centres without compromising care.

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# Reliability, Technical Error of Measurements and Validity of Length and Weight Measurements for Children Under Two Years Old in Malaysia

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## SUMMARY

The National Health and Morbidity Survey III 2006 wanted to perform anthropometric measurements (length and weight) for children in their survey. However there is limited literature on the reliability, technical error of measurement (TEM) and validity of these two measurements. This study assessed the above properties of length (LT) and weight (WT) measurements in 130 children age below two years, from the Hospital Universiti Kebangsaan Malaysia (HUKM) paediatric outpatient clinics, during the period of December 2005 to January 2006. Two trained nurses measured WT using Tanita® digital infant scale model 1583, Japan (0.01kg) and Seca® beam scale, Germany (0.01 kg) and LT using Seca® measuring mat, Germany (0.1cm) and Sensormedics® stadiometer model 2130 (0.1cm). Findings showed high inter and intra-examiner reliability using 'change in the mean' and 'intra-class correlation' (ICC) for WT and LT. However, LT was found to be less reliable using the 'Bland and Altman plot'. This was also true using Relative TEMs, where the TEM value of LT was slightly more than the acceptable limit. The test instruments were highly valid for WT using 'change in the mean' and 'ICC' but was less valid for LT measurement. In spite of this we concluded that, WT and LT measurements in children below two years old using the test instruments were reliable and valid for a community survey such as NHMS III within the limits of their error. We recommend that LT measurements be given special attention to improve its reliability and validity.

## KEY WORDS:

*Anthropometry, Children, Intra-examiner, Inter-examiner, Reliability, Validity technical error of measurement*

## INTRODUCTION

Anthropometric measurements, such as weight and length, are used to assess nutritional status and growth in children. All anthropometric measurements require equipment. Whatever equipment is chosen and whoever does the measurement, it will be subjected to some degree of measurement error. These include within and between examiners variability, technical and mechanical limitations. Among the many measurement methods, anthropometry

generally demonstrates the largest standard errors and lowest correlation coefficients<sup>1</sup>.

Various terms are used to describe anthropometric measurement error. These include reliability and validity<sup>2</sup>. Reliability is the degree to which within-subject variability is present and is due to factors other than variance of measurement error or physiological variation. The second type of measurement error; validity, is the extent to which the 'true' value of a measurement is attained. The technical error of measurement (TEM) is another accuracy index to express the error margin in anthropometry. It has been adopted by the International Society Standardization Advancement in Kinanthropometry (ISAK) for the accreditation of anthropometrists in Australia<sup>3</sup>. The TEM index allows anthropometrists to verify the accuracy degree when performing and repeating anthropometrical measurements (intra-examiner) and when comparing their measurement with measurements from other anthropometrists (inter-examiner)<sup>3</sup>.

The Third National Health and Morbidity Survey, Malaysia 2006<sup>4</sup> which was a nationwide community survey, included a nutritional status assessment component for children. They wanted a validation of the anthropometric measurements that were to be used. This is because despite the importance of accurate and reliable anthropometric measurements, there are relatively few papers<sup>5</sup> addressing reliability and validity issues of these assessments. In fact, search in the Cochrane Reviews Database<sup>6</sup> of the term "anthropometric measurement in children", "anthropometric measurement", and "TEM" failed to yield any matching review paper. This paper attempts to assess the inter- and intra-examiner reliability of weight (WT) and length (LT) measurements and their respective technical error of measurements. We also examined the validity of measurements of WT and LT compared to the measurements using reference instruments that have been used in standard clinical practice in Malaysia.

## MATERIALS AND METHODS

This cross-sectional study had a convenient sample of 130 children, age less than 2 years (including infants) who were clinically stable. They were recruited from the Hospital

Universiti Kebangsaan Malaysia (HUKM) paediatric outpatient clinics, during the period of December 2005 to January 2006. The exclusion criteria were children with obvious physical disabilities and body deformation. The sample size was determined as Walter *et al*<sup>7</sup>, with two replicates per subject; the expected reliability coefficient (r) of at least 0.8 ( $H_1 : \rho_1 = 0.8$ ), the reliability of 0.7 ( $H_0 : \rho_0 = 0.7$ ) or higher to be minimally acceptable,  $\alpha = 0.05$  and  $\beta = 0.2$  (corresponds to 80% power); this would require a total number of 117.1 subjects. Using a 10% over-estimate to account for poor response, the final target sample size was 130.

Two trained examiners with background in public health nursing did WT and LT measurements of each subject. The choice of two examiners was deliberate and it was simply because of logistic reasons, and that a pair was the minimum required number for inter examiner reliability. Selection of only one of the examiner for intra examiner reliability was also not influenced in any way. Both examiners were not part of the research team and were therefore study blinded. On the day of the assessment, each examiner performed and recorded the measurements on their own. They were specifically told not to recall their previous readings. The data capture form was designed in such a way that the examiners were asked to fold over recordings of the previous readings immediately after it was recorded to minimise recall bias. The process of measurement is shown in Figure 1.

The LT of the subject was obtained by using two instruments 1) Seca® measuring mat, Germany (0.1cm) as “test” instrument, which was ‘improvised’ by attaching a non-stretchable tape on the right side of the mat to allow measurements of up to the nearest 0.01 cm on both sides of the mat and 2) Sensormedics® stadiometer model 2130 (0.1cm)<sup>8</sup> as “reference” instrument. The subject body weight was taken using two instruments 1) Tanita® digital infant scale model 1583, Japan (0.01kg) as “test” instrument and 2) the Seca Beam scale Germany (0.01 kg) weighing machine for WT<sup>9</sup> as “reference” instrument. The measurements were done using study specific procedures as described in the Technical Manual of NHMS III<sup>4</sup>.

#### Statistical analysis

Statistical analyses for reliability were done using ‘change in the absolute mean’, intraclass correlation coefficient (ICC) and Bland and Altman plot<sup>10</sup>. Absolute mean is a crude way for checking for difference or agreement between two readings. We also tested the difference for significance using independent t test and paired t test for absolute means for between and within examiners respectively. Correlation coefficient (r) was used as a more objective way of assessing reliability. It was computed using ICC to demonstrate the strength of the relationship (similarities) between two measurements. The values for reliability coefficient range from 0 to 1. A coefficient of below 0 indicates “no reliability”, >0 to <0.2 is slight reliability, 0.2 - <0.4 is fair reliability, 0.4 - <0.6 is moderate, 0.6 - < 0.8 is substantial and 0.8 - 1.0 is almost perfect reliability<sup>11</sup>.

Bland and Altman was used to provide an illustration of the spread of differences in readings, the mean difference and the

upper and lower limit of agreement both for inter as well as intra-examiner reliability. There is no such ‘acceptable’ range for Bland and Altman plots. The technical error of measurement (TEM), which is an accuracy index<sup>3</sup> was also calculated. It is essentially the standard deviation between repeated measures. The lower the TEM obtained, the better the reliability. The acceptable ranges for Relative TEM using beginner anthropometrist levels for intra-examiner is < 1.5% and inter-examiner < 2.0%<sup>3</sup>. The formula for TEM calculation<sup>12</sup> is;

$$\frac{\sum D^2}{2N}$$

The formula for percentage TEM is as below;

$$\%TEM = \frac{TEM}{\bar{X}} \times 100$$

The formula for coefficient of reliability R is;

$$R = 1 - \left\{ \frac{(TEM)^2}{SD^2} \right\}$$

Using the above formula, the coefficient of reliability R can be determined, which ranges from 0 (not reliable) to 1 (complete reliability). Inter-examiner reliability refers to how consistent/in agreements were the readings from the two examiners on the same subjects. Intra-examiner reliability refers to how consistent/in agreements were the readings from the same examiner on the same subjects but at two different time points.

In addition to these, the coefficient of variation (CV) is calculated to further determine the precision of measurements methods. The CV provides a general “feeling” about the performance of a measurement. CVs of 5% or less generally give us a feeling of good method performance, whereas CVs of 10% and higher are bad<sup>13</sup>.

In order to compare the variability of the two methods; LT and WT, the percentage of coefficient of variation (% CV) was calculated using the data from the inter as well as the intra examiner. Percentage of Coefficient of variation is therefore a good indicator to use when comparing methods<sup>14</sup>. For validity, the ‘accuracy’ of the measurements using the test instruments was compared with their respective measurements using reference instruments. This was done on the basis of an underlying assumption that the reference readings were at least close to, if not the actual ‘true’ readings. Here again comparison was made using ‘change in the mean’, ICC and Bland and Altman as described above.

Measures of validity are similar to measures of reliability. With reliability, you compare one measurement of a variable on a group of subjects with another measurement of the same variable on the same subjects. With validity, you also compare two measurements on the same subjects. The first measurement is for the variable you are interested in, which is usually some practical variable or measure. The second

measurement is for a variable that gives values as close as you can get to the true values of whatever you are trying to measure. We call this variable the criterion variable or measure<sup>15</sup>.

## RESULTS

### Sample characteristics

The mean age of 130 children in the study was  $279.3 \pm 186.4$  days. Boys and girls were almost equally represented (57.69% and 42.31% respectively). Malay children formed the majority (70%), followed by Chinese (24.6%) and Indians (3.1%).

### Reliability

#### Inter-examiner reliability

There were three ways in which inter-examiner reliability was examined. The first was by change in the mean. Table I shows that there was an average 0.1 kg difference for WT but no difference detected for LT.

The second method was by correlation coefficient. Results of correlation coefficient of inter examiner analysis using intra-class coefficient (ICC) are as in Table II. The ICC for LT was 0.9880 and for WT was perfect agreement 1.0000 which means strong correlation between readings from the two examiners for WT and LT respectively. These indicated high degree of reliability between the two examiners for both measurements.

The third method was using the Bland and Altman plot. For WT, Fig 2 shows that the measurement taken from examiner #2 is consistent with examiner #1 with an average difference of 0.0 kg, upper limit at 0.2 and lower limit of -0.2 kg. For LT, Fig 3 shows that on average, the measurement taken from examiner 1 is 0.1 cm higher than that of examiner #2. The upper limit of agreement is 4.1 while the lower limit is -3.9 cm. The points were scattered closely to zero which was consistent with ICC analysis of almost perfect agreement.

#### Intra examiner reliability

Similar analysis was performed for intra-examiner reliability. Absolute differences were very minimal, WT 0.1 kg and LT 0.3 cm (Table I). The ICC for both WT and LT was almost perfect; 0.9900 and 0.9990 respectively indicating the strong correlation between the readings at time1 and time2 from the first examiner for WT and LT respectively. The Bland and Altman plot showed that for WT, the average mean difference across all values of readings were 0.0 kg with upper limit of +0.2 kg and lower limit of -0.2 kg (Fig 4). For LT, the average was -0.1 cm and upper limit of +3.6 cm and lower limit of -3.8 cm (Fig 5).

#### Coefficient of variation

Variability of readings were minimal for inter-examiner, the CV for LT was 1.8% and for WT was 0.8% which indicated good precision. Similar results were observed for intra-examiner readings at 1.6% and 1.1 % respectively. (See Table II)

#### Validity

Table I shows comparison of measurements using test instrument versus reference instrument in 129 subjects. There was a mean absolute difference of 0.2 kg for WT but no

absolute difference for LT. With an intra-class correlation coefficient close to 1 (Table II), there is a high degree of reliability for both WT and LT measurements obtained using the two instruments. Another way of looking at accuracy is by the Bland & Altman Plot. Fig 6 shows the plot for WT measurement. On average, the measurements taken from the test instrument were consistent with the reference instrument. At maximum, the difference can be up to 0.2 kg and at minimum -0.3 kg. Fig 7 shows the plot for LT measurement. On the average the test instrument is recording 0.2 cm higher than the reference instrument with upper limit of 2.1 and lower limit of -1.7.

#### Technical Error of Measurement

The result for the TEM and R is tabulated in Table III. The relative TEMs for inter and intra examiners for WT were 0.8% and 1.1% respectively. The relative TEMs for inter and intra examiners for LT were 2.1% and 1.9%. The estimate for inter examiner for LT is marginally acceptable but that of intra slightly exceeded the acceptable values. This study also found that all the R values (for inter and intra, WT and LT) were above the 0.95 suggested cut-off<sup>2</sup>. This means that the human error for measurements in the study was small; all below the acceptable 5% mark.

## DISCUSSION

Anthropometric measurement is important in assessing nutritional status. However its interpretation depends greatly on the degree of reliability and validity findings. This study in particular estimated the two basic properties for the weight and length measurement in children below two years old. The commonly used indices for reliability include technical error of measurement (TEM), relative TEM (%TEM), coefficient of reliability (R) and intraclass correlation coefficient (ICC) 2. We report all of the above and in addition we also calculated the coefficient variation (CV) and Bland & Altman plot. The validity aspect was examined in a similar way as above<sup>14</sup>.

Changes in the mean, correlation coefficient and Bland and Altman plots revealed a high degree of inter-examiner reliability. The p values of the change in the mean showed no statistical significance. It was also found, by Bland and Altman, that for WT, the two examiners were consistent with an average of 0.0 kg and an upper limit of 0.2 kg to lower limit of -0.2 kg. However it was found that LT measurements had a broader limit of agreement where upper limit of agreement was 4.1 while the lower limit was -3.9 cm and on average, examiner 1 was recording 0.1 cm higher than the examiner 2. This is understood because in children, it is more challenging to keep the child still and stretched for a good assessment of length<sup>4</sup>. For intra-examiner reliability, the change in the mean were minimal; WT 0.1 kg and LT 0.3 cm and both differences were not significant. The ICC for both WT and LT was almost perfect; 0.9900 and 0.9990 respectively. The Bland and Altman plot showed that for WT, the readings were consistent (average mean difference of 0.0 kg) with upper limit of +0.2 kg and lower limit of -0.2 kg. However for LT, the average was -0.1 cm suggestive of some degree of error with limits of  $\pm$  about 4 cm. This wider limit range in LT measurement was explained earlier.

**Table I: Summary Statistics for reliability (inter, intra examiner) and validity (inter instrument)**

<b>Inter examiner reliability</b>				
Summary Statistics	Examiner 1 (1)	Examiner 2 (2)	Absolute Mean Diff (1)-(2)	P value
Length, cm				
N	130	129*		
Mean, (SD)	67.9 (9.5)	67.9 (9.2)	0	0.991
Median, (min, max)	67.5 (46.5, 95.0)	68.0 (45.5, 86.6)		
Weight, kg				
N	130	130		
Mean, (SD)	7.6 (2.3)	7.5 (2.3)	0.1	0.955
Median, (min, max)	7.4 (2.2, 15.7)	7.5 (2.2, 15.6)		
<b>Intra examiner reliability in the first examiner</b>				
Summary Statistics	Examiner 1 1st Measurement (1)	2nd Measurement (2)	Change in the mean (1)-(2)	P value
Length, cm				
N	130	129*		
Mean, (SD)	67.9 (9.5)	67.6 (9.2)	0.3	0.452
Median, (Min, max)	67.5 (46.5, 95.0)	67.6 (46.0, 87.0)		
Weight, kg				
N	130	129*		
Mean, (SD)	7.6 (2.3)	7.5 (2.2)	0.1	0.146
Median, (Min, max)	7.4 (2.2, 15.7)	7.4 (2.2, 15.1)		
<b>Inter instrument validity</b>				
Summary Statistics	Reference Instrument (1)	Test Instrument (2)	Change in the mean (1)-(2)	
Length, cm				
N	130	129*		
Mean, (SD)	7.5 (2.3)	7.5 (2.2)	0	
Median, (Min, max)	7.5 (2.2, 15.6)	7.5 (2.2, 15.2)		
Weight, kg				
N	129*	129*		
Mean, (SD)	67.9 (9.2)	67.7 (9.3)	0.2	
Median, (Min, max)	68.0 (45.5, 86.6)	67.7 (46.0, 88.0)		

\* 1 subject refused to participate

**Table II: Correlation Coefficient (ICC) and Coefficient of Variation of the Inter and Intra Examiners measurements**

Variables	N	Inter-examiner		N	Intra-examiner	
		ICC	Coefficient of Variation (%)		ICC	Coefficient of Variation (%)
Length, cm	128*	0.9880	1.8%	128*	0.9990	1.6%
Weight, kg	129*	1.0000	0.8%	128*	0.9900	1.1%

\* Incompleteness of data recording and patient refusals

**Table III: Inter and intra-examiner relative TEM classification results for weights and length measurements**

			TEM	%TEM	Classification* of %TEM	R **
1	WT measurement by 1st observer VS WT measurement by 2nd observer both using tanita	Inter examiner WT	0.059708	0.791446	Acceptable (< 2.0%)	0.999329
2	1st WT measurement by 1st observer VS 2nd WT measurement by 1st observer both using tanita	Intra examiner WT	0.082076	1.097031	Acceptable (< 1.5%)	0.998621
3	LT measurement by 1st observer VS LT measurement by 2nd observer both using measurement mat	Inter examiner LT	1.413007	2.083033	Marginally acceptable (< 2.0%)	0.976747
4	1st LT measurement by 1st observer VS 2nd LT measurement by 1st observer both using measurement mat	Intra examiner LT	1.308603	1.932889	Not acceptable (< 1.5%)	0.980048

\* using beginner anthropometrist cut-off values for "other measures" (Norton K, Olds T, editors. Antropometria. Argentina: Biosystem, 2000)

\*\* R is coefficient of reliability



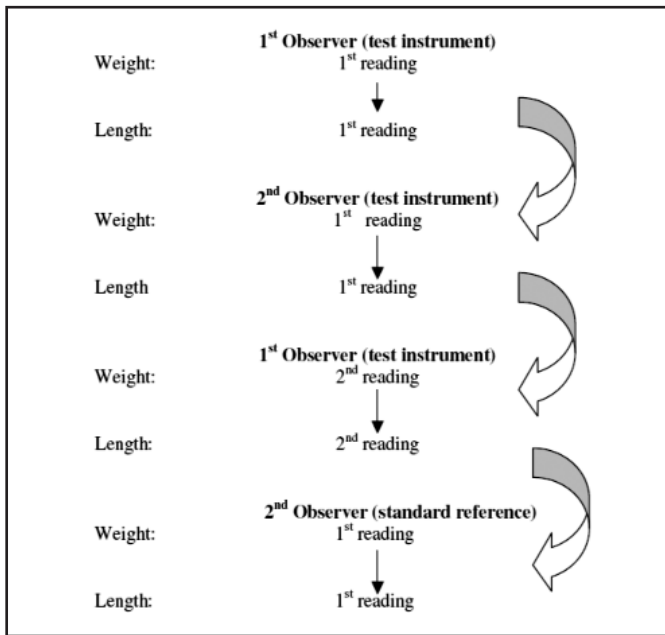


Fig. 1: Process of obtaining length and weight measurements

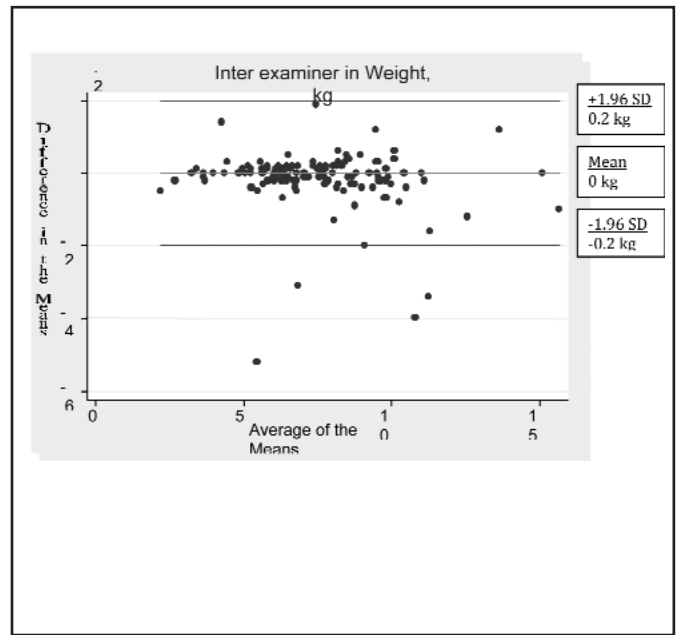


Fig. 2: Bland Altman plot on the weight measurements between examiners

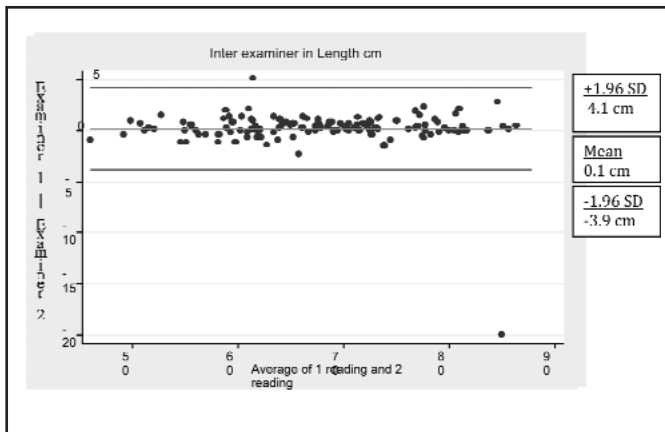
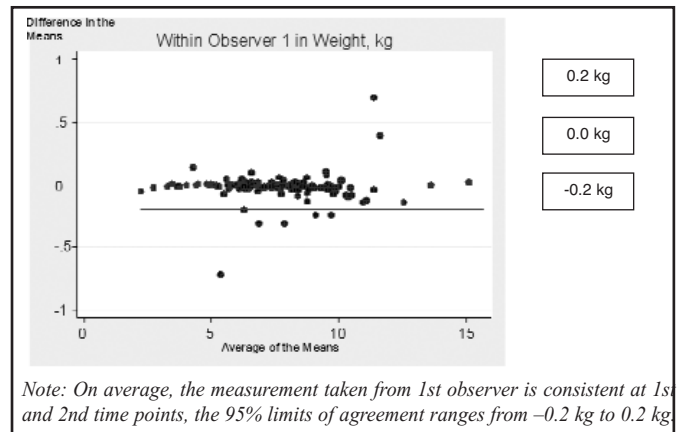
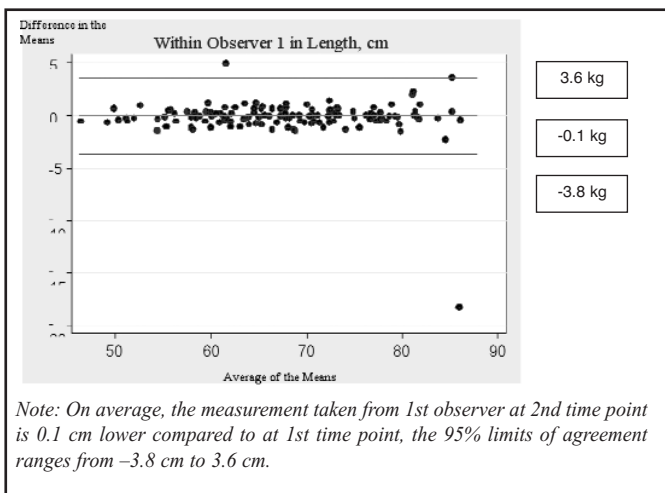


Fig. 3: Bland Altman plot on the length measurements between examiners



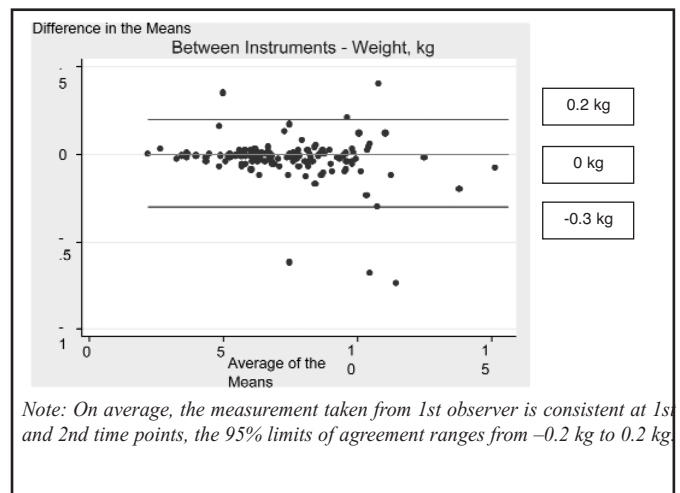
Note: On average, the measurement taken from 1st observer is consistent at 1st and 2nd time points, the 95% limits of agreement ranges from -0.2 kg to 0.2 kg

Fig. 4: Bland Altman plot on the weight measurements within observer 1



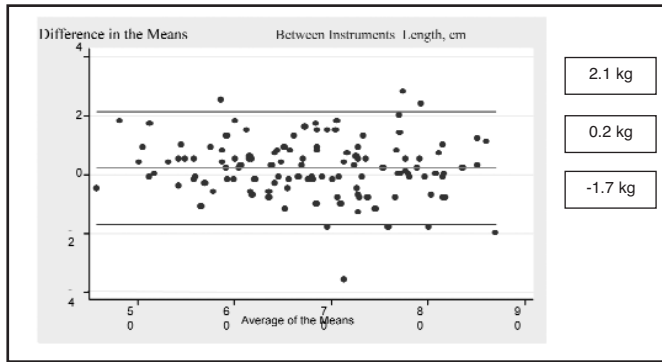
Note: On average, the measurement taken from 1st observer at 2nd time point is 0.1 cm lower compared to at 1st time point, the 95% limits of agreement ranges from -3.8 cm to 3.6 cm.

Fig. 5: Bland Altman plot on the length measurements within observer 1



Note: On average, the measurement taken from 1st observer is consistent at 1st and 2nd time points, the 95% limits of agreement ranges from -0.2 kg to 0.2 kg

Fig. 6: Bland Altman plot on the weight measurements between instruments



**Fig. 7:** Bland Altman plot on the length measurements between instruments

All three relative TEM values were within the acceptable limit except for intra examiner LT. Our findings of TEM values for LT at 1.41 cm (inter) and 1.31 cm (intra) were higher compared to the MGRS 6 countries study<sup>15</sup> which reported a range of TEMs for LT 0.23-/0.58 for intra and 0.23-0.35 for inter. This WHO study also found that teams tend to underestimate length and height that are most likely due to difficulties associated with keeping children fully stretched out and keeping still.

From the findings of R, the coefficient of reliability, all these four measurements reported less than 5% errors due to human measurement. These indicated close to excellent intra and inter examiner reliability for both measurements. The CVs for both LT and WT inter and intra were below 5%. This shows the variability was low in this sample which was a puzzling fact for LT. However the authors prefer to conclude that this study shows that LT measurement was less reliable than WT.

On the validity part, there was 0.2 kg difference in mean for WT and no absolute difference for LT. With an intra-class correlation coefficient of close to 1, there was high degree of accuracy between the two measurements for WT and LT. The Bland & Altman plot for WT measurement showed that on average, those taken from the test instrument were consistent with that of the reference instrument. At maximum, the difference was up to 0.2 kg and at minimum -0.3 kg. The Bland and Altman plot for LT showed that on average the test instrument is 0.2 cm higher which indicates some degree of systematic bias. The upper limit was 2.1 cm and the lower limit was -1.7 cm. Since this assessment is not for clinical diagnostic purposes, we were more willing to accept the  $\pm 2$  cm differences in LT, because measuring LT of younger children is rather challenging. WT was more accurate. All these findings could not be compared with that from other studies because there are hardly any papers on validity for similar measurements.

### Study Limitations

One of the limitations of the study was that we only had one professional anthropometrist in the team. Professionals add value both during the training of examiners as well as for the quality control during the study. Secondly, we did not have pre-determined training values that the examiner needed to have attained before she is appointed as an examiner for the

study. Lastly, these results were internal validity but external generalisation must be cautioned because measurements are often very much operator and instrument dependant.

### CONCLUSIONS

The LT measurement was found to be slightly less reliable and less accurate, compared to that of WT measurement. However the authors concluded that both WT and LT measured in infants and children less than two years old using Tanita digital weighing machine and Seca measuring mat is relatively reliable and valid to be used for the purpose of a community survey within the magnitude of errors that was detected. Several recommendations are also given below to further enhance the examiners' measurement techniques to improve precision and accuracy, in particular for LT measurements.

### Recommendations

The following recommendations should be taken into consideration to improve LT measurement that appeared to be less reliable and has a non-acceptable level of TEMs. Firstly, we should 'control' the examiners selected to perform these measurements for any surveys; both in terms of quality - ideally to only skilful anthropometrist - and quantity, to reduce inter examiner variability. However, if beginners are needed to act as examiners, then they should be trained and their techniques be assessed using relative TEMs against that of a skillful examiner until they reach acceptable limits or at regular intervals during the survey as a way for quality assurance.

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# Investigator-Initiated Clinical Trials in Malaysia and the Role of the Clinical Research Centre of the Ministry of Health

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## SUMMARY

The objective of this review is to better understand the concept of investigator-initiated trials and its benefits. While investigator-initiated trials can be an invaluable tool, there are several challenges in its initiation and management. However, it is for these reasons that Clinical Research Centre (CRC) had developed the Investigator Initiated Trial (IIT) Programme where financial support and technical assistance are provided to local investigators embarking on their own clinical trials. In the course of preparing the review, we found that the inclination of investigator-initiated trials has yet to be well established in Ministry of Health, Malaysia. Given the potential and impact of such trials, clinicians should be aware of their ability as well as the availability of a supportive network in mobilising their concerted research efforts. Greater research collaboration among investigators could foster more innovative, insightful and constructive research.

## INTRODUCTION

An investigator-initiated research is defined by the US Department of Health and Human Services as "research funded as a result of an investigator, on his or her own, submitting a research application."

The Code of Federal Regulations (CFR) describes a sponsor-investigator as "an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed." An investigator is the individual "who actually initiates and conducts a clinical investigation" and, for research conducted by a team, is "the responsible leader of the team." The CFR further states that "the sponsor-investigator is required to submit all technical information supporting the Investigational New Drug (IND)," even if the new drug is not used for the purpose of marketing not under manufacturer's IND<sup>1</sup>.

As defined by World Health Organisation (WHO), a clinical trial is 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.' Investigator-initiated trials (IITs) may include treatment trials, prevention trials, diagnostic trials, screening trials and quality-of-life trials. Each type of trial is with an

aim to investigate a particular aspect of the efficacy on an intervention.

The primary objective of an investigator-initiated research is academic and healthcare management rather than commercial purposes. The medical significance of IITs stems from them ensuring research independent from economic interests. Furthermore they often generate new therapeutic concepts, which might not be of interest to pharmaceutical companies but which are fully derived from academic research and initiative. As sponsor-investigator both initiates and conducts the investigation of own interest, he/she is more adamant in the achievement of the trial objectives.

In view of its primary objective, benefits of IITs are apparent from several perspectives:

- An invaluable tool in exploring questions such as comparative efficacy of one drug over another or a medical management with surgical interventional management, strategies to ease drug dosage schedules, quality of life issues, alternative systems of medicines. These are the objectives of concern in IITs and are not frequently explored in sponsored trials. New drug development or expanding the indication profile of drugs is the main priority for pharmaceutical company-sponsored trials. Now findings of these trials definitely have important bearing for practice and for establishing health related policies<sup>3</sup>. This is definitely in line with the primary goal of IIT which is to make scientific contributions and these new discoveries will ultimately lead to the advancement in medical diagnosis, treatment and prevention.
- A valuable component in evidence-based clinical practice.
- Since an IIT is not fully sponsored by the industry, thus it is more impartial. In fact, a report documenting combined data from more than 1100 studies showed that industry-sponsored clinical trials are "significantly more likely to reach conclusions that were favorable to the sponsor than were non-industry studies", possibly because of publication bias or selection of an inappropriate comparator to the drug being evaluated<sup>4</sup>.

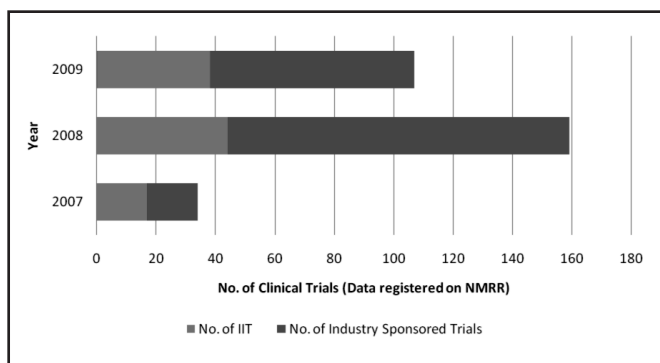
However, it takes a lot to initiate and manage a clinical trial, more so an IIT where a much higher level of administrative effort is often required of investigators. Key challenges are:

1. Lack of internal support, i.e. requiring the cooperation of a multidisciplinary team of specialists such as project managers, biostatisticians, data managers, pharmacists and monitors. This in turn raises expenses considerably.
2. Inexperience in the concepts of clinical trials and its implications such as ethical and legal considerations, trial design and protocol development, study initiation and monitoring, safety surveillance, as well as data management.
3. Financial constraints as the conduct of a trial incur cost such as study equipments, laboratory testing, logistics, human resources and other miscellaneous costs.

The fundamental difference between an investigator-initiated clinical trial and a sponsored clinical trial is that the industry does not play a leading role in IIT, as there is generally no major benefit- either scientific or commercial. As such the industry is not interested in covering the full cost of the study. In addition, sponsor-investigators have more responsibilities in an IIT as compared to being solely an investigator in an industry-sponsored trial. These responsibilities entail the need for more project resources, i.e. staff, facility and equipment.

The industry may, however, provide some funding for an IIT; although the investigator, department and/or the institution will cover the vast majority of the cost. For those IITs which receive some financial support from the industry, they commonly have a contract in place addressing the funding, responsibilities, indemnity and insurance, publication policy, ownership of data and ownership of any eventual invention of discovery as a result of the trial<sup>2</sup>.

#### Current trends of IIT in Malaysia



**Table I:** Number of Clinical Trials Registered on National Medical Research Register from Year 2007 to 2009 (Report extracted on 26 Mar 2010)

Table I illustrates a probable trend of IIT in this country as the data may not be entirely accurate as not all trials are mandatorily required to be registered with the National Medical Research Register (NMRR) and registered trials are mainly from the Ministry of Health institutions hence in such a complete data of trials would not be captured. Hence the limitation of the data but nevertheless it generally shows that the number of IITs has been increasing over the years, i.e. from 17 in 2007 to 38 in 2009. Even so, it is still apparent that the ratio of IITs to Sponsored trials over the years remains relatively low.

As mentioned IITs are mainly academically focused with the objective of translating therapeutic concepts into workable clinical studies and eventually applied to improving clinical practice. Hence it would be interesting to identify current trends of IIT by therapeutic area, i.e. the current interests of fellow healthcare professionals. Such data may not be available but the following table (Table II) does provide an overall depiction of the therapeutic areas in which research has been conducted in recent years.

Table III further illustrates the trend of IIT conducted in this country where the distribution of IITs conducted is tabulated by State. Referring to the data below, it is interesting to note that there is a geographical factor influencing the prevalence of IITs.

Interestingly, Table IV shows that there is considerable number of sites as well as patients involved in IITs considering the less significant total number of IITs conducted.

As mentioned, funding is one of the key challenges in the initiation and management of a clinical trial even more so for IITs where there is most likely a lack of financial support from the more substantial industry grants. Table IV shows the other means of funding for IITs (i.e. non-industry grants) in this country and interestingly self-funding is the most common source.

In summary, an investigator-initiated clinical trial is one in which the principal investigator is required to be well-committed in the conduct of such a clinical trial as the investigator will have to oversee the development, conduct, and management of investigator-initiated trials: tasks of which include protocol development, the peer review process, study conduct, data capture procedures, financial and clinical resources, and publication<sup>1</sup>.

#### Investigator -initiated trials (IITs) in Clinical Research Centre (CRC) Network – Past, Present & Future

##### Establishment of CRC Network

The CRC Network was established in year 2000 to promote the conduct of clinical trials supported by the Ministry of Health (MOH), Malaysia. Clinical Research Centre, Hospital Kuala Lumpur was the first to be established and the network has grown to a current seventeen branches of offices in the various states of Malaysia, each managing its own clinical research activities, either within its centre or in collaboration with other centres.

CRC is one of the research organisations under the umbrella of the National Institutes of Health of the MOH. Other research organisations include the Institute of Medical Research (IMR), Institute of Public Health (IPH), Institute of Health Management (IHM), Institute for Health Behavioral Research (IHBR) and Institute for Health Systems Research (IHSR).

The CRC Network is involved in various types of clinical research, namely clinical trials, clinical epidemiology, patient registry and national healthcare statistics initiative.

**Table II: Research Registered on National Medical Research Register by Therapeutic Area (Report extracted on 19 April 2010)**

#	2008			2009		
	Therapeutic area	No	%	Therapeutic area	No	%
1	Hepatology	20	12.6	Psychiatry	17	20.2
2	Cardiology	17	10.7	Cardiology	12	14.3
3	Oncology	17	10.7	Diabetes Mellitus	12	14.3
4	Diabetes mellitus	14	8.8	Oncology	10	11.9
5	Psychiatry	14	8.8	Infectious Disease	7	8.3
6	Nephrology	11	6.9	Respiratology	7	8.3
7	Haematology	10	6.3	Rheumatology	6	7.1
8	Infectious disease	8	5.0	Endocrine/Metabolic	5	6.0
9	Gastroenterology	6	3.8	Anaesthesiology	4	4.8
10	Medicine	6	3.8	Haematology	4	4.8

**Table III: Distribution of IITs for Research Registered on National Medical Research Register by State (Report extracted on 26 Mar 2010)**

#	State	Investigators Initiated Trials			
		Year 2008		Year 2009	
		No. of trials	No. of trials (%)	No. of trials	No. of trials (%)
1	Selangor Darul Ehsan	18	31.03	9	22.64
2	Sarawak	1	1.72	7	15.56
3	Pulau Pinang	8	13.79	4	8.89
4	Johor Darul Takzim	3	5.17	10	22.22
5	Wilayah Persekutuan	10	17.24	7	15.56
6	Perak Darul Ridzuan	1	1.72	1	2.22
7	Sabah	4	6.90	0	0.00
8	Negeri Sembilan Darul Khusus	4	6.90	0	0.00
9	Kelantan Darul Naim	2	3.45	1	2.22
10	Kedah Darul Aman	1	1.72	3	6.67
11	Pahang Darul Makmur	2	3.45	0	0.00
12	Terengganu Darul Iman	2	3.45	0	0.00
13	Melaka	2	3.45	0	0.00
14	Putrajaya	0	0.00	3	6.67
	Total	58	100	45	100

\*Note: Total exceeds total number of research registered (c.f. Table I) as a research may be conducted in more than one state

**Table IV: Cumulative Number of Investigative Sites and Patient Enrollment for IITs Registered on National Medical Research Register (Report extracted on 26 Mar 2010)**

Year	No. of IITs	No. of sites involved	Total no. of patients involved
2008	44	143	3195
2009	38	53	2417

**Table V: Distribution of IITs for Research Registered on National Medical Research Register by Funding Source (Report extracted on 26 Mar 2010)**

#	Funding Source	Number of IITs	
		Year 2008	Year 2009
1	International Grant	2	1
2	MOH Grant	8	2
3	University Research Grant	-	1
4	Self-Funding	32	32
5	Others	2	4
	Total	44	40

\*Note: Total does not correlate with total no. of IITs (c.f. Table I) as an IIT may have different sources of funding

*Clinical trials conducted in CRC Network*

The CRC Network conducts both IITs and industry sponsored-trials. In addition, the network also provides clinical trial-related services such as professional development courses to train investigators and other healthcare professionals in the conduct of clinical research, as well as organising regular research consultative clinics as a service for clinicians working in the MOH to assist them in overcoming any problems which may arise during the course of their clinical research efforts.

Under the purview of National Institutes of Health (NIH), the CRC Network promotes the conduct of quality and ethical clinical research to improve patient outcome.

*Significance of IIT in Malaysia*

It has been shown that findings of several IITs have not just made an impact academically but also played significant role in shaping current medical practical guidelines in Ministry of Health.

A randomised, multicentre, open-label trial evaluating two peritoneal dialysis systems or also known as the CAPD Trial<sup>5</sup> had a decisive impact on the Ministry of Health policy on utilisation of the type of peritoneal dialysis system in its dialysis program.

Another example would be a controlled randomised trial evaluating the efficacy of mycophenolate mofetil in the induction therapy of proliferative lupus nephritis – the

second of such trial in the world to confirm the efficacy of this new immunosuppressant agent<sup>6</sup>.

Apart from establishing efficacious data, another IIT with the aim of establishing therapeutic equivalence of a biogeneric and original product was conducted<sup>7,12</sup>. The study is one with economical implications as original epoetin is costly hence with proven efficacy of a biogeneric epoetin, treatment cost would be reduced thereby improving access to therapy. Being the first ever comparative study of a biogeneric and original product, the necessity for rigorous evaluation on biologics was also established.

From the examples above, it is apparent that the conduct of IITs improves the knowledge base for both clinicians and investigators and may shape current medical practice to suit the desired patient outcomes in specific patient demographics within the Malaysian local population. It is also observed that although IITs may be conducted at a small scale, they provide the ground-level evidence which might improve medical practice and often, also the impetus from which further repercussions on medical practice can be actively sought and examined.

As the investigator owns the scientific development of the trial, there is much motivation in conducting the trial to completion and with the ultimate aim of making a scientific contribution by publishing trial results. CRC Network has a good track record of publications as illustrated in the table below.

Year	Number of publications/manuscripts
2002	4
2003	5
2004	7
2005	5
2006	16
2007	18
2008	42
2009	49

Source: Listing of CRC's Research Reports & Journal Publications (31 Dec 2009)

Out of which, the following are some IIT publications conducted by Ministry of Health investigators:

#	Study Title	Publication
1	A Randomized Controlled Trial to Evaluate the Effects of Conversion to Low Calcium Dialysate in Stable CAPD Patients <sup>8</sup>	Nephrology 2008; 13 (Suppl.), A77
2	A Randomized, Multicentre, Open-label Trial to Establish Therapeutic Equivalence Between the Carex and Ultra Disconnect Systems in Patients on Continuous Ambulatory Peritoneal Dialysis <sup>9</sup>	Peritoneal Dialysis International, Vol. 23, Peritoneal Dialysis International, Vol. 23,
3	Direct Stenting Compared to Conventional Stenting in Diabetic Patients Undergoing Elective Angioplasty for Coronary Artery Disease (DECIDE): A multicenter, open label, randomized, controlled efficacy study <sup>10</sup>	American Heart Journal 2004, 148: 1007-11
4	A Randomized, Multicenter, Open-Label Trial to Determine Peritonitis Rate, Product Defect, and Technique Survival Between ANDY-Disc® and UltraBag® in Patients on CAPD (CAPD-II Trial) <sup>5</sup>	American Journal of Kidney Disease 2006; 48 (3): 464-472
5	Randomized trial on the therapeutic equivalence between Eprex and GerEPO in patients on haemodialysis <sup>7</sup>	Nephrology 2007; 12, 431-436
6	Randomized controlled trial of pulse intravenous cyclophosphamide versus mycophenolate mofetil in the induction therapy of proliferative lupus nephritis <sup>6</sup>	Nephrology 2007; 12, 431-436
7	A multicenter study to determine the efficacy and safety of a generic atorvastatin <sup>11</sup>	Medical Journal Malaysia, Volume 64, No 2, June 2009 pages 150-154.
8	An Observational Cohort Study to determine the long-term Safety and Efficacy of GerEPO for the treatment of renal anaemia in patients with Chronic Kidney Disease <sup>12</sup>	Nephrology 2009;14:264
9	A Randomized Prospective Study to Investigate the Electrolyte Abnormalities Associated with Oral Sodium Phosphate for Bowel Preparation of Patients for Colonoscopy <sup>13</sup>	Med J Malaysia Vol 64 Supplement B August 2009 pg 76

### Role of CRC Network in the Future of IIT Development

The current development of investigator-initiated clinical trials requires much input from all parties of the healthcare arena. Thus, the CRC Network offers an IIT program to provide financial assistance and technical support to local investigators intending to initiate their own clinical trials. Such a program will not only assist in the smooth-running of clinical trials, but also see local investigators through all clinical trial matters, including compliance to trial regulations, trial insurance and professional indemnity, trial design and protocol development, study initiation and monitoring, pharmacovigilance, data management and training services.

The future research areas move towards covering the pertinent healthcare issues at hand, and all research endeavours should ideally receive adequate supporting resources including funding, a team of well-motivated research personnel and properly laid-down research guidelines and protocols. The current spectrum of clinical trial services rendered by clinical trials unit (CTU) in CRC HKL is one example in which the CRC Network is providing a supporting network of resources to facilitate the initiation, conduct and completion of clinical trials.

Besides, greater research collaboration between industry and academy should foster a better research effort among them. The future direction of the CRC Network is to conduct a better conglomeration of high-quality clinical trials that not only increases scientific value of clinical research, but also spurs other researchers to move towards more innovative, insightful and constructive research.

### CONCLUSION

The aims of this description are to provide a fair and balanced view of the current status of IIT in this country as well as the output from the Clinical Research Centre Network (the CRC Network). Though there is limitation to the quantitative figures reported here as data extracted are solely on the basis of trial registration on the NMRR hence information are mainly from the Ministry of Health. By detailing a snapshot of all activities (past and present) conducted within the network, it should enable all potential investigators to understand the supporting role of this network, motivate clinicians to be potential investigators in mobilising their concerted research efforts to uphold the quality of all types of clinical research within all arenas of healthcare in Malaysia.

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# Malaysia Shape of the Nation (MySoN): A Primary Care Based Study of Abdominal Obesity In Malaysia

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## SUMMARY

Abdominal obesity (AO), measured by waist circumference (WC), is a stronger predictor of subsequent development of cardiovascular disease (CVD) than generalised obesity, which is measured by body mass index (BMI). This study aimed to measure WC and prevalence of AO in Malaysians visiting primary care physicians. 1893 patients between the ages of 18 and 80 attending primary care clinics in Malaysia were recruited over two days for this multi-centre cross-sectional study. Pregnant women were excluded, their medical history, weight, height and WC were examined. The prevalence of co-morbidities were as follows: (1) CVD-4%, lipid disorder-17%, hypertension-26%, diabetes-14% and any of the clinical characteristics of CVD/lipid disorder/hypertension/diabetes-38%. The mean BMI for men and women was  $25.62 \pm 4.73$  kg/m<sup>2</sup> and  $26.63 \pm 5.72$  kg/m<sup>2</sup>, respectively. Based on WHO criteria for BMI (overweight, 25-29.9 kg/m<sup>2</sup>; obese, >30 kg/m<sup>2</sup>), 34.2% were overweight and 20.4% were obese. The mean WC for men and women was  $89.03 \pm 13.45$  cm and  $84.26 \pm 12.78$  cm, respectively. Overall, 55.6% had AO and there was higher prevalence among women (based on International Diabetes Federation criteria: WC  $\geq 90$  cm for men and  $\geq 80$  cm for women). AO was present in approximately 71% patients with lipid disorder, in 76% with hypertension and in 75% with diabetes. Patients with AO were also at a higher risk of developing co-morbidities. Malaysia has a high prevalence of AO and associated cardiovascular risk factors. This needs to be addressed by public health programs, which should also include routine measurement of WC.

## INTRODUCTION

Obesity is a chronic metabolic disorder associated with cardiovascular disease (CVD) as well as increased morbidity and mortality worldwide, in both developed and developing countries. The prevalence of obesity has reached epidemic levels in both first world and developing countries<sup>1</sup>. The 1996 Second National Health and Morbidity Survey (NHMS 2) reported the prevalence of overweight and obesity, according to calculated body mass index (BMI), to be 20.7% and 5.8% respectively<sup>2,3</sup>.

Recent conflicting evidence on the association of BMI with cardiovascular (CV) and obesity-related health risk casts doubt on its usefulness<sup>4,5</sup>. It is believed that the global burden of obesity has been substantially underestimated due to

reliance on BMI in previous studies<sup>6</sup>. It has also been shown that Asians are prone to diabetes, hypertension, and dyslipidaemia at lower levels of BMI<sup>7,9</sup>, and that the same level of BMI connotes a greater degree of obesity in Asians compared with Caucasians<sup>10-12</sup>.

Newer evidence suggests that abdominal obesity (AO), which is measured by waist circumference (WC), is a stronger predictor than generalised obesity (defined by elevated BMI) of subsequent major coronary event, vascular mortality, diabetes and the metabolic syndrome<sup>13-16</sup>. Therefore, in recent years, increasing interest has been focused not just on obesity as an individual risk factor, but also on type 2 diabetes, hypertension and dyslipidaemia, all of which together constitute the metabolic syndrome.

NHMS2 findings showed the prevalence of diabetes to be 8.2% (as compared to 6.3% in NHMS1 in 1986)<sup>2</sup>. The WHO has estimated that in 2030, Malaysia would have a total number of 2.48 million diabetics compared to 0.94 million in 2000 – a 164% increase<sup>17</sup>. Patients with diabetes have a two to three fold higher incidence of CVD than non-diabetic patients, and CVD is responsible for the majority of hospital admissions for diabetic individuals<sup>18</sup>. Thus, obesity has become a major clinical and public health problem that threatens to overwhelm already extended healthcare services in Malaysia.

The increasing attention on the epidemic of obesity and its associated health problems has brought into focus the lack of nationally representative cross-sectional data for the Malaysian population. This has become an obstacle to monitoring the magnitude of the current and future obesity problems, and to evaluating the effectiveness of intervention strategies.

The purpose of Malaysia Shape of the Nation (MySoN) study was therefore to estimate the distribution of WC and the prevalence of AO in a population of Malaysian patients visiting primary care physicians. Secondary objectives were to estimate the prevalence of specific CV risk factors (hypertension, diabetes or dyslipidaemia) and to estimate the prevalence of AO in such sub-groups of patients. The study also offered an educational opportunity for physicians to learn about WC measurement, and about CV and metabolic consequences of AO.

## MATERIALS AND METHODS

This multi-centre cross-sectional study was conducted at 93 primary care clinics in Malaysia. The study was conducted in accordance with the principles laid by the 18th World Medical Assembly (Helsinki, 1964) and all subsequent amendments and as per the guidelines for Good Epidemiology Practice<sup>19</sup>. The study proposal was approved by the Medical and Research Ethics Committee of the Malaysian Ministry of Health. Data release consent was obtained from all the subjects included in the study.

### *Study Population and Sampling*

The study population consisted of adult men and women (age >18 and <80 years) attending primary care clinics in both the public and private sectors across the country on the 22nd and 23rd June 2005. Pregnant women were excluded from the study.

The sampling frame for the public primary care clinics was obtained from the National Medicines Use Survey of the Ministry of Health and for the private clinics from IMS<sup>20</sup>. Public primary care clinics were stratified by 14 states in Malaysia. For each state, a quota of clinics was selected based on the size of the population in that state. Figures for the population were obtained from the National Population and Housing Census of 2000<sup>21</sup>.

A total of 93 clinics were selected by simple random sampling. Each patient satisfying the selection criteria and visiting a physician's office during these predefined half-days was asked to participate in the study.

### *Study Assessment*

The relevant data were obtained from patients' medical records, by face-to-face interviews and direct measurements. The socio-demographic variables such as age, gender, ethnicity, education level, occupation, smoking as well as medical history (CVD, lipid disorders, hypertension, diabetes, post-menopause, and hormonal replacement therapy) were also collected.

Body weight, height and WC were measured by the attending physician. Body weight (without shoes in light indoor clothing) was measured using a bathroom spring balance to the nearest 0.1 kg. Height (without shoes) was measured using a measuring tape attached to a rigid wall to the nearest 0.1 cm. WC was measured using a measuring tape in a horizontal plane at a mid-point between the lower rib and the iliac crest. Measurement was made at the end of normal expiration with the tape parallel to the floor and the tape snug but not compressing the skin. All physicians attended centralised training on standardised protocol for body weight, height and WC measurement. A standardised measuring tape was provided to all physicians.

### *Study Definitions*

BMI is defined as the ratio of weight in kilograms to square of height in meters. For the purpose of this analysis, BMI was categorised according to the classification system recommended by the WHO Technical Report Series<sup>1</sup> as follows:

- Underweight, <18.5 kg/m<sup>2</sup>
- Normal, 18.5-24.9 kg/m<sup>2</sup>
- Overweight, 25-29.9 kg/m<sup>2</sup>
- Obese, ≥30 kg/m<sup>2</sup>

Abdominal obesity was defined according to the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) criteria of WC ≥102 cm for men and WC ≥88 cm for women<sup>22</sup>, as well as in accordance with the WHO and International Diabetes Federation (IDF) criteria for Asians, i.e., WC ≥90 cm for men and WC ≥80 cm for women<sup>23-24</sup>.

### *Statistical Methods*

In order to provide sufficiently precise estimates, the sample size calculation took into consideration the expected prevalence of AO among patients visiting a primary care physician and the precision that we were willing to accept. Using prevalence from previous studies, which ranged from 20%-50%, and 95% confidence intervals of 17.6%-22.6% and 46.8%-53.1% respectively, it was calculated that we would require a sample size of 1000 subjects. All statistical tests were performed at the 5% level of significance using 2-sided tests.

Continuous variables were described by summary statistics such as mean, median, standard deviation and cumulative percent. Categorical (nominal/ordinal) variables are summarized by the frequencies of each category.

## RESULTS

### *Baseline Characteristics*

A total of 1,893 subjects (47.5% women) were enrolled in the study. About 56% were provided by public primary care clinics (29 centres) and 44% by private practitioners (64 centres). The demographic characteristics of enrolled subjects are shown in Table I.

The mean age was 44 + 14 years. About 49% of the sample was of Malay ethnic origin and the majority (about 78%) had attained less than tertiary education. This was as expected from a sample that is representative of the Malaysian middle-aged population. More than 68% had never smoked. However, 4% of the study population had existing CVD, while 17% had lipid disorder, 26% hypertension and 14% diabetes. About 38% had one of the clinical characteristics of CVD / lipid disorder / hypertension / diabetes. Clearly, this is more typical of a population attending outpatient clinics rather than the general Malaysian population.

### *Mean Body Mass Index and Waist Circumference*

The mean BMI and WC by gender, ethnicity and age are presented in Table II.

The mean BMI for men was 25.62 ± 4.73 kg/m<sup>2</sup>, while for women it was 26.63 ± 5.72 kg/m<sup>2</sup>. Women had higher mean BMI than men among all groups (except for Chinese) and in all age groups till the seventh decade, after which the mean BMI values of the two sexes converged. Among women, Indians had the highest BMI, followed by Malays and Chinese. Among men, Chinese had the highest BMI followed by Indians, Malays and others.

Mean WC for men was 89.03 ± 13.45cm, while for women it was 84.26 ± 12.78cm. It was higher in men than in women for all ethnic groups. In all ethnic-gender groups, BMI and WC rose with increasing age till fifth or sixth decade, thereafter it declined. The rise in BMI with age was steeper for women than for men.

Table I: Baseline Characteristics of Patients Enrolled in the Study

Baseline Characteristics	Men N= 899	Women N= 993	All* N=1893
Age in Years (Mean + SD)	44 ± 14	44 ± 14	44 ± 14
Ethnicity [Number (%)]			
Malay	425	505	930 (49.1)
Chinese	263	291	555* (29.3)
Indian	174	159	333 (17.6)
Others	26	32	58 (3.1)
Missing	11	6	17 (0.9)
Mean Body Weight in Kg (Mean + SD)	71.9 ± 14.4	63.9 ± 14.2	67.7 ± 14.8
Primary Care Clinic [Number (%)]			
Public	534	526	1060 (56)
Private	365	467	832 (44)
Level of Education [Number (%)]			
Less than High school	279	382	661 (34.9)
High school	415	399	814 (43)
Tertiary	204	207	412*(21.8)
Missing	1	5	6 (0.3)
Occupational Status [Number (%)]			
Employed	726	545	1271 (67.2)
Unemployed	63	366	429 (22.7)
Retired	92	47	139 (7.3)
Incapacitated for work	3	12	15 (0.8)
Missing	15	23	38 (2)
Smoking Status [Number (%)]			
Never	356	948	1304 (68.9)
Former	153	17	170 (9)
Current	388	24	412 (21.8)
Missing	2	4	6 (0.3)
Known Cardiovascular Disease (CVD) [Number (%)]	48 (5.3)	31 (3.1)	79 (4.2)
Known Lipid Disorder [Number (%)]	163 (18.1)	162 (16.3)	325 (17.2)
Known Hypertension [Number (%)]	240 (26.7)	259 (26.1)	499 (26.4)
Known Diabetes Mellitus [Number (%)]	124 (13.8)	136 (13.7)	260 (13.7)
Known Post-menopausal [Number (%)]	NA	282 (28.4)	282 (14.9)
CVD / Lipid Disorder / Hypertension / Diabetes Mellitus (any of the clinical characteristics) [Number (%)]	357 (39.7)	369 (37.2)	726 (38.4)

SD = standard deviation

\* Information on gender missing for one Chinese patient

Table II: Mean Body Mass Index and Waist Circumference by Socio-Demography Factors

Characteristics	Body Mass Index (kg/m <sup>2</sup> )		Waist Circumference (cm)	
	Mean	SD	Mean	SD
Age				
15-19	22.78	5.09	75.79	13.04
20-24	23.20	5.00	76.21	11.95
25-29	25.06	6.13	81.29	13.60
30-34	25.80	5.00	85.26	12.99
35-39	26.98	5.42	88.12	14.44
40-44	26.60	5.11	87.02	11.34
45-49	27.16	5.01	89.83	13.46
50-54	27.33	4.84	89.76	11.82
55-59	27.61	5.40	92.29	12.48
60-64	25.80	4.43	87.76	10.55
65-69	25.75	4.47	88.73	11.13
70-74	25.39	4.94	88.19	12.81
75+	23.83	4.16	82.61	10.27
Gender				
Male	25.62	4.73	89.03	13.45
Female	26.63	5.72	84.26	12.78
Ethnicity				
Malay	26.78	5.82	86.21	13.82
Chinese	24.86	4.42	85.20	12.86
Indian	26.54	4.89	89.89	12.44
Others	25.21	3.91	83.22	10.93

SD = standard deviation

Table III: Distribution of Body Mass Index by Socio-Demography Factors and Patient Diagnosis Status

Socio-Demography Factors or Patient Diagnosis Status	Body Mass Index (kg/m <sup>2</sup> )*			
	Underweight n (%)	Normal n (%)	Overweight n (%)	Obese n (%)
Age				
15-19	7 (20.59)	18 (52.94)	6 (17.65)	3 (8.82)
20-24	16 (10.74)	94 (63.09)	26 (17.45)	13 (8.72)
25-29	14 (7.18)	100 (51.28)	46 (23.59)	35 (17.95)
30-34	10 (5.24)	77 (40.31)	66 (34.55)	38 (19.90)
35-39	7 (3.52)	68 (34.17)	78 (39.20)	46 (23.12)
40-44	9 (4.07)	87 (39.37)	75 (33.94)	50 (22.62)
45-49	4 (1.75)	83 (36.40)	86 (37.72)	55 (24.12)
50-54	6 (2.58)	66 (28.33)	106 (45.49)	55 (23.61)
55-59	3 (1.74)	52 (30.23)	62 (36.05)	55 (31.98)
60-64	5 (4.76)	44 (41.90)	40 (38.10)	16 (15.24)
65-69	3 (3.66)	39 (47.56)	28 (34.15)	12 (14.63)
70-74	4 (9.52)	17 (40.48)	16 (38.10)	5 (11.90)
75+	4 (10.53)	20 (52.63)	11 (28.95)	3 (7.89)
Gender	92 (4.87)	765† (40.50)	646 (34.20)	386 (20.43)
Male	47 (5.23)	375 (41.76)	327 (36.41)	149 (16.59)
Female	45 (4.55)	389 (39.29)	319 (32.22)	237 (23.94)
Ethnicity				
Malay	49 (5.27)	334 (35.95)	312 (33.58)	234 (25.19)
Chinese	32 (5.77)	268 (48.29)	191 (34.41)	64 (11.53)
Indian	11 (3.32)	129 (38.97)	118 (35.65)	73 (22.05)
Others	0	30 (52.63)	19 (33.33)	8 (14.04)
Known Cardiovascular Disease (CVD)				
Yes	2 (2.53)	34 (43.04)	26 (32.91)	17 (21.52)
No	89 (4.94)	727 (40.39)	618 (34.33)	366 (20.33)
Known Lipid Disorder				
Yes	5 (1.54)	94 (29.01)	136 (41.98)	89 (27.47)
No	86 (5.54)	666 (42.88)	506 (32.58)	295 (19)
Known Hypertension				
Yes	7 (1.4)	119 (23.85)	199 (39.88)	174 (34.87)
No	85 (6.14)	643 (46.42)	445 (32.13)	212 (15.31)
Known Diabetes				
Yes	3 (1.16)	76 (29.34)	109 (42.09)	71 (27.41)
No	88 (5.41)	687 (42.25)	537 (33.03)	314 (19.31)
Post-menopause				
Yes	10 (3.53)	97 (34.29)	106 (37.46)	70 (24.73)
No	34 (5.01)	281 (41.38)	204 (30.04)	160 (23.56)
CVD / Lipid Disorder / Hypertension / Diabetes Mellitus (any of the clinical characteristics)				
Yes	13 (1.79)	204 (28.14)	290 (40)	218 (30.07)
No	79 (6.79)	561 (48.2)	356 (30.58)	168 (14.43)

\*Body mass index classification based on WHO Technical Report Series, 2000:

Underweight, <18.5 kg/m<sup>2</sup>

Normal, 18.5-24.9 kg/m<sup>2</sup>

Overweight, 25-29.9 kg/m<sup>2</sup>

Obese, >30 kg/m<sup>2</sup>

†Information on gender missing for one patient

### Prevalence of Obesity

The percent distribution of BMI according to WHO classification<sup>1</sup> is presented in Table III. Overall, 34.2% subjects had BMI in the overweight group, 20.4% in the obese group, and 40.5% in the normal group, while 4.9% subjects were underweight. Both overweight and underweight were more common among men than women, but obesity was more common among women. Indians had the highest prevalence of overweight, followed by Chinese, Malays and other indigenous groups. However, Malays had the highest prevalence of obesity.

Table IV presents the percent distribution of WC according to the classification of AO by the WHO and IDF<sup>23-24</sup>. Overall 55.6% of the population had AO, with a higher prevalence among women. Indians had the highest prevalence of AO, followed by Malays, Chinese and other indigenous groups.

There was high prevalence of obesity and AO in sub-groups of patients with co-morbid conditions such as hypertension, diabetes or dyslipidemia (Tables III and IV). Based on measurement of WC, a very high percentage of patients were at increased CV risk in each sub-group: AO was present in approximately 71% with lipid disorder, in 76% with hypertension and in 75% with diabetes. In fact, patients with AO were also at a higher risk of developing co-morbidities (Figure 1).

### DISCUSSION

Abdominal obesity poses a major challenge to health worldwide and is associated with CV risk. There have been few studies on obesity in the Malaysian population<sup>25-27</sup>. The MySoN study provides valuable data about the prevalence of AO and associated CV risk factors such as hypertension, diabetes or dyslipidemia in Malaysia.

Table IV: Distribution of Central Obesity by Socio-Demography Factors and Patient Diagnosis Status

Socio-Demography Factors or Patient Diagnosis Status	Waist Circumference (cm)*	
	Normal n (%)	At Risk n (%)
Age		
• 15-19	27 (79.41)	7 (20.59)
• 20-24	120 (80.54)	29 (19.46)
• 25-29	126 (64.62)	69 (35.38)
• 30-34	92 (48.17)	99 (51.83)
• 35-39	80 (39.80)	121 (60.20)
• 40-44	99 (44.80)	122 (55.20)
• 45-49	78 (34.06)	151 (65.94)
• 50-54	66 (28.33)	167 (71.67)
• 55-59	45 (26.16)	127 (73.84)
• 60-64	41 (39.05)	64 (60.95)
• 65-69	32 (39.02)	50 (60.98)
• 70-74	17 (40.48)	25 (59.52)
• 75+	17 (44.74)	21 (55.26)
Gender	840 (44.40)	1052 (55.60)
• Male	467 (51.95)	432 (48.05)
• Female	373 (37.56)	620 (62.44)
Ethnicity		
• Malay	418 (44.95)	512 (55.05)
• Chinese	271 (48.92)	283 (51.08)
• Indian	115 (34.53)	218 (65.47)
• Others	30 (51.72)	28 (48.28)
Known Cardiovascular Disease (CVD)		
Yes	30 (37.97)	49 (62.03)
No	805 (44.65)	998 (55.35)
Known Lipid Disorder		
Yes	95 (29.23)	230 (70.77)
No	739 (47.52)	816 (52.48)
Known Hypertension		
Yes	122 (24.45)	377 (75.55)
No	716 (51.59)	672 (48.41)
Known Diabetes		
Yes	66 (25.38)	194 (74.62)
No	771 (47.36)	857 (52.64)
Post-menopause		
Yes	71 (25)	213 (75)
No	286 (42.06)	394 (57.94)
CVD / Lipid Disorder / Hypertension / Diabetes Mellitus (any of the clinical characteristics)		
Yes	201 (27.69)	525 (72.31)
No	639 (54.8)	527 (45.2)

\*Waist circumference specific values based on International Diabetes Federation consensus worldwide. Abdominal obesity is defined as WC  $\geq$ 90 cm for men and WC  $\geq$ 80 cm for women

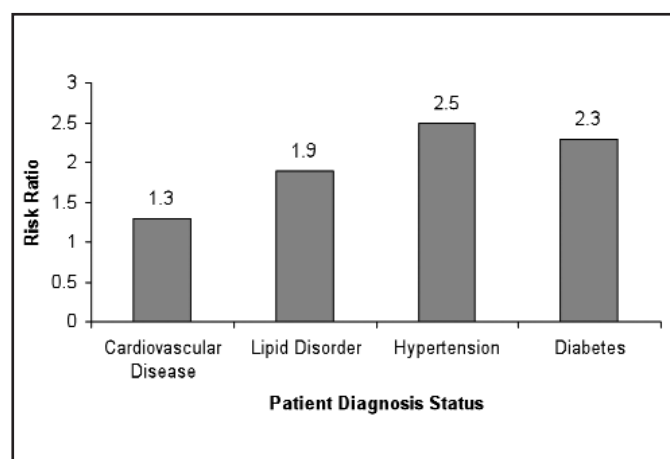


Fig. 1: Risk ratio of co-morbidities in Malaysian patients with abdominal obesity

In the MySoN study, the average value of WC was 89.03 cm for men and 84.26 cm for women. By the IDF criteria of WC for AO ( $\geq$ 90 cm in men and  $\geq$ 80 cm in women), the prevalence of AO was found to be very high (55.6%), being even higher in the female population. While AO has reached epidemic proportions worldwide, we found the prevalence of AO in Malaysia was even greater than the prevalence in western countries such as the United States of America<sup>28</sup>, Belgium<sup>29</sup> and France<sup>30</sup> or in Asian countries such as South Korea<sup>31</sup>, Singapore<sup>32</sup> and Hong Kong<sup>33</sup>.

Even when based on BMI, the prevalence of overweight (34.2%) and obesity (20.4%) in MySoN study was higher than that observed in the NHMS 2 and previous Malaysian studies. In these studies, the prevalence of overweight ranged from 20.7%-37.4%, while that of obesity ranged from 4.5%-10%<sup>2,25-26,34</sup>. A national survey on the prevalence of obesity among 16,127 Malaysians found that the overall national prevalence of obesity among Malaysians >15 years was 11.7%. The

prevalence of obesity amongst those aged >18 years has markedly increased by 280% since NHMS 2<sup>27</sup>.

This extraordinary increase in the prevalence of obesity corroborates with the greatly increased rates of CVD in low- and middle-income countries, which now bear about 80% of the global burden of CVD<sup>35</sup>. Moreover, even in the rural Malaysian population that is conventionally thought of as low-risk for CVD, there is high prevalence of overweight or obesity (45%), and other CV risk factors such as hypertension, smoking, lipid disorder and diabetes<sup>36</sup>. At the total Malaysian population level, this high prevalence of obesity probably results from a complex interaction between an inherited metabolic predisposition to fatness and changes in the population's lifestyle (i.e., higher energy and fat consumption and reduced physical activity)<sup>37</sup>.

The high prevalence of overweight and obesity in Malaysia is associated with adverse lipid and glucose metabolism as well as poor blood pressure control<sup>26</sup>. Even in our study, there was high prevalence of lipid disorder (17%), hypertension (26%), diabetes (14%) and any of the clinical characteristics of CVD / lipid disorder / hypertension and diabetes (38%). In our study, AO was more prevalent in individuals with CVD (62%) than in those without CVD (55.4%). The prevalence patterns for AO observed among patients with and without lipid disorder (70.8% vs 52.5%), hypertension (75.6% vs 48.4%) or diabetes (74.6% vs 52.6%) were similar. In fact, patients with AO were also at a higher risk of developing co-morbidities, with a risk ratio of 1.9 for lipid disorder, 2.5 for hypertension and 2.3 for diabetes.

Overweight has already been shown to play an important role in the clustering of CV risk factors in western populations<sup>38-39</sup>. It has also been shown to be an independent risk factor for CVD in populations from China<sup>40</sup> and South Korea<sup>41</sup>. This clustering is significant because people with both diabetes and hypertension have approximately twice the risk of CVD<sup>42</sup>. In Malaysia, both diabetes mellitus and hypertension are associated with significantly higher BMIs<sup>25</sup>. In an earlier Malaysian study, subjects with diabetes were more obese (38.4%) than normal subjects (24.1%), and also had a higher prevalence of hypertension and hypercholesterolemia<sup>43</sup>. The prevalence of dyslipidemia was also high in Malaysian type 2 diabetes patients<sup>44</sup>. Moreover, the control of hypertension and diabetes in Malaysia is very poor<sup>17, 45-46</sup>. Hence, unless it is addressed urgently, the rate of CVD and diabetes in Malaysia is expected to increase sharply in the near future as a consequence of the high prevalence of overweight and obesity<sup>47</sup>.

Considering the significant associations between clustering of CVD risk factors and WC, the present study suggests that high prevalence of overweight and AO may have important implications for the health care system. Because overweight significantly increases the prevalence of associated risk factors, especially hypertension, it should be considered as a major CV risk determinant<sup>48</sup>.

The MySoN study was conducted in primary care, as this was a feasible way of recruiting large numbers of individuals. Results cannot be extrapolated to the general Malaysian

population, but only to the population consulting primary care physicians. We also assessed whether the relationships between AO and CV risk factors differed across ethnic groups in Malaysia. The MySoN questionnaire did not distinguish between type 1 and type 2 diabetes. As the majority of patients with diabetes (85% to 95%) have type 2 diabetes, the observed relationships between diabetes and obesity would be primarily driven by type 2 diabetes.

An important strength of MySoN study was the physicians' training to measure WC using a standardized approach<sup>49</sup>. In this study, we chose to use WC as a measure of AO because a close relationship between WC and the amount of intra-abdominal fat has been observed using CT scans<sup>50</sup>. Since Asians may require a lower cut-off level of WC to define AO<sup>23,32</sup>, we used the WC cut-off for Asians. Also, since WC requires only a single measurement, it is easier, less time consuming and less subject to error than combining measurements of waist and hip for the waist:hip ratio. However, intra- and inter-physician variability in measuring WC was not formally assessed.

The MySoN study highlights the magnitude of the problem of obesity in Malaysia. It shows that AO is more frequent in patients with CVD, lipid disorder, hypertension and diabetes, and also increases the risk of developing these co-morbid conditions. Serious note should be taken of these findings and national guidelines must be formulated for the identification and optimal management of AO and the associated CV risk factors in Malaysia.

While the MySoN study has increased awareness of AO among primary care physicians, the importance of this risk factor remains inadequately recognized. Routine measurement of WC – a convenient and inexpensive measure in primary care – provides a clinical marker for risk of CVD and other co-morbidities. The rise in adiposity in Malaysia is likely to contribute to major increases in CV morbidity and mortality, unless adequately addressed by public health programs.

#### CONFLICT OF INTEREST

None.

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