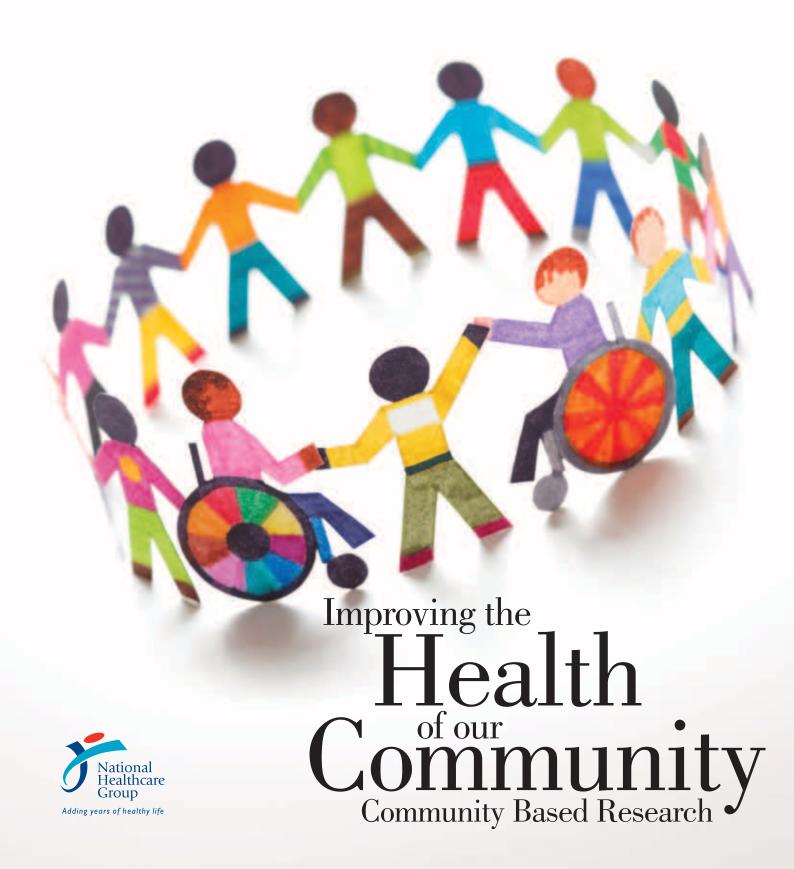


MICA (P) 166/01/2010 • A NEWSLETTER FOR THE RESEARCH COMMUNITY IN SINGAPORE



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Adding years of healthy life

Editorial team

Adeline Lu, Clara Lim, Doreen Lim, Farah Mohamed Haniff, Grace Kiew, Henry Tan, Loi Mee Mum, Ng Hwee Hian, Norsalleha Bte Salim, Siti Zawiyah, Selina Xiao, Valerie Wee, Wenald Loh, Yeo Kian Wah

From The Editor-in-Chief

Dear Colleagues and Readers,

Time flies, and this is the sixth issue of Catalyst, which we aim to bring to you latest news, development and updates of the research climates and activities in Singapore and around the region.

We heard good news - more funding and resources will be invested into Singapore's Biomedical Sciences Industry over the next 5 years. Certainly, this will inject the adrenalin that will propel and drive biomedical research to the next level, and bring about greater benefits to the people in Singapore, from both economical and patient care aspect.

To do that, we need to nurture more Clinician-Scientists (CS) and Clinician Investigators (CI). We need passionate people to help translate new discoveries into useful clinical applications that will improve patient care. We need to think out of the box and seek innovative ways to enable, facilitate and support our clinicians to venture into the CS and CI tracks.

To greater benefit larger pool of patients, it is also imperative to look at population-based, community-based research concurrently. Bench to Bedside research is not a mean to an end. We need to extend research from Bench to Bedside, and to Population, and back to Bench again. We need to understand population needs and

issues, and "translate" these problems into bench and bedside studies, and then applying it back to the population as useful solutions. Collaboration loops between basic scientists, CS, CI, and clinicians can happen in both directions.

In this issue, we aim to profile Community-Based Research, the downstream, research activities that yield results with great impact to the large populations. In our past issues we featured both Translational & Clinical Research (TCR) and Health Services Research. We hope that with this issue's feature, you will have a better appreciation of the entire research spectrum and envisage how collaborations can occur at any stage and levels.

NHG and NUHS will also jointly organise the 1st Singapore Health & Biomedical Congress (SHBC) on 12th and 13th November 2010. SHBC evolved from the former NHG Annual Scientific Congress (ASC), and aims to set a greater platform at the national level, for sharing of knowledge and best practices, and facilitate greater collaborations between all researchers.

I hope you will enjoy reading the Catalyst and look forward to having your feedback.

Yours Sincerely,

Kin Poo

Your Newsletter, Your Comments

Do you have any of these:

- Research articles to share?
- Research topics that you want covered?
- Comments/Feedbacks on published contents of this newsletter?
- Comic strips/cartoon illustrations that is science/research-related that can bring smiles to your colleagues?

If you have answered "YES" to any of the above, we invite you to write in and share with us your thoughts, feedback on published articles or cartoon clips (original materials, jpeg format please).

And if your contribution is accepted for print, we will send you a token of

Modes of contribution:

By Mail

Editorial Team – Catalyst Newsletter Research & Development Office National Healthcare Group Pte Ltd 6 Commonwealth Lane #04-01/02 GMTI Building Singapore 149547

By Email

researchtraining@nhg.com.sg

appreciation, with compliments from the Editorial team!

Do remember to add in your contact details, where applicable, for our future communications with you.

The Editorial Team

Community Health Research

in Singapore

Karen Cheong

Manager Research and Evaluation Department Research and Strategic Planning Division Health Promotion Board

he Ottawa Charter for health promotion is an important milestone in health promotion as it shapes the ideology of health promotion via community development (World Health Organisation, 1986). It highlighted the importance of empowering people to take control over their health and improve their health, and also underlined the importance of taking a social ecological approach in addressing issues which encompass the dynamic relationship between the individual, interpersonal, community, organisational and governmental level. Health promoters need to focus on modifying community structures,

processes and policies in order to optimise

community health. What is the role for community health research in such a structure? Community health research seeks to understand the health needs of the community members and helps to empower the community by assisting its members to identify health-related issues and to realise their assets or potentials which they can leverage on to improve health outcomes.

The Research and Evaluation Department at Health Promotion Board of Singapore actively engages in community health research and in the process, foster relationships and establish networks with stakeholders and community. For example, we conducted a seminal school health survey (Health Promotion Board, 2006) among students in 2006 to better understand their health behaviours and social determinants of health for programme and policy planning purposes. We worked closely with the Ministry of Education and schools to design and conduct the study. In-depth interviews and focus groups discussions were conducted with students during the development of the survey questionnaire. The study findings provided important

Glealth promotion is the process of enabling people to increase control over, and to improve their health.

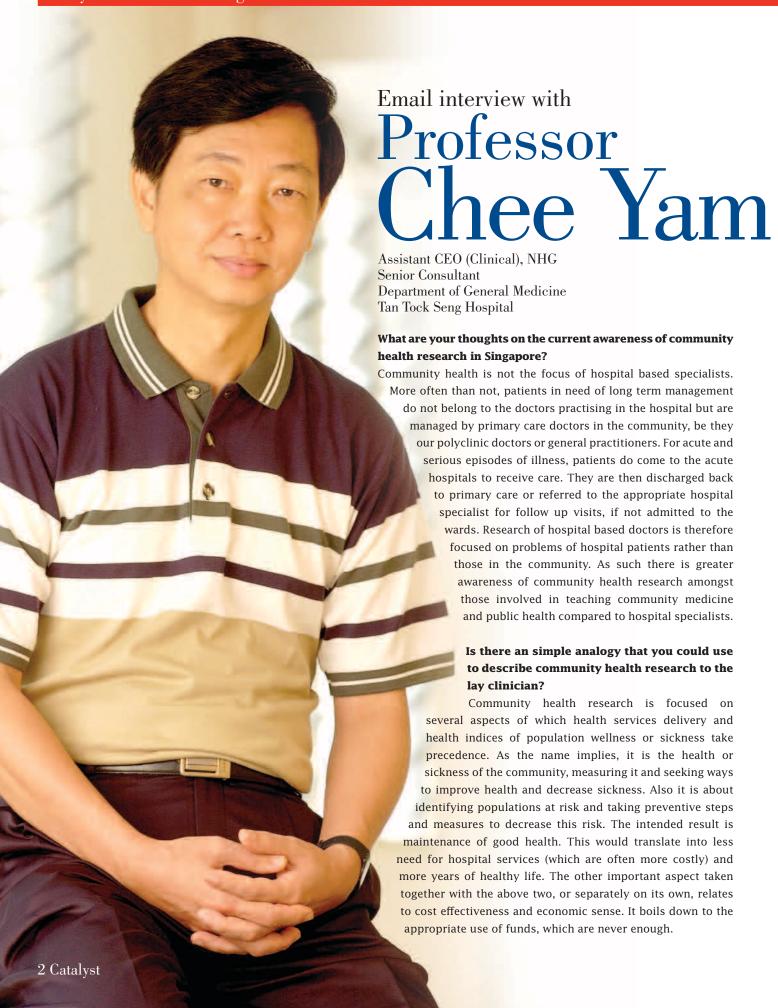
(World Health Organisation, 1986)

baseline information on health behaviours including the prevalence of smoking, binge drinking, sexual behaviours, risks of mental health disorders, physical activity and dietary practices of school-goers. Research findings were then shared with our stakeholders and relevant external agencies involved in youth-related work to better formulate health promotion programmes for collaboration with stakeholders. A blueprint on health promotion among adolescents was developed based on our research findings.

In essence, the strategic value in community health research goes beyond understanding of community health needs. It integrates participatory networks with partners to ensure supportive environments for sustainable health.

World Health Organisation. 1986. "The Ottawa Charter for Health Promotion" Health Promotion International 1(4): iii-v.

Health Promotion Board. 2006. Students' Health Survey 2006: Highlights of Findings among Secondary School Students. Singapore. http://www.hpb.gov.sg/uploadedFiles/HPB_Online/Publications/student-health-survey-2006c.pdf



Cheng

What do you think are the key achievements of NHG in the area of community health research?

The birth of the Health Services & Outcomes Research (HSOR) department at NHG (cluster level) has been a great achievement. It was started before MOH decided on reclustering NHG from one cluster to the present 4 (NHG, NUHS, Alexandra Health System and Jurong Health System). The purpose of this reclustering is to facilitate and expedite more vertical integration of care for patients living in the region served by the new cluster. So instead of being hospital centric, the new challenge is to facilitate patients moving from one level of care to the next when appropriate within the cluster's regional influence, with patient records easily accesible to all care givers within this continuum of care in both directions. So the research is about how to provide better care with less waste at each appropriate level of care. It would translate to better care at lower costs once such appropriate care is moved out of acute hospitals.

What was it about community health research that kept you interested?

My interest stems from witnessing the common every day scenario of crowded outpatient clinics, emergency departments and wards. For a time, adding more doctors to the hospital system seemed to be the obvious answer (more hands make

light work). But that too has its limits because the hospital is built to house a fixed number of beds, clinics, operation theatres, etc. So the next obvious question to ask is "why are there so many patients coming to the hospital?" In part, the answer is that the facilities outside the hospital may not have the capacity nor capability to render the appropriate care to them. So health services research can frame the questions for these problems and find some solutions that make sense to the whole system, rather than from the viewpoint of hospitals alone. Solutions should apply to the nation, not just one cluster system, or one public hospital.

What do you like most about your job?

My job is challenging in different ways. No two days are the same although I try to keep each week's events roughly similar. This in part is based on the fact that my outpatient clinics is fixed for Mondays, Wednesdays and Fridays and the time slots per clinic session are also fixed. I still enjoy seeing patients with multiple and complicated medical problems affecting several body systems and parts, trying to connect if possible all these to one or two medical diagnoses, and trying to prevent or retard complications. The other delight is making a diagnosis to explain the patient's condition when others had not been able to connect the dots of evidence to make a coherent whole. Time is on my side in such cases; no fault of the doctors who saw them earlier as some signs or symptoms may not have manifested then. The rest of the time is spent teaching medical students and doing administration. Again I am privileged to do the latter at different levels from the MOH, to the cluster and down to the hospital. And lately there are the challenges of the new residency programs and the new medical school.

How do you find time for your family?

Weekends are sacrosanct in that where possible it is private time for family and self, rather than for official work engagements. An occasional Saturday at hospital annual dinners is welcome, as are medical education talks, conferences and workshops. So out of 52 Saturdays available yearly maybe one Saturday a month I will agree to these activities.

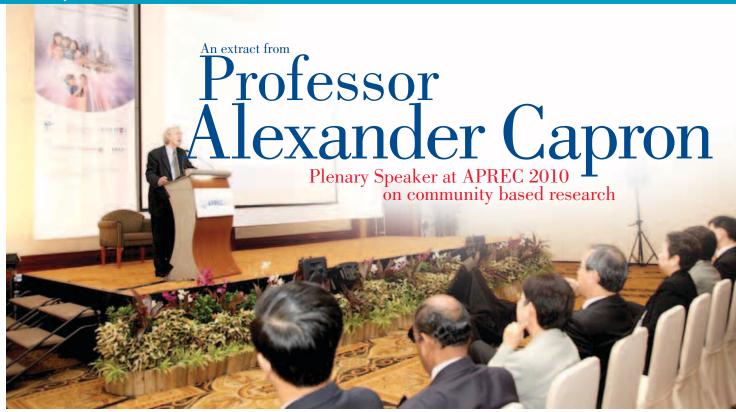
What do you like to do in your spare time? Do you have any hobbies?

There will be time for hobbies, sports and holidays but these need to be well planned well in advance. For hobbies, one week, sports two weeks, and holidays 6 months in advance. Hobby time is Saturday mornings, tending to fish, birds and garden. Sports is usually golf after 5 pm on weekdays. Sun exposure is good for vitamin D. Should it rain too often, then swimming would take the place of golf. Then there are overseas trips that are part of work and this can be made enjoyable and relaxing rather than taxing.

Does your personality and love for your hobbies help in making decisions in your daily work?

Basically, it is about apportioning time for specific activities to ensure work and life balance. When at work, work with little distractions. I do not carry my Blackberry and handphones to meetings, I am fully focused on the agenda at hand. So when off work, it is to do other things having planned and done the work for that day or week or month. I dislike rushing things, doing things at the last minute. So proper planning is vital for a relaxed life of work and play. Work schedules should be realistic to enable good work to be done; right work done right the first time with the minimum of energy, stress and fuss. Any worries should be for coming events rather than events gone past.

Community Health Research Feature



Professor Alexandra Capron

University Professor, Scott H. Bice Chair in Healthcare Law, Policy and Ethics, University of Southern California Co-Director of the Pacific Center for Health Policy and Ethics
Past President of the International Association of Bioethics Secretary
Board of Directors, PRIM&R, United States

What are your thoughts on the current status of Research Ethics in Asia?

The amount of research and the quality of ethical reviews has risen greatly. A decade ago, research institutions in Asian countries typically did not have Research Ethics Committees (RECs). Most of the countries did not yet have regulations setting the standards for prospective ethical review of research and hence most research did not receive such review. It is true that in some countries - especially very large countries where a good deal of research occurs - some research still goes on without review but that happens much less frequently now. Many countries have put much effort into this, like Thailand, Singapore as well as in China and India. Particularly in some of the smaller countries, the percentage of research that gets reviewed and the quality of review are on par with other regions in the world. I think the people around here seem to be very eager to be very educated about the

global ethical norms. Although clinical trial sponsors may find it convenient to go to places where they would not find as much red tape as in the United States or Europe, they also do not want to conduct trials in places with very poor review because that's where things blow up in their faces. If a research project is not properly reviewed and a problem arises, people will look at the

What do you think are the potential issues we might face in community-based research?

In research that takes place mainly at Phase 3, let me begin with some issues that we see in the United States. The nature of the issues will probably vary from community to community. Three issues to highlight are the following:

 a) First is the ethical requirement that research should be responsive to the needs of the community. This standard can be implemented in a negative way by saying that research should not

6 I think the people around here seem to be very eager to be very educated about the global ethical norms, 9

sponsor and the researchers and say the standards are not as required here and the consent process wasn't good, nor was there a thorough evaluation of the benefit-risk ratio, and so forth. This is bad research, which is then bad for the research sponsor.

be done in a community for which it is not relevant, in the sense that it concerns a health condition that is not of importance to the community or that any treatment developed in the research will not become available in the near future for patients in the community. When you do such research, you are potentially harming people without offering a future benefit to them or others in their community. It is perfectly true that individuals participating in research are often in research that does not benefit them directly, yet even then they are potentially contributing to the well-being of people they care about. If I participate in research concerning a disease I have now, and that helps the researchers find a treatment that will help my friends, relatives and children in the future, then I am a true co-participant with the researchers and not just a human guinea pig. Yet, having identified the importance of the standard of "relevance to the population being studied," we still have to ask, "who is going to implement that standard?" Is the REC or IRB going to do it? How are they going to do it in a way

less assertive about their rights. They are potentially less demanding in their expectations of research and less likely to ask a lot of questions. In the United States, many of our great teaching hospitals are located in parts of cities where the population in the immediate surroundings consists primarily of poor people. It is not unusual for research to originate from these kinds of big public hospitals and hospitals that care for the poor. Naturally, they look to their immediate community when they are going to select subjects, yet these are often people who are vulnerable due to their poverty and social status. So, how do we avoid that? How do we take conscious steps to contribute to research equitably? If the diseases in question occur in many different communities, which individuals or groups (sponsors, researchers, RECs, or who?) should be held responsible to ensure that we not select only the organizations think about responding to the needs of the community by treating community equitably, the definition of a community becomes very important. Is it a geographical area or is it a subset of a population defined by other characteristics? When we talk about a "community," we are referring to people who have some form of common selfidentity. It may be a geographic identity but may also be based on other things such as their occupations. They can be a community even if they are dispersed geographically, depending on what characteristics are most relevant to them. Each person can thus be a part of numerous different "communities," depending on the factors with which he or she identifies. A population may reside in part of neighborhood (with the result that the neighborhood bears a name, like "Chinatown" as the place that Chinese immigrants first resided in a city), or the population in question



If research organizations think about responding to the needs of the community by treating community equitably, the definition of a community becomes very important.

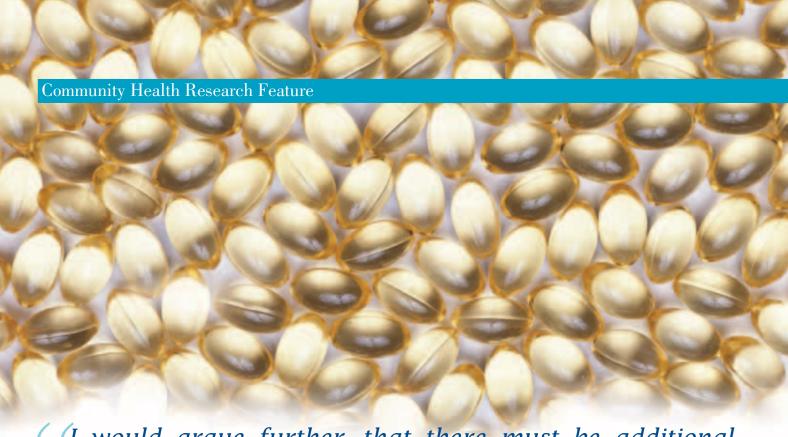
that does not accidentally interfere with research that is appropriate? And, on the affirmative side, how can they stimulate appropriate research? Decisions about what research to undertake really depend on the Ministry of Health and/or private sponsors, who need to identify, and respond to, the needs of the community.

b) The second issue is Justice. We often think about this ethical principle in terms of the selection of individuals as research subjects. But it is also relevant in the selection of a community for research because the choice of certain locales may make it easier to get participants who are less powerful and

vulnerable community as the study population, just as the REC expects researchers not to enroll subjects who have inadequate ability to make both an informed and a free consent?

The final issue that arises in United States' communities is that we are both economically and ethnically a very diverse country. In major cities and some rural parts of the country, there are a large number of immigrants coming from nearby countries such as Mexico as well as from more distant parts of the world. For example, in my home county of Los Angeles, I think there are about 90 languages spoken by large numbers of people. So, if research

may be evenly distributed among different neighbourhoods. In either case, it may be united by ethnicity or other characteristics and may or may not speak with one voice. For research involving an ethic community, the diseases itself may have a connection to the population's place of geographic origin, where it was more prevalent than among people coming from other places. Advantageously, the community may have a way of expressing its collective view, where researchers-and perhaps RECs-are able to talk to the leaders of the community and gain their input on the design and conduct of research. We can identify legitimate



64 would argue further, that there must be additional ethical review and that in many cases it is necessary – and not inconsistent with good science – to obtain consent from the research subjects individually.

representatives of the community whom we can approach to invite the community to participate and who can respond sensitively to the particular concerns of the community.

So these factors that arise in community-based research in the United States may or may not occur in every situation in Asia. It is dependent upon the characteristics of the community, that is, whether it is an ethnically homogenous community, whether people move in and out often, and whether they are very alike in the work and activities of life that they undertake.

As we do more community research, what are the anticipated / additional risks we have to undertake? In the States, how do they manage the risks and increase the protection for community subjects?

They are several types of research. However, the first risk of community based research is when conducting research that is not particularly relevant to the community. This is where the community is being used or research being created even though it is not beneficial to them.

A second type of risk is the people who supposedly represent the community are not representative of the community or do not have the interest of the whole community at heart, having instead their own personal interest. Some suggestions have been made that it is alright to do research that does not produce any medical payoff to the community if we have other similar benefits to the community (for example, if the research sponsor built a road or gave equipment to the medical school). I have a concern with this situation as the benefits offered by sponsors may flow mostly to medical professionals or other powerful groups of people rather than to the population from which participants are recruited for the research.

The third issue arises in community research that mainly involves public health where the researchers are attempting to determine the effects of different interventions on the community as a wholefor example, a community-based vaccine trial, where part of the effect in stopping the transmission of a communicable disease comes from the percentage of people who are immunized in a community. It may be

necessary to design such a trial using what is called cluster-randomization, that is, where geographic groups or communities are the unit of measurement and they are randomized rather than individuals. But then what is the relationship between being a resident of the community and participating in the trial? What role would individual informed consent play? If I want to do a clinical trial, I could not just go to the neighbourhood leader or tribal chief and get his permission to do the trial. I would need individual consent, based on an explanation of the trial, including the way individuals are randomized. But what about with the community-based trial? Here one might have 50 people, all lined up for the injection for example, and some researchers would say that they do not need to ask the individuals, but may have to go with the consent of the community representative, because this is public health research and the effects on the community is what is really being studied, and the research is dependent on there being a high level of vaccination. At the very least, in such designs, the ethical acceptability of the research is dependent

upon there being a legitimate way of getting community consent. I would argue further, that there must be additional ethical review and that in many cases it is necessary—and not inconsistent with, good science—to obtain consent from the research subjects individually.

Are there challenges faced in recruiting subjects?

There are several challenges faced in the United States. First, people need to make an informed and voluntary choice. So, they have both to be capable of understanding information about the research and to be so situated that they are free either to agree or decline to participate in research. This is a problem when recruitment occurs in a community where subjects do not have access to good health care. The only opportunity for them to get health care is by participating in a research trial. That is very unfortunate because it means that the voluntariness of their consent is in doubt.

Another problem which is not unusual is that people are recruited in trials by their own treating doctors. People join research because they think it is therapeutic and represents the best treatment they could have. In actual fact, it is still a trial.

So these are problems that are probably happening everywhere. This will be a good example of people at risk of misunderstanding whether it is research. In many communities, it is understood that at the teaching hospitals, you will get care from doctors in training as well as fully qualified doctors and you will be invited to participate in research studies. As we increasingly try to bring research out into the community, we find that research is only done in clinical trials in highly controlled settings by a researcher or a university hospital. It may or may not work when it is introduced to the community at large. We need to distinguish between efficacy in care and measuring the clinical effectiveness of a new treatment in practice.

In summary, community-based research is increasingly important and has great value for the community but

It is certainly true that a similar set of overall objectives in terms of treating people with respect and fairness can be supported by an articulation of somewhat different principles; this is apparent in the concept of community welfare, which is often mentioned in Asian bioethics.

involves the issue of informed consent and voluntariness.

Should we be keeping up with the old standards and guidelines or adapt to those in the United States? What are your recommendations?

I am of two minds about that. On the one hand, it is probably actually beneficial to people in Asia to follow international standards. It is beneficial both for the scientists, since it makes it possible for

them to collaborate with researchers from other parts of the world and to have their study results published in international journals, and it is genuinely beneficial for the population

involved in the study. On the other hand, I also recognize that the language of the standards and the way they are framed is reflective of Western European and North American ideas about ethics. It is certainly true that a similar set of overall objectives in terms of treating people with respect and fairness can be supported by an articulation of somewhat different principles; this is apparent in the concept of community welfare, which is often mentioned in Asian bioethics. Still, I think the differences between the East and the West are often exaggerated. After all, in the West, research is undertaken in order to produce new knowledge of value to the community. (This is sometimes expressed more abstractly as "the advancement of science," but more concretely we are talking about human studies which is an applied science, so the purpose is really to benefit the community.) Thus, we in the West actually place a great deal of emphasis on "the community" and not only on "the individual." Likewise, in Asia I think it is understood that when something of value to the community is gained through the involvement of individuals who take on a more than average level of risk (e.g. as research subjects) and something good

comes out of it, they should be respected and protected from avoidable harm. So we have to ask whether there are certain ways of protecting them and their interests

that are consistent with their being part of "the community"? One of the ways we use is having a Research Ethics Committee. One can see that as a means to protect the autonomy of the individual (perhaps that is the simplest way of expressing the US view) or one can see it as an expression of the community's obligations to its members (perhaps that is one way of expressing the Asian view). Thus, research ethics involves East Asian values as well, though perhaps we need to use a slightly different language or give a different emphasis or explanation so that people will recognize their own cultures in the procedures and expectations established

to govern research with human beings.





IMPROVING HEALTH IN OUR COMMUNITY

A Holistic and Integrated Approach

Formerly NHG Annual Scientific Congress (ASC)

12 & 13 November 2010

Suntec Singapore International Convention and Exhibition Centre

Event Highlight

Integration of Care Track

Community partners: Building sustainable and effective bridges 13 November 2010 (1400 – 1730hrs)

A/Prof Chin Jing JihSenior Consultant, Integrative &
Community Care,
Tan Tock Seng Hospital

ffective and sustainable care integration involves building strong bridges of partnerships among care providers based on alignment of vision, mission, anchored on a spirit



of collaboration and mutual respect. Such bridges help to nurture trust, build wider communitarian perspectives, and amalgamate medical and social aspects of elder health, thereby enabling a more consistent and cohesive approach towards achieving desirable health outcomes for the elderly in a better, cheaper and faster system.

At the Integration of Care track, speakers from Tan Tock Seng Hospital's Division of Integrated & Continuing Care and its community care partners including Home Nursing Foundation and Renci Hospital & Medicare Centre will attempt to share some of their approaches, early experiences and challenges in their endeavours thus far to build effective and sustainable bridges of care in the Central region of Singapore.

For more information on the $1^{\rm st}$ Singapore Health & Biomedical Congress (SHBC) 2010, please visit our website at www.shbc.com.sg.

Exponential progress in medicine and medical knowledge has been realized in the last decade. As such the delivery of care to patients has become much more complex and a multi-disciplinary and integrated approach is not just necessary but mandatory for patient management. In line with this important change in the clinical landscape, this year's theme for the 1st Singapore Health and Biomedical Congress is focused on the integration of care from hospital to the community. The major tracks are identified according to major organ system and within each tracks, the program will highlight the different aspects and healthcare professions involved in the management of a medical condition, highlighting the multi-faceted and multidisciplinary integration of care

> A/Prof Chng Wee Joo Chairman, Scientific Committee 1st Singapore Healthcare & Biomedical Congress

NHG-NUS Clinician Leadership in Research (CLR) Programme

Community Health Research in the Emergency Department

Dr Eric Wong

Associate Consultant, Emergency Department Tan Tock Seng Hospital

ingapore is an aging society. In the Emergency Department (ED) of Tan Tock Seng Hospital, 25% of our total daily admission consists of elderly patients. This poses a unique challenge. The fast-paced ED is not designed to manage large numbers of elderly patients who are usually admitted with atypical symptoms and have multiple comorbidities. Our previous study showed that 70% of elderly patients admitted to the ED Observation Unit (EDOU) have at least one hidden geriatric syndrome not detected during the initial assessment. Failure to identify and address these unmet needs put the patient at risk of future adverse event.

We initiated the Geriatric Emergency Medicine in 2006 to cater to this problem. By working closely with geriatricians, community hospitals, and allied health workers, we provided geriatric assessment to patients admitted to our EDOU. As a result, there was a reduction of adverse events, such as ED reattendance, future hospitalization and functional decline. However, this comprehensive geriatric assessment is costly and more time consuming. It would be impossible to conduct such screening for all elderly patients present at the ED.

My study was therefore designed to answer a simple question: "Which elderly ED patients are at-risk, and therefore may benefit from geriatric assessment prior to discharge?" Two widely used risk stratification tools, ISAR (Identification of Seniors At Risk) and TRST (Triage Risk Screening Tools) were validated in our local setting, and their strength in identifying high-risk geriatric patients were compared. This was done by instituting a 13-question questionnaire for all patients above the age of 65 years old who were discharged from the ED. These patients received follow-ups on the 1st and 3rd month post-discharge and the incidence of hospitalisation, re-attendance to ED, falls and functional decline were compared.

We recruited more than 550 patients over 3 months. It was found that a patient was at higher risk of an adverse event if he stayed alone, had more than 5 regular medications, had difficulty in walking, had cognitive impairment or had visited an emergency department at least once in the past month. While ISAR was better at predicting falls, TRST offered better predictive value at foreasting ED re-attendance, future hospitisation, and functional decline. These results are comparable with previous studies conducted in Western countries, which allow us to extrapolate these findings to our local population.

With these results in hand, we now screen all elderly ED patients using TRST. Patients with a positive TRST score are deemed at-risk and offered further geriatric assessment to identify hidden needs. As the old saying goes, "prevention is better than cure", and prevention starts the moment our patient come through our doors.



14th SHS – NHG Combined Clinical Research **Coordinators Society** (CRCS) Forum

he 14th SHS - NHG Combined Clinical Research Coordinators Society (CRCS) Forum with "Informed Consent" as the topic, was held on 1st Oct 2010, at the Singapore General Hospital Post Graduate Medical Institute, with Associate Professor (A/Prof) Tan Ru San as the speaker. A/Prof Tan is a Senior Consultant from the Department of Cardiology and Director of Clinical Trials at the National Heart Centre Singapore. His sub-specialty interest being non-invasive diagnostic cardiac imaging, he has clinical experience in cardiovascular magnetic resonance imaging, echocardiography and nuclear cardiology.

A/Prof Tan shared the definition of Informed Consent from the Singapore Good Clinical Practice (GCP), general elements of an Informed Consent and the role and responsibilities of the Clinical Research Coordinators (CRCs) in obtaining consent.

Though A/Prof Tan mentioned that "While the Principal Investigator is primarily responsible for the overall design, conduct and management of the clinical trial, the CRC supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study".

To further drive home the message on Informed Consent,

A/Prof Tan also shared his experience when his unit was audited by the Health Sciences Authority (HSA) for GCP, and that it is important for a de-briefing session to be The next CRCS Forum will be held jointly with the Clinical Research Professionals (CRP) on 10 Dec 2010

Health Products (Clinical Trials) Regulations & GCP Inspections

Speakers

Dr Lisa Tan

Regulatory Consultant, Clinical Trials Branch, HPRG HSA Ms Sumitra Sachidanandan

Compliance Inspector, Clinical Trials Branch, HPRG, HSA

National University Health System (NUHS)

For more information, please visit our website at www.research.nhg.com.sg/Search-for-Course.htm.

120 participants taking time off their busy schedules to attend it. The topic was tailored to provide the audience with a broad understanding on the proper procedure for obtaining consent from subjects.

The majority of the participants were from the various





n 28th July 2010, we had the pleasure of having Ms Shannon Neo, Senior Manager from Singapore Workforce Development Agency (WDA) and Mr Tan Chee Boon, Senior Lecturer (Life Sciences) from the School of Chemical and Life Sciences of Nanyang Polytechnic (NYP) share with our audience of Research Administrators on the Workforce Skills Qualifications (WSQ) Certified Assistant Clinical Research Coordinator (CRC) Programme – a joint initiative by NYP and WDA. This followed the recent launch of Consortium cum WSQ Programme for the Clinical Research Industry in June 2010.

Ms Neo and Mr Tan addressed the course outline, motivation and benefits of the programme in this hour-long lunch talk at Conference Room 2 of Tan Tock Seng Hospital.

The WSQ Certified Assistant Clinical Research Coordinator Programme is driven by the purpose of establishing a competent pool of CRCs to address the skilled manpower shortage in the industry, and is catered to both existing CRCs and new entrants.

Comprising of 350 training hours, the course is structured in 10 core and elective modules that are endorsed by the





WDA Clinical Research Technical Committee which consists of representatives from key industry players. This 40-week part-time certified course commences in October 2010.

Parties interested in this programme, please contact Ms Geraldine Yong (geraldine_yong@nyp. gov.sg) or Mr Tan Chee Boon (tan_chee_boon@nyp. gov.sg) for more information.



1st Asia-Pacific Research Ethics Conference (APREC) 2010

Pre-Conference IRB Workshop



he Asia-Pacific Research Ethics Conference (APREC) 2010 is proud to host the PRIM&R Institutional Review Board (IRB) Workshops 101 and 201, held on 16th September 2010 at Orchard Hotel Singapore. The workshops attracted numerous participants from various countries.

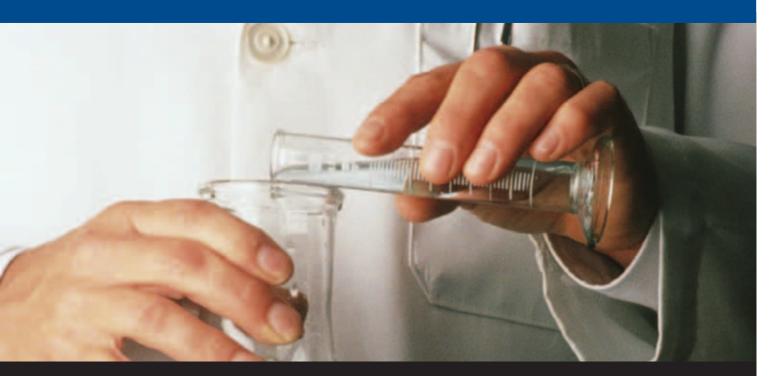
The IRB 101 provides participants with fundamental knowledge of the development of the IRB/ or ethics review systems, the underlying principles and regulations governing human subject research and IRB operations, and the challenges faced in human research subject protection.

The IRB 201 is the advanced level of training for IRB members and staff with foundational understanding of IRB operations. Participants in this course examine in-depth processes for research review and explored the ethical considerations for minimising risks to research subjects, ensuring reasonable

risk and benefit ratio, and maintaining equitable selection of subjects.

The workshops were conducted by faculty members from the Public Responsibility in Medicine & Research (PRIM&R) Dr Jeffrey Cooper, Ms Elizabeth Bankert, Mr David Borasky and Ms Helen McGough. The instructors have many years of experience in research ethics and IRB operations and effectively translate theoretical knowledge to practical knowledge to participants at the workshops.

Overall, participants had the opportunity to share and discuss the challenges they face at their institutions when reviewing research studies, with the speakers. Such lively interactions generated positive feedback, and even before the conference had concluded, there were already queues on the next run of these workshops!



PCR Teasers – Try these!

NHG's Proper Conduct of Research (PCR) Workshops are designed to provide Investigators and Clinical Research Coordinators with foundational knowledge of good research practices and familiarize them with the regulatory requirements. The Workshops are run twice a year by the Research Training & Development Unit (RTDU), at 3 different levels - Basic, Intermediate and Advanced.

Below are a few quiz questions taken from the PCR Basic Courses. Try them!

Question 1 The last patient last visit is over and the collection of individually identifiable data has been done. The data has been analysed and manuscript sent to various journals. The study is said to be:

(a) Ongoing (c) Terminated (b) Completed (d) Suspended

Question 2 Dr Magneto is the Prinicpal Investigator (PI) of a trial testing the safety and efficacy of high doses of zinc for strengthening immune system. He has been sent on Health Manpower Development Programme (HMDP) training in USA for 1 year. What should be done?

- (a) Dr Magneto remains as the PI
- (b) Dr Magneto asks Dr Iron, Co-I to cover.
- (c) Dr Magneto nominates Dr Iron, Co-I as PI for Domain Specific Review Board (DSRB) and Health Sciences Authority (HSA) approval.
- (d) Goldie, the Study Coordinator can take over the study since she does almost everything anyway.

Question 3 Mr Lung is a study subject in a trial, and was admitted to TTSH A&E with high fever, chills, breathlessness, and was warded in Intensive Care Unit (ICU), diagnosis unknown. He was subsequently diagnosed with pneumonia and died two weeks later. The PI has assessed the death as unrelated. What are the reporting timelines for the death?

(a) Within 7 working days(b) Within 7 calendar days(c) Within 24 hrs(d) None of the above

Question 4 Dr Smiley wants to conduct research involving a retrospective chart review of 60 of his patients who were treated in 2004 for clinical depression with an FDA approved drug. Clinical information will be recorded on research data forms and identifiers will be maintained until the data are analysed. The study may be reviewed by:

(a) Exempt(b) Expedited(c) Full Board Review(d) Does not require review

Did you get them right?



aunched on 1st September 2010, the NHG's Proper Conduct of Research Online aims to provide new and existing Clinical Research professionals (such as Clinical Research Coordinators, Research Administrators and nurses) with timely access to essential tools and knowledge via an online learning platform.

The Proper Conduct of Research courses are structured in a modular system comprising of three Basic modules, i.e. PC101-PC103, tailored to equip participants with the knowledge and skills on basic training in proper conduct of research.

Each course consists of lectures and workshops conducted by regulatory agency personnel, pharmacists and experienced Clinical Research professionals who are pioneers in the local scene. There is also a short quiz at the end of each course to help reinforce comprehensive understanding.

Benefits of Attending PCR Online

- All-Year-Round Training with 24/7 Access Anytime, Anywhere
- Customised Learning to Meet Individual Needs
- Shorter Training Time
- On-demand Availability of Refresher or Quick Reference Materials

REGISTER NOW at www.research.nhg.com.sg.

For more information, you may contact NHG Research Training & Development Unit at researchtraining@nhg.com.sg.

NHG RDO Training Calendar for November - December 2010						
Date	Time	Training Programme	Course Category	Course Module	Venue	No of Seat
Ongoing	0000-2359	Proper Conduct of Research Online – Basic I-III	Proper Conduct of Research	PC101-103	http://www.elearning.nhg.edu.sg	120
02 & 03 Nov	0900-1700	STRATA Workshop	Research Methodology	RME	E–Learning Lab (Newton & Galileo), Level 3 Tan Tock Seng Hospital	30
26 Nov	0900-1630	NHG Proper Conduct of Research Workshop for SC – Advanced II	Proper Conduct of Research	PC302	Advanced Surgery Training Centre, STLab, Level 2 Kent Ridge Wing, National University Hospital	30
10 Dec	1500-1800	Combined Clinical Research Professionals – Clinical Research Coordinators Society Forum	Clinical Research		National University Heakth System Auditorium, Level 1, Kent Ridge Road, NUHS Tower Block	300