

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

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Newsletter

AFIRE STUDY has been going for about 8 months, and 353 subjects have been recruited in the study (206 adults and 147 pediatrics). We are 22.1% from the expected 1600 subjects. Below are the details of the enrollment:



*510 – RSUP dr Hasan Sadikin, Bandung 550 – RSUP dr Wahidin, Makassar 570 – RSUD dr Soetomo, Surabaya 520 – RSUP Sanglah, Denpasar 560 – RSUP dr Kariadi, Semarang 580 – RSUP dr Sardiito, Yogyakarta

Reasons for exclusion

A total number of 1,062 patients have been screened since the study began. The reason "Other"* is the highest amongst the remaining reasons for exclusion with 55.6% of it due to the unwillingness of potential subjects to sign ICF, and the remaining 44.4% is for patients who had received medical intervention prior to current hospitalization. History of hospitalization in the past 3 months follows on the second place. In the chart below, we can see the summary of screen failure reasons tabulated from 6 active sites between October 2013 and February 2014.



Inclusion criteria

- Age >= 1 year
 Acute febrile illness requiring hospitalization (fever defined as temperature recorded >= 38.3C during the first 24 h period of hospitalization
- 3. Hospitalized within the past 24 hour
- 4. Willing to allow storage of blood and other specimen for use in future studies of infectious disease

Exclusion criteria

- A. Hospitalized within the first 3 months, not including current hospitalization for acute febrile illness
- B. Inpatient transfer from another hospital
- C. A known medical disorder or other circumstances, which in the opinion of the PI might make the participation of the individual unsafe or difficult -UN-

TB STUDY

TB Lab Meeting, which was attended by laboratory representatives from all INA-RESPOND sites, was held on February 27-28 in Jakarta. This meeting was led by dr. Dewi Lokida from RSUD Tangerang to clear up the remaining questions about the study specimen and its repository. Crucial decisions about type of tests, culture media, and amount of specimen were made. Other important information regarding sites' lab facilities, lab certification, and training needs were also identified.

Sputum specimen is vital in this INA102 study. Technical procedures for sputum retrieval and the amount of sputum taken for this study have been determined. A minimum of 2cc sputum will be taken from subject for each step, enrollment and follow-up visits. The specimen will be used for microscopic testing, molecular testing and culture. Löwenstein-Jensen is the preferred media for culture due to its sensitivity. Special training about standard specimen collection procedures, specimen processing and shipping will be conducted for the appointed lab technicians. With the laboratory parts of the protocol settled, we are one step closer into the protocol finalization.

Meanwhile, the Protocol Specialists, dr. Santo and dr. Retna are visiting all 8 participating sites to gather information on TB patients management. We are hoping to put all the puzzle pieces in place by the end of April 2014 and have a final protocol - finally. Once we have it, we can move on with the submissions, procurements, trainings, and other remaining preparation steps. It is expected that we can hold an Investigator Meeting in August and have the first subject recruited before this year ends. Such an excitement to look forward to in the next few months! -AP-

-SK-

SEPSIS STUDY It is yet to be decided whether we are going forward with SEAICRN Sepsis Study or not. A meeting is planned in Jakarta on April 14 to get a final decision about Indonesia's participation in this study. The decision will be conveyed to the rest SEAICRN network

members during the meeting in Bangkok this April.

HIV STUDY

HIV STUDY dr. Siti Nadia's (Head of HIV Management Sub-Directorate) visit to NIH office earlier in March proved to strengthen the commitment between US NIH and Indonesia NIHRD in conducting HIV Study in Indonesia. An HIV research consortium will be formed to get the HIV study protocol concept firmed up before October 2014. -SK-

Scientific Corner

HAI... Hospital-Acquired Infections

-Dr. Dewi Lokida, SpPK, dr. Herman Kosasih, Sonia K-

A nosocomial infection (Greek nosos "disease", komien "to care for". Roman military hospital orderlies were called nosocomi) or also called "hospital-acquired infection" (HAI) can be defined as an infection acquired in hospital by a patient who was admitted for a reason other than that infection. The infection was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge, and also occupational infections among staff of the facility. Infections occurring more than 48 hours after admission are usually considered nosocomial. HAI may be indicated by the occurrence of fever or clinical syndromes at specific infections sites (e.g. urinary, pulmonary, surgical wound) as shown in Table I.

The history of hospital infection can be traced back to 2,500 years ago when early hospitals in India, Egypt, Palestine, and Greece set some hygienic standards. The hygienic conditions which prevailed were mainly base on religious concepts of ritual purity and seemed to have been greatly superior to those that were tolerated less than 100 years ago in the hospitals of Christian Europe.

During the Late Middle Ages era, physicians who attempted basic aseptic procedures were persecuted or neglected by their colleagues. After the discoveries by Pasteur, Koch, and Lister that began the 'Bacteriological Era', HAI was better understood, and aseptic procedures were applied resulting in the significant decrease of HAIs cases.

From the early 20th century to the discoveries of antibiotics (1940s) and up until today, a number of microbes such as *Streptococcus pyogenes* (1927), *Staphylococcus aureus* (1950s), methicillin-resistant *Staphylococcus aureus* (MRSA) (1960s), vancomycin-resistant *Enterococcus, Klebsiella oxytoca, Psesudomonas aeruginosa, Serratia marescens* and resistant *Candida albicans* have been known to cause HAI. Several factors that may facilitate the transmission of the microbes include invasive medical procedures, over-crowded wards, poor infection control practices, and decreased immunity patients, particularly elderly, patients with underlying diseases, and patients under chemotherapy.

HAI affects both developed and resource-poor countries. The prevalence survey conducted under the auspices of WHO in 55 hospitals of 14 countries representing 4 WHO regions showed that an average of 8.7% of hospital patients had nosocomial infections. At any time, over 1.4 million people worldwide suffer from infectious complications acquired in hospital. The highest frequencies of HAI were reported from hospitals in the Eastern Mediterranean and South-East Asia Regions (11.8 and 10.0% respectively), with a prevalence of 7.7 and 9.0% respectively in the European and Western Pacific Regions. In Indonesia, the only available data is from RS Penyakit Infeksi Sulianti Saroso, 2003: Surgical site infection 18,9%, Urinary tract Infection 15.1%, catheter site infection 26.4% and pneumonia 24.5%.

The HAI rate in patients in a facility is an indicator of quality and safety of care. To minimize the risk of HAI, currently HAI prevention committee is established in every hospital. This committee consists of physicians, nurses and other hospital authorities. Their missions are to plan, conduct and evaluate hospital program in preventing HAI. This committee is assisted by IPCN (Infection, Prevention and Control Nurse) to monitor the number of HAI cases by surveillance. The development of a surveillance process to monitor HAI rate is an essential first step to identify local problems and priorities, and evaluate the effectiveness of infection control activities. Surveillance, by itself, is an effective process to decrease the frequency of hospital-acquired infections.

The simplest and easiest practice of HAI prevention is through hand-washing which should follow the WHO recommendation (see pictures). This simple program may be applied by the AFIRE team to assist the HAI preventian program at your site. In relation to AFIRE study, HAI is a special concern because it shows similar symptom, which is fever. It is of utmost important to distinguish whether the fever is acquired from community or hospital. We do not want to mix this study with HAI surveillance for sure.

Source: WHO Prevention of hospital-acquired infections – A practical guide, 2nd edition Selwyn, Sydney. Hospital infection: the first 2500 years. *Journal of Hospital Infection* 1991; 18 (Supplement A), 5-64. http://www.optimusise.com/history-hospital-infection.php



Figure 2. An artist's impression of the interior of the ancient Greek hospital ward (Abaton) shown in Figure 1. Note open colonnade along the left side (i.e. excellent ventilation), bare store also to serve as the patients' beds (i.e. minimum of 'fomities' to transmit infection) and the traditional role of anakes in Greek therapy as a very cost-effective placebo. "Temple sleep' (incubation) was a central feature of hospital treatment (Caton, 1899).

Type of nosocomial Simplified criteria infection		
Surgical site infection	Any purulent discharge, abscess, or spreading cellulitis at the surgical site during the month after the operation	
Urinary infection	Positive urine culture (1 or 2 species) with at least 10 ⁵ bacteria/ml, with or without clinical symptoms	
Respiratory infection	Respiratory symptoms with at least two of the following signs appearing during hospitalization: — cough — purulent sputum — new infiltrate on chest radiograph consistent with infection	
Vascular catheter infection	Inflammation, lymphangitis or purulent discharge at the insertion site of the catheter	
Septicaemia	Fever or rigours and at least one positive blood culture	

How to Handwash?



Informed Consent

What is meant by "informed" consent?

"Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation." (CIOMS, International Ethical Guidelines, Commentary on Guideline 4)

What is meant by "comprehension"? That is, how do investigators ensure that subjects understand information about the study, and how is this implemented in accordance with GCP?

"The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice." (The Belmont Report)

"Informing the individual subject must not be simply a ritual recitation of the contents of a written document. Rather, the investigator must convey the information, whether orally or in writing, in language that suits the individual's level of understanding. The investigator must bear in mind that the prospective subject's ability to understand the information necessary to give informed consent depends on that individual's maturity, intelligence, education and belief system ... The investigator must then ensure that the prospective subject has adequately understood the information. The Investigator.

gator should give each one full opportunity to ask questions and should answer them honestly, promptly, and completely. In some instances the investigator may administer an oral or a written test or otherwise determine whether the information has been adequately understood." (CIOMS, International Ethical Guidelines, Commentary on Guideline 4)

Source: WHO – Handbook for GCP: Guidance for Implementation

-SK-



SQUAD

Forum

The Scientific Team

INA-RESPOND is a network of leading universities and large hospitals in Indonesia. These institutions assign their prominent infectious disease researchers to participate actively in the network. To assist these researchers in implementing their ideas, INA-RESPOND secretariat has a department called "Scientific Department", led by dr. Herman Kosasih. One part of this department that will be introduced briefly in this newsletter is the protocol development and publication division. This division consists of dr. Herman himself, dr. Nugroho Susanto (better known as Santo), and several NIHRD Center 2 researchers: dr. Retna Mustika, dr. Dona, dr. Heni, and dr. Armaji. This together with the study PIs, site specialists, monitor, and data manager to ensure the study runs smoothly and resolve scientific issues when arise.

This division also provides assistance for INA-RESPOND members in publishing their research results. Most of you may still remember the Manuscript Writing Workshop held in January 2014, which was attended by more than 50 participants including 21 authors. After the workshop, we continue helping the authors polish their manuscript, together with their mentors, statisticians, and English language editors. Hopefully, in the upcoming months we can see several manuscripts published in highly respected international journals.



From left to right: dr. Herman, dr. Santo, dr. Armaji, dr. Heni, dr.Retna, dr. Dona

-HK, NS-

"In particular, no one shall be subjected without his free consent to medical or scientific experimentation." (United Nations International Covenant on Civil and Political Rights)

showed a well-defined round lytic lesion in the

body of the right pubic bone with surrounding

sclerosis. Chest X-ray was unremarkable.

Cytology from fine-needle aspiration of the

swelling showed epitheloid cells, a few



The Curious Case of Thigh Swelling

A 17-year-old girl presented herself with a progressively enlarging painless lump of 5 months duration in the medical aspect of the superior and anterior right thigh. Physical examination showed a 12 x 8cm cystic swelling in the adductor region of the right thigh deep to the adductor muscles (Figure 1). Pelvic X-Ray



Figure1. A swelling thigh

ep to multinucleated giant cells, -Ray eosinophilic material (caseation).

Before treatment



and granular

After treatment

What is your diagnosis?

Please email your diagnosis to <u>INA.Secretariat@s-3.com</u> for a chance to win a souvenir. We are looking forward to receiving your answer by April 26, 2014, at 12.00pm.

-HK-

The winner of March Quiz is dr. Syndi from site 510 March Quiz Answer: Fluid, Food, Fly, Fingers, Fomites, Feces

Best Wishes for INA101 team members celebrating their birthday in April:

- 4 Apr Hofiya Djauhari, MSi (Laboratory Technician site 510)
- o 6 Apr dr. Heni Kismayawati (Protocol Team Center 2)
- o 22 Apr dr. M.M.D.E.A.H. Hapsari, SpA(K) (Co-PI Site 560)
 - 27 Apr Prof. Emiliana Tjitra (Protocol Co-PI AFIRE)

Padda Bible And A

Upcoming Events in April	10: AFIRE Interim Analysis Meeting (Bandung), 14: Sepsis Meeting (Jakarta), 22: HIV Meeting (Semarang), 23-24: NSC Meeting (Semarang).	
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