INA RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

INA-RESPOND Secretariat. Badan Litbangkes, Kemenkes RI, Building 4, Level 5, Jln. Percetakan Negara No.29, Jakarta, 10560. Phone: +62 21 42879189. Email: INA.Secretariat@s-3.com. Website: www.ina-respond.net

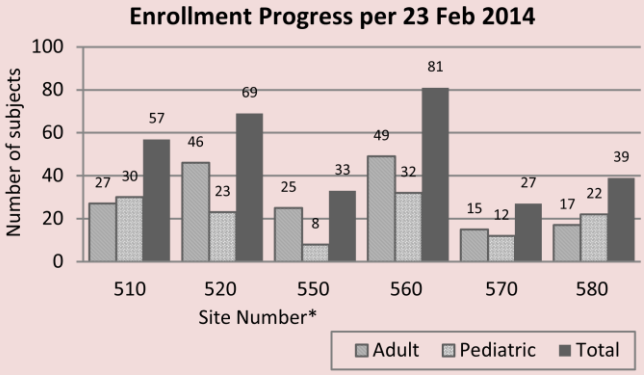
Newsletter

Issue #6
March 2014

AFIRE STUDY

Up to February 23, 306 subjects (179 adults and 127 pediatric) out of 870 patients screened have been enrolled.

Below are the details of the enrollment per February 23:



*510 – RS. Hasan Sadikin, Bandung
550 – RS. Wahidin, Makassar
570 – RS. Dr. Soetomo, Surabaya
520 – RS. Sanglah, Denpasar
560 – RS. Dr. Kariadi, Semarang
580 – RS. Dr. Sardjito, Yogyakarta

Detailed screening and enrollment progress is available in portal folder: Studies\INA101\Screening progress.pdf
or go to the following link:
https://ina-respond.s-3.com/EdmFile/getfile/797233

Documents Update

This month the Secretariat releases two documents:

- CRF Completion guideline version 3.0 dated 10 Jan 2014. The document is available on portal at https://ina-respond.s-3.com/edm/index/806165
- Memo dated February 25.

Please review and take heed of the information in the documents.

Refresher: Obtaining Informed Consent

Here are some of the things that need to be remembered related to obtaining informed consent:

1. **Recruiting unconscious or too-ill to consent subjects.**

   The investigator must seek informed consent from the parent, spouse, or legal guardian. An impartial witness should be present during the entire informed consent and should sign and date the consent form as well. You should make sure that the consent to remain in the study must be obtained at the earliest feasible opportunity if they become capable of giving consent themselves.

2. **Illiterate subject.**

   If you encounter a subject who cannot read or does not understand what is written on the consent form, an impartial witness must be present during the entire consent process. The witness will give his signature and date the consent form. By signing the consent form, the witness attests that the information in the consent form was accurately explained to and apparently understood by the subject, and the subject freely gave his consent.

3. **Re-consenting ongoing subject.**

   Please ensure that you are using the most current version of ICF every time you ask for a subject's consent.

Please triple check the signed ICF and ensure everything is completed properly.

TB STUDY

The INA-RESPOND network has finished the grand design of TB Protocol. However, a few concerns regarding patient flow and specimen management still need to be straightened out. Since each site has different procedure in handling these issues, the Protocol Specialist is going to visit all sites to see how each site manages TB patients and to check sites' facilities. The information will be useful in crafting the TB protocol into something that is applicable across all sites.

In light of this, a TB Laboratory meeting was held on Feb 27-28 by inviting lab personnel from all participating sites. The discussion in the meeting covered all important points that needed to be resolved including lab work flow and work load as well as specimen management.

HIV STUDY

It has been decided that the INA-RESPOND network is going to adopt the Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART) Study conducted in South Africa. The adopted PopART will be customized and tailored to fit Indonesia's situation, condition, and needs.

In part of developing the study protocol and strengthening Indonesia and US cooperation especially in HIV studies, Dr. Siti Nadia, Head of HIV Management Sub-Directorate, is attending an HIV conference and visiting NIH office on March 8.

SEPSIS STUDY

Queen Sirikit hospital in Thailand is the first site that started to recruit subjects for the Sepsis study. The remaining sites in Thailand and Vietnam are expected to be activated as soon as local EC approvals are obtained and site contracting issues are resolved. In the meantime, sites are expected to complete their trainings to ensure they are ready by the time the aforementioned documents become available.

Indonesia is gearing up for the Sepsis study by reviewing and making some adjustments to the study documents to fit Indonesia's environment.

Scientific Corner

One of the surprising things about science is that it is actually almost impossible to prove anything true. Instead, all we do is show that things are false. So instead of proving our hypothesis, we just try to prove that all of the alternatives are wrong. This is what we called by "null hypothesis". A P-value is the evidence against a null hypothesis. It does not tell you that the null hypothesis is correct or right, only if there is significant evidence to reject it or not. Commonly a P-value under 0.05 is considered significant. To compute the P-value, you have to know what kind of distribution you were expecting. There are chi-squared distributions, normal distributions, t-distributions, etc. depending on how many variables you have and what kind of data you are collecting.

In Goodarzi, 2013, the authors wrote in the table that the duration of disease between both groups in their research is not significantly different with P-value 1.123. This is a simple mistake that could be avoided if the authors understand what P-value is. The definition of P-value is the probability of getting the result as or more extreme than our research if the null hypothesis is true. Because P-value is a probability, it means that the minimum value of P-value will be >0.000 and the maximum value will be 1. Hartopo, 2013, made a conclusion in his abstract that "*Hospital adverse events were better predicted by eGFRMDRD than by eGFRCKD-EPI (AUC, 0.698; 95%CI: 0.596-0.800, p<0.01 versus AUC, 0.693; 95%CI: 0.591-0.796, p<0.01)*". It is a less obvious mistake than Goodarzi but still if you didn't read it carefully you will be confused why there are two P-values in that sentence. Because the P-values are not for the comparison between two AUC but they are for each AUC that tested each AUC is higher than 0.5.

These may be just an honest mistake by the authors (and the reviewers or the editors), and no harm is done. On the other hand, the authors of both articles might not really understand about P-value and any statistical analyses that they wrote in their journals, which leaves us wondering whether or not we could trust their results. Now that we have better understanding of P-Value, we should be more meticulous to avoid making similar errors.

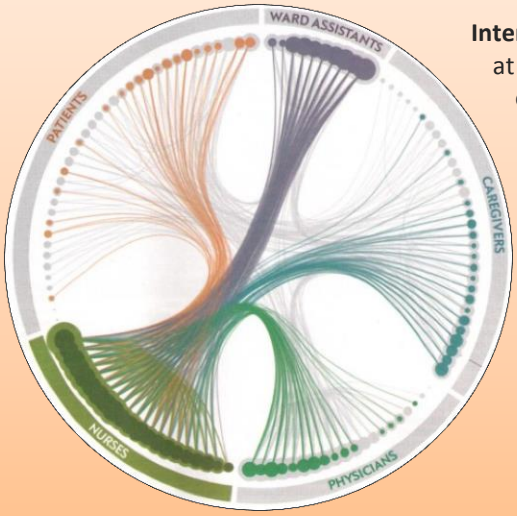
Source: Goodarzi, D., Cyrus, A., et al (2013). "The Efficacy of Zinc for Treatment of Chronic Prostatitis.";
Hartopo, B.A., Setianto, B.Y., et al (2013). "Predictive Value of Different Estimated Glomerular Filtration Rates on Hospital Adverse Events Following Acute Myocardial Infarction."

Nurse should take priority in strategies for preventing or controlling hospital outbreak

European researchers put radio-frequency identification (RFID) badges to 119 people in pediatric ward. These people consist of nurses, patients, ward assistants, caregivers, and physician.

The tags registered face-to-face interactions and the potential spreading of airborne pathogens. It was found out that nurses interacted with the widest variety of people across the ward. Thus, the study indicates that nurse is an essential hospital personal who can restrain germ spreading.

Source: Matson J (2012). Tag – You're Sick. Scientific American, November.



Interactions - Each line represents at least one face-to-face contact of one minute or more, within a range of about 1.5 meters, between individuals (*circular nodes*) in the pediatric ward.

Groups - Nurses interact with people all over the ward – in an outbreak, their movements could spread disease.

GCP forum

Why should monitoring be performed?

In a nutshell, monitoring should be done to review:

- Human research subject safety
- Compliance verification of all applicable regulatory and ethical requirements
- Quality and integrity verification of clinical data collected, documented, and reported by the clinical research site

So, these are what a clinical monitor practically does

Site initiation visit (SIV) usually occurs after the site has completed all regulatory requirements and has obtained IRB approval for the study conduct at their site. The initiation visit is the last step before the study site is activated for enrollment. On this visit, the Monitor reviews and discuses approved approaches to the study procedures.

Site close-out visit (SCV)

When a study has been completed at a site, a close-out visit occurs. Any open queries on data, study drug, and remaining trial materials must be dealt with correctly.

Site monitoring visit (SMV)

At the beginning of a study, a monitoring plan that includes the frequency and duration of periodic monitor visits was set up. The focus of these visits is to evaluate the way the study is being conducted and to perform source document verification. These visits can occur every few weeks and can take less than one day up to several days at a time. It is important for site to be familiar with the data entry expectations and documentations.

INA RESPOND

SQUAD

Site 520 – RS Sanglah, Denpasar, Bali

From left to right: Prof Tuti (NSC Member), dr. Dwi Lingga (Site co-PI), dr Jaya (RA), dr. Susila (Site PI), dr Tyas (RA), Yanti (LT), Nila (LT)

This month we will get acquainted with research team members from site 520, RS. Sanglah - Bali. This site is the recipient of the first INA-RESPOND Site Award, which was presented at the NSC meeting in January. How can they come together and become a solid team? Site 520's research team, which is led by dr. I Made Susila Utama, holds a daily meeting every morning where each member updates his work and dr. Susila can sign and review all study documents. Moreover, let us not forget our NSC member at site, Prof. Ketut Tuti Merati, who always provides her guidance for this team to get through challenges. Good communication between site members has definitely benefited dr. Jaya and dr. Tyas, our Research Assistants, to help maintain study subjects. We hope that site 520's dedication can be an inspiration for other sites to achieve the best of standards in conducting AFIRE study.

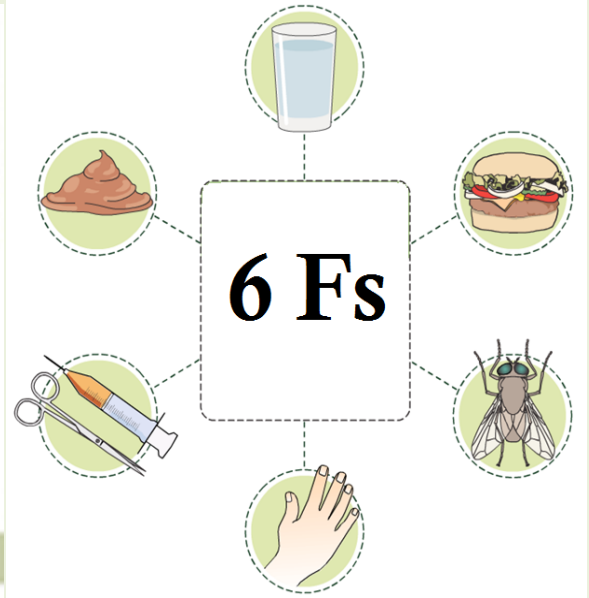
QUIZ TIME!

dr. Gina Samaan is an epidemiologist who has recently been deployed to a remote area to investigate the causes of a large outbreak. After scrabbling around looking for clues, she finally gets some hints of what is actually going on.

But first, she has to identify the outbreak's 6 (six) modes of transmission, which coincidentally start with the letter **F**!

So, please help dr. Gina find these 6Fs by sending your answers to us at INA.Secretariat@s-3.com **before March 26.**

Participants who can answer correctly will



The winner of February Quiz is dr. Annisa Salmah from site 560

January Quiz Answer: Leptospirosis.

February Quiz Answer: Across: 1. NIHRD 4. Legal 5. PI 8. Bias 11. Protocol 12. SAE 13. Ethical 14. Assent;
Down: 1. NIAID 2. RSUP 3. Belmont 6. Guardian 7. Violation 9. Sanglah 10, ICF.

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

- 11 Mar – **Eni Yuwarni** (Project Assistant)
- 16 Mar – **Yanti Triswan** (Secretariat INA-RESPOND)
- 24 Mar – **Yayu Nuzulurrahmah** (Secretariat INA-RESPOND)
- 28 Mar – **dr. Tri Wibawa, PhD** (Site PI 580)
- 30 Mar – **Prof. David Muljono** (NSC Member)

Also, good news:

- Wedding celebration - **Dr Mega Hayyu Isfiati** (RA Site 580)
- New baby born - **Dr Heny Yuniarti** (RA Site 510) and **Dr Yenni Risniati** (Central 2 NIHRD)

Upcoming Events

March: AFIRE Study Interim Analysis meeting; Sepsis meeting; HIV and TB protocol core team monthly meeting

INA-RESPOND Newsletter

Advisor : **dr. M. Karyana, dr. Herman Kosasih**
Editor in Chief : **Anandika Pawitri**
Language Editor : **Dedy Hidayat S.**
Editorial Board : **Anandika Pawitri, Nugroho Harry Susanto, Sonia Kusumawardani, Nurhayati, Mila Erastuti**
Contributors : **All INA-RESPOND network members**
Thanks to : **INA-RESPOND Network and Partners**

We would like to hear from you. Go ahead and send us your scientific articles, team profile, or feedback about the newsletter to INA.Secretariat@s-3.com

Source for quiz article: http://emedia.rmit.edu.au/infection_control