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Newsletter

June 2017



In This Issue

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AFIRE Manuscript Writing Workshop and TRIPOD Interim Analysis meeting? Find the latest information related to the AFIRE study (INA101) and TRIPOD (INA102) in this edition. For more information, contact us at the INA-RESPOND Secretariat,

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There are many terms in a research related to procedural documents, such as policy, guideline, and procedures. Do you what they are and how each of them differs? Get the information here!

Antibiotic Prophylaxis for STIs Prevention: Should or Shouldn't?

Sexually transmitted diseases encompass 30 different bacteria, protozoa, fungi, viruses and parasites. More than half are known to produce genital lesions. Aside from the immediate impact of the infection, these infections can increase the risk of getting other diseases, as well as be associated with unfavourable reproductive outcomes. Pregnant women with STIs are prone to unwanted pregnancy outcomes, such as stillbirth, neonatal death, low-birth-weight and prematurity, sepsis, pneumonia, neonatal conjunctivitis, and congenital deformities.

In sexually active people, prevention of STIs is best achieved through combined strategies using counselling and behavioural interventions. Interestingly, new biomedical interventions for STIs i.e. the use of antibiotic prophylaxis was discussed at the Conference on Retroviruses and Opportunistic Infections (CROI) 2017 in Seattle, USA. Although it was labelled as new biomedical intervention, antibiotic prophylaxis for STIs is not a novel strategy. Read more about it in this edition.

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Please, Sign Here; I Will Keep Your Secrets to the Grave

Confidentiality... What is it and how important is it to our research?
Can we turn a blind eye on this issue when conducting our studies?

Read this edition's Comic Corner to learn more about it

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"Put this memo in an envelope marked 'Confidential'. Drop it on the floor in the hall. Make sure you do not seal the envelope. That way, we can be sure all employees will read the memo."

Save The Date

Important Events & Meetings

1 June Pancasila Day
 25-26 June Eid al Fitr 1438 Hijriah
 July TRIPOD Interim Analysis @Double Tree
 August NSC Meeting & Symposium @JW Marriot
 AFIRE Manuscript Writing Workshop
 @Double Tree



June Birthday

10 Jun	dr Delly Chipta Lestari	INA101 Co-PI Site 530
13 Jun	dr Dewi Lokida	Head of Lab Secretariat
17 Jun	dr Anggraini Alam	INA101 Co-PI Site 510
21 Jun	dr I Made Susila Utama	INA101 Site PI Site 520
27 Jun	dr Ni Made Tyas Dwi Arsanti	INA101 RA Site 520
30 Jun	Prof Dr Usman Hadi	INA101 Site PI Site 570

Announcement

The month of Ramadan is here. After a month of fasting, it's a day of rejoice and bliss; it's a day of blessing and peace; it's a day to reflect and ponder; it's a day to celebrate together; it's a day to apologize for all our sins, and be grateful for another chance to start over a new beginning.

Wishing you happy Eid al Fitr. May the day delight and the moments measure all the special joys for all of you to treasure. May the year ahead be fruitful too, for your home and family and especially for you.

Happy Eid Mubarak!



INA-RESPOND Study Updates

By:

dr. Nurhayati

dr. Anandika Pawitri

AFIRE Study (INA101) Updates



This cohort observational study will be closed soon. A total of 1,492 subjects (864 adults and 628 children) were enrolled from July 2013 to June 2016. All Case Report Forms and queries have been uploaded, resolved, and completed. Data quality assurance was done, and the Self Evidence Correction document has been approved by the investigators. The INA101 study database was locked on 29 May 2017 because all process on study database lock was completed,

Many ideas and thoughts related to the results of the study were given by site investigators to be written. Currently the site investigators are preparing and drafting some manuscripts to be discussed at The 2nd INA-RESPOND Manuscript Writing Workshop (MWW) which will be held in August 2017. Investigators are invited to the workshop. It is expected that the manuscript will be finalized after the 2nd MWW and ready to be submitted to several International Journals. Thank you to all investigators for the hard work, dedication, and commitment in this study.

For further information about this study please go to: <http://www.ina-respond.net/afire-study/>

TRIPOD (INA102) Updates

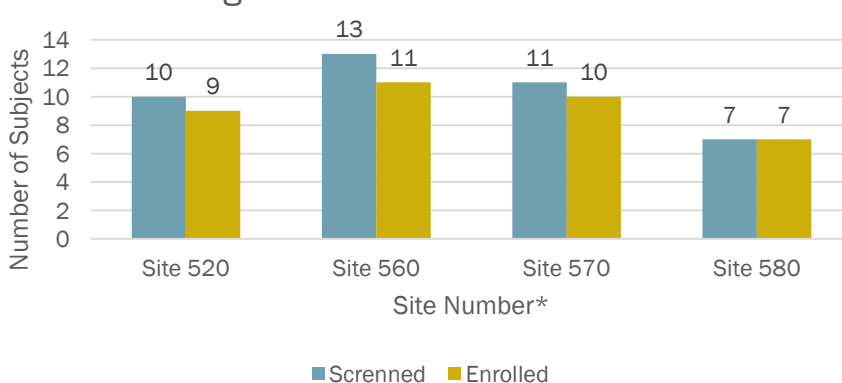
Screening and Enrollment

Entering the 17th week of recruitment, the site teams have enrolled 37 subjects. Site 560 – RSUP dr Kariadi, Semarang is the top recruiter with 11 subjects. Enrollment progress up to June 5, 2017 can be seen in the graphic. Currently, we are preparing to conduct an interim analysis, which will be held at the end of July 2017. Protocol PI, Co-PI, and Site PIs from all active sites are invited to the meeting.

Site Activation

Good news from site 590 – RSUP Persahabatan, Jakarta. The study contract has been signed. The Clinical Research Site Specialists are

Screening and enrollment at each sites



*Site Number code :

520 – RSUP Sanglah, Denpasar

560 – RSUP dr Kariadi, Semarang

570 – RSUD dr Soetomo, Surabaya

580 – RSUP dr Sardjito, Yogyakarta

preparing to conduct Site Preparation Visit at site 590.

For further information about this study please go to: <http://www.ina-respond.net/tripod-study/>

Comic Corner:

Sign Here; I Will Keep Your Secrets to the Grave

By:

dr. Aly Diana



"Put this memo in an envelope marked 'Confidential'. Drop it on the floor in the hall. Make sure you do not seal the envelope. That way, we can be sure all employees will read the memo."

"Confidential" or "Confidentiality" are some of the words we often see when we are writing a research proposal, especially when the study involves humans as its respondents.

In common English, confidential means "intended to be kept secret" (Oxford Dictionary), but in the research language, confidential has a deeper meaning. **Confidentiality** pertains to "the **treatment of information** that an individual has disclosed in a **relationship of trust** and with the expectation that it **will not be divulged** to others without permission in ways that are inconsistent with the understanding of the original disclosure".

During the informed consent process, it is our duty to tell the respondents about the measures that will be taken to protect the confidentiality of the collected information/data and about the parties who will or may have access to it (e.g., research team). When the respondents signed the informed consent, it means that he/she has already taken some time to decide about the adequacy of the protections and the acceptability of the possible release of private information to the concerned parties.

Therefore, every researcher must uphold the confidentiality agreement as promised in the informed consent form. We have to remind ourselves that ethical approval has been given by the Institutional Review Board (IRB) after

considering whether there are adequate provisions to maintain the confidentiality of the identifiable data at each segment of the research, from recruitment to maintenance of the data. It is our responsibility to follow what we have written.

The highlight here is to recognise ways to maintain/protect confidentiality; and not to treat it as a part of an automatic process to provide all required documents and make the IRB satisfied and granted the ethical clearance. It really takes a great effort to maintain confidentiality, and it should be done seriously.

In most cases, confidentiality can be ensured by implementing good data collection and storage practices. We should make certain that all members of the study team have been trained in these issues and understand not to discuss participants outside of research environment/context. In general, access to information about individual participant should be restricted to the researcher, his or her advisor (if applicable), and any research assistants on a need-to-know basis.

Care should be taken to avoid breaches of confidentiality in which this information is divulged to anyone else. Sadly, sometimes the information is divulged only for the sake of creating gossips or stories during lunch time. This practice not only does harm against

psychological, social, and legal right of our participants but also damages our credibility as good researchers.

The following are examples of practices that may be implemented to increase the level of confidentiality:

- Use study codes on data documents (e.g., completed questionnaire) instead of recording identifying information;
- Keep a separate document that links the study code to subjects' identifying information locked in a separate location and restrict access to this document (e.g., only allowing primary investigators access);
- Encrypt identifiable data;
- Remove cover/face sheets containing identifiers (e.g., names and addresses) from survey instruments containing data after receiving from study participants;
- Properly dispose, destroy, or delete study data/documents;
- Limit access to identifiable information;
- Securely store data documents within locked locations; and/or
- Assign security codes to computerized records.

Take home message: As all secrets meant to be kept, hopefully, all of us can be a good secret-keeper. Promise is a promise.



Latest News:

Antibiotic Prophylaxis for STIs Prevention: Should or Shouldn't?

By:

dr. Dona Arlinda

Sexually transmitted infections (STIs) are spread mainly through sexual contact (vaginal, oral, or anal sex.) It encompasses 30 different bacteria, protozoa, fungi, viruses and parasites. More than half are known to produce genital lesions. Four are currently curable, i.e. syphilis, gonorrhoea, chlamydia and trichomoniasis. The other 4 are incurable viral infections, i.e. HIV, hepatitis B (HBV), herpes simplex virus (HSV or herpes), and human papillomavirus (HPV).

Aside from the immediate impact of the infection, STIs can increase the risk of getting other diseases, as well as be associated with unfavourable reproductive outcomes. The risk of getting HIV infection is three times more likely in those with herpes and syphilis. Pregnant women with STIs are prone to unwanted pregnancy outcomes, such as stillbirth, neonatal death, low-birth-weight and prematurity, sepsis, pneumonia, neonatal conjunctivitis, and congenital deformities. Certain types of HPVs are known to be associated with cervical cancer, which is one of the leading and deadly cancers in women. STIs such as gonorrhoea and chlamydia are major causes of pelvic inflammatory disease (PID) and infertility in women.

Prevention of STIs

In sexually active people, prevention of STIs is best achieved through combined strategies using counselling and

behavioural interventions for primary prevention, promotion of barrier method such as male or female condoms, increasing access to accurate and inexpensive rapid tests such as those for HIV and syphilis, better access to treatment and notification to sex partners, vaccines for HBV and HPV, as well as other biomedical interventions such as male circumcision, vaginal microbicides, etc.

At the Conference on Retroviruses and Opportunistic Infections (CROI) 2017 in Seattle, USA, new biomedical interventions for STIs i.e. antibiotic prophylaxis were discussed. Jean-Michel Molina from the University of Paris Diderot, Paris and Saint-Louis Hospital, Paris summarised several different timings and strategies for using antibiotic prophylaxis for the prevention of STIs, i.e. as post-exposure prophylaxis, for the treatment of incubating STIs in sex partners, as a periodic presumptive treatment (PPT), as mass drug treatment, or as daily or on-demand prophylaxis.

Although it was labelled as new biomedical intervention, antibiotic prophylaxis for STIs is not a novel strategy. Before the era of penicillin, a publication in JAMA, 1943 reported a single dose of sulfathiazole as post-exposure prophylaxis was very effective in preventing chancroid and gonorrhoea. In subsequent years, similar effective reports of post-exposure prophylaxis for gonorrhoea using oral

penicillin or minocycline were published. Targeting incubating STIs in sex partners is recommended by CDC and publications supporting this strategy dated back since 1971. Provision of antibiotic prophylaxis in timely manner in high-risk individuals (periodic presumptive treatment / PPT) was shown to reduce the incidence of STIs and HIV. Reports supporting this data can be found in 2004 and a systematic review in 2012 concluded PPT can be use as short term control measure. Mass drug administration for elimination of yaws or trachoma has shown to have reduced the incidence of gonorrhoea and genital *Chlamydia trachomatis* infection. Daily doxycycline given to HIV-infected men who have sex with men (MSM) with prior syphilis resulted in fewer STIs.

Despite a number of studies supporting the strategy, antibiotic prophylaxis can produce unwanted or adverse consequences, such as selection for antibiotic resistance, changes in the presentation of STIs, impact on human microbiome, tolerability issues, increasing cost, etc. Antibiotic resistance is a major threat for STIs especially gonorrhoea because compare to *Chlamydia trachomatis* and *Treponema pallidum*, *Neisseria gonorrhoea* is prone to select resistance due to ability to alter its genetics. Any successful control for STIs after the administration of antibiotic prophylaxis is usually followed by rebound to pre-

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Report:

Visit to Uganda

By:

Dwi Arie Pramanto

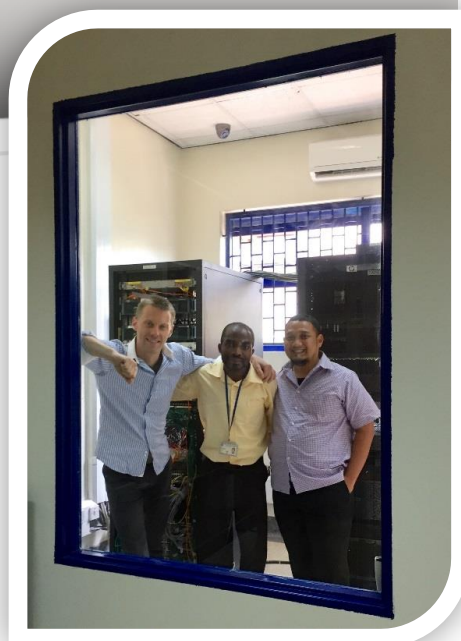
A couple of months ago I got the opportunity to visit Uganda Virus Research Institute (UVRI) in Entebbe and Rakai Health Sciences Program (RHSP) in Kalisizo, Uganda. I stayed in Uganda for 12 days to observe, study, and help with some of the IT-related activities together with the IT team and the IBRS/ICER team.

On the first day, I was taken to Uganda Virus Research Institute (UVRI) in Entebbe. UVRI is one of the most important facilities related to the Rakai Health Sciences Program. This is where some of RHSP's operational activities, especially those related to Network and Data management, are done. The internet is a crucial facility to have in data management. Unfortunately, it is really difficult to get a good Internet Service Provider (ISP) in Kalisizo, where RHSP is located. As a solution, the provision of Internet is distributed

directly through the Data Center at UVRI in Entebbe to RHSP in Kalisizo via fiber optic cable.

The next day, I was taken around to see RHSP's facilities. RHSP has several rooms for operations such as finance, IT, data management, PI's office, and storage. It even has a guest house, where I stayed in for 9 days. The compound also has laboratory for specimen testing and clinic for examining and treating (outgoing) patients. In addition, RHSP has several fields outside of the premises to reach more patients. Patients can visit these fields to get checked and their samples taken. Research Assistants will take the CRF and samples to RHSP on the same day.

As an IT specialist, I was involved in some of RHSP's IT activities. One of them was meeting with the IBRS/ICER team, where I learnt how the team members work to solve some of their issues and how they inform the latest updates in their fields of expertise. I was also shown and explained about their IT Support Ticketing System: how it works, how to manage, make request, report, and plan each change, correction, and solutions made—all recorded in the system. In addition, I was shown their monitoring system which maps all connected device in the network, so IT staff can easily monitor and find out its



location.

On day 11-12, I was back at UVRI in Entebbe. This time, I was trusted to help with some IT-related tasks such as changing, installing, and configuring device (router, PDU, and solar panel.) In addition to the scarceness of good ISP in Uganda, stable/reliable source of electricity is also a big concern. Power is often off and for a long time. To resolve this issue, solar panels are installed as a back-up power after UPS.

Overall, my trip to Uganda was rewarding and worthwhile. I learned many interesting things, and hopefully, some of them can be applied to our INA-RESPOND's network to improve the quality of the IT Support Management.

intervention rate. Thus, antibiotic prophylaxis for STIs is currently not recommended and results of ongoing trials should be carefully analysed.

Selected references:

Eagle H, Gude AV, et al. Prevention of gonorrhea with penicillin tablets; preliminary report. *Public Health Rep.* 1948;63(44):1411-5.

Harrison WO, Hooper RR, Wiesner PJ, Campbell AF, Karney WW, Reynolds GH, et al. A trial of minocycline given after exposure to prevent gonorrhea. *The New England journal of medicine.* 1979;300(19):1074-8.

Schroeter AL, Turner RH, Lucas JB, Brown WJ. Therapy for incubating syphilis. Effectiveness of gonorrhea treatment. *JAMA.* 1971;218(5):711-3.

Kaul R, Kimani J, Nagelkerke NJ, Fonck K, Ngugi EN, Keli F, et al. Monthly antibiotic chemoprophylaxis and incidence of sexually transmitted infections and HIV-1 infection in Kenyan sex workers: a randomized

controlled trial. *JAMA.* 2004;291(21):2555-62.

Steen R, Chersich M, Gerbase A, Neilsen G, Wendland A, Ndowa F, et al. Periodic presumptive treatment of curable sexually transmitted infections among sex workers: a systematic review. *AIDS.* 2012;26(4):437-45.

Mitja O, Houine W, Moses P, Kapa A, Paru R, Hays R, et al. Mass treatment with single-dose azithromycin for yaws. *The New England journal of medicine.* 2015;372(8):703-10.

Marks M, Bottomley C, Tome H, Pitakaka R, Butcher R, Sokana O, et al. Mass drug administration of azithromycin for trachoma reduces the prevalence of genital Chlamydia trachomatis infection in the Solomon Islands. *Sex Transm Infect.* 2016;92(4):261-5.

Bolan RK, Beymer MR, Weiss RE, Flynn RP, Leibowitz AA, Klausner JD. Doxycycline prophylaxis to reduce incident syphilis among HIV-infected men who have sex with men who continue to engage in high-risk sex: a randomized, controlled pilot study. *Sex Transm Dis.* 2015;42(2):98-103.

STANDARD OPERATING PROCEDURE

The importance of Procedural Documents in INA-RESPOND Network

By:

Mila Erastuti

Louis Grue

During the Network Steering Committee (NSC) meeting on 9 March 2017, a new structure for INA-RESPOND was discussed. In the last year, the INA-RESPOND Secretariat in conjunction with the NIHRD and NIH/NIAID has developed policies, guidelines, SOPs and the supporting documents under the description of procedural documents. This will support the new structure of the INA-RESPOND network.

The purpose of having the policies, guidelines, SOPs and supporting documents within the INA-RESPOND network is to build the foundation of a Clinical Quality Management System for the INA-RESPOND network. A quality management system (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction (ISO9001:2015). It is expressed as the organizational goals and aspirations, policies, processes,

documented information, and resources needed to implement and maintain it. This will ensure INA-RESPOND will produce a quality product (Quality Clinical Data), participant safety, and business continuity. The procedural documents also provide a standard for training to standardized processes and to reduce training time for new employees.

Procedural Documents within INA-RESPOND

Policy is a formal, brief, and high-level statement or plan that embraces an organization's general beliefs, goals, objectives, & acceptable procedures for a specified subject area. Policies always state required actions and may include pointers to standards. Policy attributes include compliance (mandatory), disciplinary actions (if someone failed to comply), the desired results of the policy (not the means of implementation), and detailed descriptions defined by standards and

guidelines. Currently, INA-RESPOND Secretariat is managing the 4 INA-RESPOND policies: Publication Policy; Specimen Ownership, Access and Use Policy; Training and Development Policy; and Data Privacy Policy.

Guideline is general statements, recommendations, or administrative instructions designed to achieve the policy's objectives by providing a framework in the procedures. A guideline can change frequently based on the environment and should be reviewed more frequently than standards and policies. A guideline is not mandatory, rather a suggestion of a best practice. Hence "guidelines" and "best practice" are interchangeable.

Procedures known as an SOP (Standard Operating Procedure) describes the process: who does what, when they do it, and under what criteria. They can be text based or outlined in a process map. A series of steps taken to accomplish an end goal, procedures

The Owner develops the SOPs/Procedural Documents

The draft of SOPs/ Procedural Documents will be submitted for 1st review to Chair of INA-RESPOND, and Sponsor (NIAID and Leidos)

All input and suggestion will be elaborated and submit it to the owner.

The Owner review and approve with the changes

SOPs/Procedural Document signed by Owner, Chair of INA-RESPOND and sponsor

define "how" to protect resources and are the mechanisms to enforce policy. Procedures provide a quick reference in times of crisis, and procedures help eliminate the problem of a single point of failure.

Forms and Other Documents: Forms are documentation that is used to create records, checklists, surveys, or other documentation used in the creation of a product or service. Records are a critical output of any procedure or work instruction and form the basis of process communication, audit material, and process improvement initiatives.

Revision of the current effective SOPs/Procedural documents requires completing the Procedural Document Change Request Form and signature by Chair of INA-RESPOND.

All history of revision of SOPs/Procedural Documents listed in the Procedural

Document Change Request Log. Approval for any supporting document is using internal and external approval form. Currently, INA-RESPOND Secretariat developed the policies, guidelines, SOPs and supporting documents as mentioned in the table below.

Those INA-RESPOND procedural documents are archived in the INA-RESPOND portal with link: https://edms.ina-respond.net/Network/Operations/INA-RESPOND_SOPs/ and the Trial Master File Binders.

Any new INA-RESPOND Procedural Documents will be distributed via email to related employee after fully approved. The employee will do self-training on those documents within 2 weeks and complete the Training Documentation Form.

By having INA-RESPOND Procedural Documents, we can understand the constraints of our job without using a 'trial and error' approach, as key points are visible in well-written policies and procedures. The procedural documents enable the workforce to clearly understand individual and team responsibilities, thus saving time and resources. We are working off the same page; we can get the "official" word on how they should go about their tasks quickly and easily. Clearly written procedural documents provide legal protection.

If you think that we need new procedural documents, please do not hesitate to contact us at MErastuti@ina-respond.net. We will convey your ideas to the Chair of INA-RESPOND and sponsor or discuss them with the related divisions, if needed.

No	Type of Procedural Documents	Effective	Draft	Total
1	Policies	0	4	4
2	Guidelines	18	2	20
3	SOPs	44	4	48
4	Forms	53	9	62
5	Templates	50	12	62
6	Logs	25	5	30
7	Checklists	10	2	12
	Total	200	38	238

INA-RESPOND Newsletter

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