

Drug Resistance as Barrier in Treatment for Prevention

by dr. Retna Mustika.

As mentioned in the previous update, treatment for prevention on HIV has barriers. One of them is drug resistance which is considered as a key-issue in chronic and infectious disease. The Leading factor for drug resistance occurrence is patient's adherence. This adherence relies on the willingness and ability of people on treatment to remain in care and follow their prescribed course of antiretroviral drugs.

Some factors influencing adherence have been identified such as side effects, economic factors, and factors related to vulnerable populations. Data analysis showed that 61 percent of patients changed or discontinued their ART regimen; 24 percent did so because of an adverse event. In India and Africa, a major barrier to adherence is the economic factor. Without intervention, adherence rates to long-term medication in high income countries are approximately 50%, while adherence in low and middle income countries may be even lower. Barriers to adherence to ART among the vulnerable population such as MSMs, sex workers, and transgender can be manifold at individual, health systems, and programmatic levels. Health systems should interface with each other to address the needs of vulnerable population especially in the context of ART adherence.

Various interventions have been designed to improve treatment adherence. Currently, there are more than 30 psychological theories of behavior change, making it difficult to choose the most appropriate one when designing interventions. Behavioral, cognitive, and mixed between these two interventions including emotional support, and financial support, should be promoted to improve adherence. It needs to be delivered as part of a comprehensive package of prevention methods. Behavior Change Counseling (BCC) intervention, which is increasingly popular, gives evidence that this intervention out-perform traditional intervention. But again, there is only few researches evaluating the feasibility of implementing such interventions in routine practice in health care facilities, including in Indonesia. TROPIC study should ponder the method of intervention to improve the adherence. So, TROPIC can recommend the best strategy to implement ARV treatment for prevention.



The AFIRE Interim Analysis meeting was successfully held on 4-5 February 2015 in Bekasi. The meeting was attended by Protocol Core Team members as well as Site PI from every participating site and one of the two study Research Assistants at sites. How did the meeting go and what came out of it? Find the report in this edition!

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Ebola outbreak in Guinea, West Africa came into public knowledge on 22 March, and since then it has claimed more than 8,200 people in the region. Fortunately, from the 7 countries the outbreak is affecting, only four countries remain; Nigeria, Senegal, and Congo have declared the outbreak to be over. In this month's edition, we will try to learn a little more about the virus.

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Studies' Progress and Updates

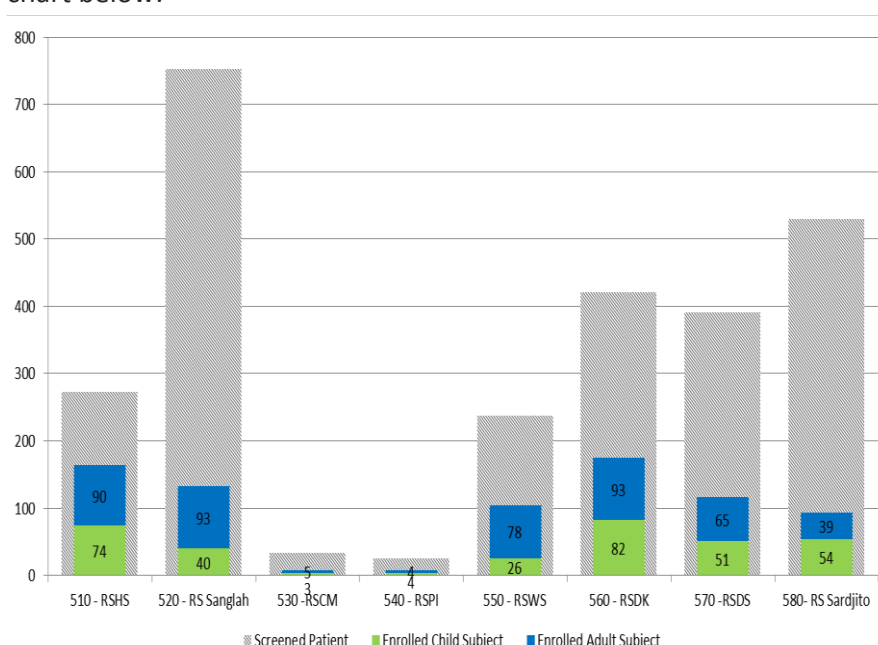
by dr. Anandika Pawitri,
dr. Herman Kosasih,
dr. Nugroho Harry Susanto,
dr. Nurhayati,
dr. Retna Mustika.



Picture 1 Sepsis Team at Site, Makassar

AFIRE STUDY

The AFIRE study just held its second interim analysis early this month. The following is the update on screening and enrollment. Up to February 1, from 2,662 screened patients, 801 subjects have been enrolled. The 3 most-common reasons for exclusion are hospitalization within the last 3 months, medical intervention history, and inpatient transfer from another hospital. Description of screening and enrollment progress can be seen in the chart below:



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>

*510– RSUP dr Hasan Sadikin, Bandung

520 – RSUP Sanglah, Denpasar

530 – RSUPN dr Cipto Mangunkusumo, Jakarta

540 – RSPI Prof Dr Sulianti Saroso, Jakarta

550 – RSUP dr Wahidin, Makassar

560 – RSUP dr Kariadi, Semarang

570 – RSUD dr Soetomo, Surabaya

580 – RSUP dr Sardjito, Yogyakarta

For further information on this study, go to:

<http://www.ina-respond.net/afire-study/>

SEPSIS

The start of Sepsis study in Indonesia titled “An Observational Study of the Causes, Management, and Outcomes of Community-acquired Sepsis and Severe Sepsis in Southeast Asia” is just around the corner. Our site in Makassar is expected to start by the end of February and is planned to recruit 2 subjects per week. To catch up with sites in Thailand and VietNam, Makassar will increase the recruitment rate as soon as the site team get used to the study activities. Following Makassar, Yogyakarta will be the second site to start the study. Ethical clearance has been approved by local IRB, and Site Preparation Visit will be conducted on March. Jakarta site, dr. Cipto Mangunkusumo hospital, is in the middle of IRB process for protocol submission.

TRIPOD

Persahabatan Hospital will be the first site to start the TRIPOD study. A request for research approval was submitted to Persahabatan Hospital's Research and Education Department on January 13. Upon approval, the Secretariat will conduct SPV, which is expected to be scheduled early March 2015. Meanwhile, the Secretariat is preparing the SPV slides, Site Regulatory Binder, Subject and CRF folders. The INA102 CRF Completion Guideline version 1.0 and annotated CRF have been finalized and approved. On January 29, the Secretariat had a meeting with the site study team to update them on the study preparation and to obtain further information related to site assessment questionnaire.

Birthdays and Celebrations!

February

- ✚ 2 February – **Dr. Indri Hapsari Putri** (INA101 Research Assistant at site 560)
- ✚ 7 February – **dr. Anandika Pawitri** (INA-RESPOND Secretariat)
- ✚ 17 February – **Ms Dwi Astuti Purwaningsih** (INA101 Lab Technician at site 580)
- ✚ 28 February – **dr. Khie Chen SpPD-KPTI** (INA101 Co-PI at site 530)

On this occasion, we would like to congratulate **dr. Venty Mulianasari** (INA101 Research Assistant at site 560) for the birth of her first daughter and welcome **dr. Fritzie** (INA101 Research Assistant at site 510) and **dr. Munawir** (INA101 Research Assistant at site 550).

We would also like to express our sincere gratitude for **dr. Linda Choerunnisa** (INA101 Research Assistant at site 510), **dr. Annisa Salmah** (INA101 Research Assistant at site 560), and **dr. Patricia Tauran** (INA101 Research Assistant at site 550) who will be leaving their respective posts. Thank you for your time and dedication to the INA-RESPOND network.



ReDefine STUDY

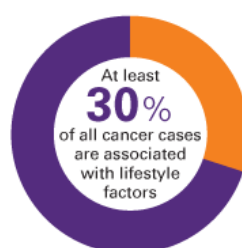
Under this study, INA-RESPOND is involved in the study initiation visit, study monitoring, and DSMB. The first face-to-face DSMB meeting was held on November 26-27, 2014.

The site started screening in December 2014, and currently a total of 3 subjects have been enrolled out of the 10 screened subjects.

The first Site Monitoring Visit (SMV) was conducted on January 20-22, and a follow up letter was sent to the Site PI on February 5 along with a Source Document Worksheet Guidance for the study team. The second SMV is scheduled for April 15-17.

Save The Date

This year Indonesia plans a bigger action to launch at World Cancer Day. Aside from the annual World Cancer Day on the road, which involves health workers, cancer survivors, and volunteers working together to distribute cancer education flyers on the main streets in capital cities throughout the country, there will also be a series of seminars for various audiences at the Ministry of Health. Social programs will also be a part of this act, including donation of healthy food packages to cancer patients in hospitals. This act is coordinated nationally by the National Cancer Control Committee (*Komite Penanggulangan Kanker Nasional*). For further information, please contact kankerindonesia@gmail.com



2015
World Cancer Day
Reduce Your Risk

#WorldCancerDay
#NotBeyondUs



Network Steering Committee Meeting and Network Annual Meeting

The next NSC Meeting will be held on **29-30 April 2015**. The venue for the meeting has not been determined. We will be sending emails to the participants once it is confirmed.

FOR MORE INFORMATION

Please contact Mr. Dedy Hidayat or Ms. Yuyu Nuzulurrahmah at +62 21 42879189 ext. 102 or 112 during office hours (08.00 – 16.00)



INTERIM ANALYSIS MEETING

by dr. Herman Kosasih & dr. M. Karyana

The INA101 Interim Analysis meeting was held for 2 days, from February 4-5 at Hotel Harris, Bekasi. It was attended by the Network Steering Committee members, Site PIs, and Research Assistants.

On the first day, each site gave its screening and enrollment report along with the most-common reasons of exclusion and some issues related to the screening and enrollment process. Sites reported that there was a decrease in enrollment nearing the end of 2014. However, it has started to go up again in the last month. The implementation of BPJS did not cause any major decrease to the number of enrolled patients at sites, contrary to what we had initially suspected. Moreover, sites that have received their JCI accreditation have better chance to conduct screening as the hospitals allow all hospitalized patients including the ones in VIP room to participate in the study,

The meeting continued to the second day, where the participants talked and discussed about antibiotics use, etiologies diagnoses per age group, clinical and hematology findings from the three most-common etiologies (dengue, salmonella typhi, and leptospira), blood culture results, and details of death cases including the underlying disease.

Key Items and Action Points

The following are the key items and action points from the interim analysis meeting:

1. Data for several variables should be cleaned up. The variables include clinical diagnosis, comorbidities, complications, and cause of death. Site team should be available when Data Management needs clarification. Site Specialists will make time to discuss this issue.
2. Changes in the interpretation of blood culture results should be made. Cases that need further discussion on sites should be followed up by Data Management staff.
3. Subsequent to the meeting, the Secretariat will send a list of topics of interest to all the meeting



Picture 2 Interim Analysis Meeting, Bekasi

participants. The participants should inform their interest within a week. Sites are only allowed to choose two topics and two researchers. Clean data will be shared by the Data Management staff to these interested researchers.

4. A small meeting, attended by the PIs, microbiologists, and a representative from pediatrics, has to be conducted to discuss all the issues raised during the interim analysis. Date of the meeting will be decided and announced in the near future.
5. Influenza test should be encouraged to subjects with pneumonia. Also, respiratory specimens should be collected. Considering the low-rate result of blood culture, other biological specimens, such as urine, feces, and LCS are very important, in particular, when subjects have syndromes whose etiologies can only be identified by using these related specimens.
6. The isolate of all culture positive test results will be stored for future study.
7. Manuscripts describing the preliminary results of AFIRE will be written as soon as possible. There will be two manuscripts, one for pediatrics and the other for adults.
8. An algorithm for further testing on specimens from indefinite cases will be prepared. Assays for identifying bacterial infections (16s rRNA) and three etiologies (dengue, typhoid, and leptospirosis).
9. The Secretariat will check the protocol for the possibility to use buffy coat for 16s rRNA, leptospira, or rickettsia infections. If it is not possible, an approval from NIHRD IRB needs to be obtained.
10. Manuscripts and further studies using AFIRE specimens will be presented during the NSC meeting at the end of April 2015.

A GLIMPSE of EBOLA

by dr. Armaji Kamaludi Syarif

Ebola virus disease (EVD) or Ebola hemorrhagic fever (EHF) is a severe and often fatal disease in human caused by the Ebola virus. The symptoms usually occur two days to three weeks after the infection with the presence of fever, fatigue, sore throat, muscle pain, and headache. These symptoms are usually accompanied by nausea, vomiting, and diarrhea, as well as the decline in liver and kidney function and bleeding problems.

The virus may be transmitted through contact with blood or body fluids of an infected animal (usually a monkey or bat). The spread through the air has never been recorded in the natural environment. It is believed that fruit bats can carry the virus without being sick. Once an infection in humans takes place, the disease can spread to other people. Men who survived the disease can still spread it through sperm for nearly two months. In the process of diagnosis, usually other diseases with similar symptoms, such as malaria, cholera, and other viral hemorrhagic fever should be excluded first. To confirm the diagnosis, blood samples are tested for antibodies against the virus, or the virus itself.

Prevention of transmission of Ebola includes efforts to reduce the spread of disease from infected animals to human, from human to human. This can be done by checking the animals for infection, as well as killing and disposing of animals exposed to the Ebola virus. Cooking animals' meat properly before consumption and wearing protective clothing during meat processing may also be useful. Moreover, regular hand washing after visiting patients at hospitals or at home is required. Fluid and tissue samples of patients with the disease should be treated with extreme caution. Last but not least, it is important to have good hygiene and to keep the environment clean.

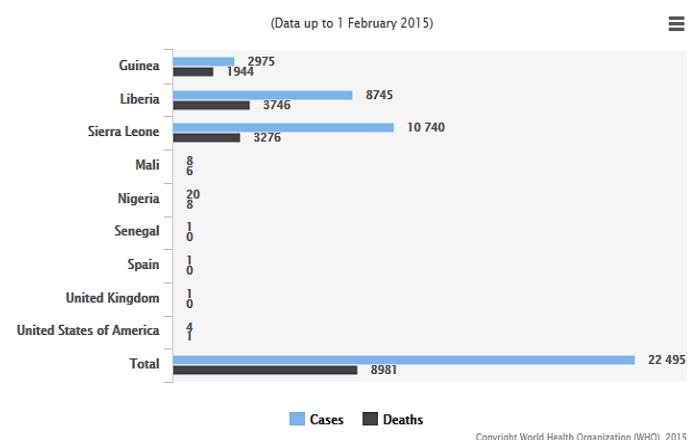
There is no proven treatment available for this disease yet. Efforts to help those affected include the provision of oral rehydration therapy (water that is slightly sweet and salty to drink) or intravenous fluids.

The disease has a high mortality rate: often kill between 25% and 90% of people infected by the virus. EVD was first identified in Sudan and the Democratic Republic of Congo. The disease is usually endemic in tropical regions of Sub-Saharan Africa. From 1976 (when it was first identified) to 2013, less than 1,000 people per year got infected. The largest outbreak to date is an outbreak of Ebola in West Africa in 2014, striking Guyana, Sierra Leone, Liberia, and Nigeria. In August 2014, more than 1,600 cases were identified. Efforts are still underway to develop a vaccine.

Ebola Situation Report

Ebola Situation Report - 4 February 2015

- Weekly case incidence increased in all three countries for the first time this year. There were 124 new confirmed cases reported in the week to 1 February: 39 in Guinea, 5 in Liberia, and 80 in Sierra Leone.
- Continued community resistance, increasing geographical spread in Guinea and widespread transmission in Sierra Leone, and a rise in incidence show that the EVD response still faces significant challenges.
- As the wet season drawing near, which will especially make access to isolated areas more difficult, there is a urgent need to end the epidemic in as wide an area as possible.



Source:

<http://www.who.int/mediacentre/factsheets/fs103/en/>
http://www.who.int/csr/don/2014_08_04_ebola/en/
<http://apps.who.int/ebola/en/ebola-situation-report/situation-reports/ebola-situation-report-4-february-2015>

Site Preparation Visit - Sepsis Study (SEA050)

Makassar - the Secretariat staff conducted Site Preparation Visit on January 27 – 28 as part of Sepsis study preparation activities. Check out these photos taken on-site during the visit!



Picture 5 Sepsis Team at Site Makassar and the Secretariat Staff



Picture 4 Data Management Training
From left to right: dr. Harun, dr. Kartika, Ms. Kanti, dr. Anandika



Picture 5 Specimen Collection Training
Ms. Arahmaniar and dr. Dewi Lokida



Picture 6 Data Entry to Open Clinica – Tryout
Sepsis Research Assistants: dr. Harun (left)
and dr. Kartika (right)



Picture 7 Specimen Processing
Sepsis Lab Technician, Ms. Arahmaniar,
working on specimen form

INA-RESPOND Newsletter

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Chief Editor
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Thanks to
Disclaimer

: dr. M. Karyana, dr. Herman Kosasih
: dr. Anandika Pawitri
: Dedy Hidayat S, S.Kom
: dr. Armaji Kamaludi Syarif, dr. Nurhayati, dr. Nugroho Harry Susanto,
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