INA-RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

NEWSLETTER

May 2018

NETWORK STEERING COMMITEE 2ND MEETING 2018

TEAMWORK: MY battle to SURVIVE

The 28th EUROPEAN CONGRESS ON CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES

SAYING HELLO TO EMERGING FUNGAL THREAT: CANDIDA AURIS

NATIONAL INSTITUTE OF HEALTH RESEARCH AND DEVELOPMENT
MINISTRY OF HEALTH REPUBLIC OF INDONESIA
2018

The Hermitage Hotel,
A Tribute Portfolio Hotel,
Jakarta

Photo: Dedy Hidayat

INA-RESPOND newsletter

MASTHEAD

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M. Karyana

EXECUTIVE EDITOR

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Dedy Hidayat

ART DIRECTOR

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SENIOR WRITERS

Aly Diana, Dona Arlinda, M. Helmi Aziz, Mila Erastuti

REVIEWERS & CONTRIBUTING WRITERS

Anandika Pawitri, Dona Arlinda, Dedy Hidayat, Lois E. Bang, Louis Grue, Maria Intan, M. Ikhsan Jufri, Neneng Aini, Nurhayati

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INA-RESPOND Network & Partners

INA-RESPOND Secretariat

Badan Penelitian dan Pengembangan Kesehatan, RI Gedung 4, Lantai 5.
Jl. Percetakan Negara no.29,
Jakarta, 10560
www.ina-respond.net

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INA-RESPOND Newsletter

TRIPOD & INA-PROACTIVE Study Updates

By: ANANDIKA PAWITRI, CALEB L. HALIM, LOIS E. BANG, M. IKHSAN JUFRI, VENTY MULIANA SARI

Screening and Enrolment

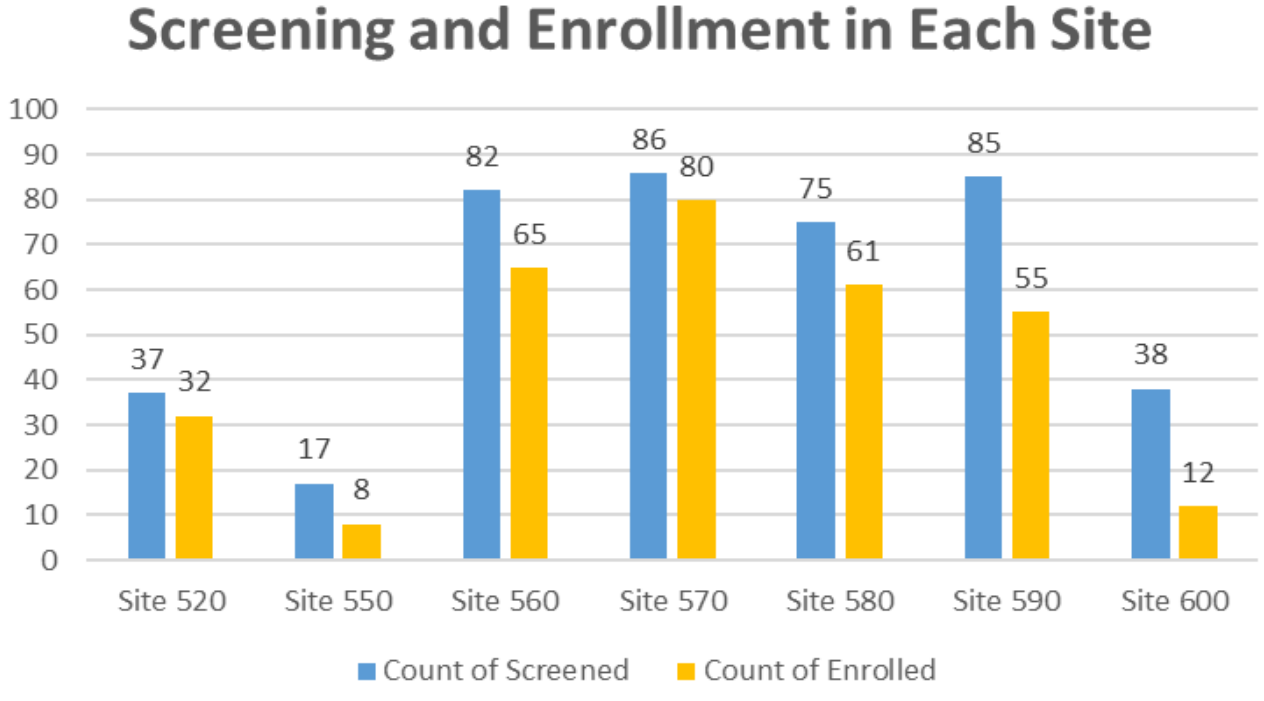
INA102

Up to 14 May 2018, sites have enrolled 313 subjects. Enrolment progress until 14 May 2018 can be seen in the graphic below. Site 570, RSUD dr Soetomo, is still the top recruiter with 80 subjects. Enrolment by site 520, RSUP Sanglah which was previously stopped is expected to continue since the site contract has been signed. We are waiting for the hospital's permission to be released.

New TRIPOD Sites Preparations

INA-RESPOND Secretariat staff (Site Specialists, Data Management, Monitor) conducted the Site Assessment Visit (SAV) to Site 540 – RSPI Prof dr. Sulianti saroso, Jakarta on 11 May 2018. INA-RESPOND secretariat discussed study feasibility with Site 540's TRIPOD study team and talked about the steps that will be done after the SAV.

Site 510 – RSUP Hasan sadikin, Bandung has the signed site contract and hospital permission letter from Director of RSHS and now working on circulating the IRB reliance agreement between Dean of FK UNPAD, Director of RSHS and Head of FK UNPAD/RSHS Ethics committee. Site team also looking for Research Assistant for TRIPOD study and prepare the study office to place the TRIPOD study supplies.



INA104

Five months have passed since INA-PROACTIVE study enrolled its first subject. Up to 11 May 2018 a total of 118 subjects have been enrolled. Tangerang Hospital has enrolled 50 participants for INA-PROACTIVE study while Adam Malik Hospital, Wahidin Hospital, and Soetomo Hospital have enrolled 69 participants (30, 29, and 10 participants respectively). Our newest activated site, RS Cipto Mangunkusumo, has enrolled 6 subjects. The study participants comprises 108 adult subjects and 10 pediatric subjects.

Form the table we can see 2 sites have not been activated yet. Currently, site 560 is expecting the hospital's permission, and site 580 is waiting for authorization from the hospital and ethical clearance from the local Ethics Committee.

Until now, 11 sites have signed the contract for INA-PROACTIVE study. The three newest sites joining the study are: site 590 (Persahabatan Hospital), site 630 (Moh. Ansari Saleh Hospital, Banjarmasin), and site 650 (Budi Kemuliaan Hospital, Batam). Site 630 and site 650 are new INA-RESPOND network sites that received positive results from our Site Assessment Visit (SAV) in April 2018. Site 630's Site Preparation Visit (SPV) is scheduled mid May, while SPV for site 590 and 650 is planned in June 2018.

During the Network Steering Committee (NSC) meeting, all NSC members are committed to assisting the study preparation process, so more sites can be activated in the near future and our enrolment rate will increase quite significantly.

Site	SPV	SIV	Activation	Enrolled Subjects
Site 610 (Tangerang Hospital)	19-20 Dec 2017	22 & 27 Dec 2017	09 Jan 2018	50
Site 600 (Adam Malik Hospital)	7-8 Feb 2018	12-13 Feb 2018	12 Mar 2018	30
Site 550 (Wahidin Hospital)	13-14 Feb 2018	19-20 Feb 2018	13 Mar 2018	29
Site 530 (Cipto Hospital)	21-22 Feb 2018	13-14 Mar 2018	3 May 2018	6
Site 570 (Soetomo Hospital)	20-21 Mar 2018	4—5 Apr 2018	26 Apr 2018	10
Site 560 (Kariadi Hospital)	11—13 Apr 2018	23 –24 Apr 2018	-	-
Site 580 (Sardjito Hospital)	18—20 Apr 2018	17—18 May 2018	-	-

INA-RESPOND Network Steering Committee Meeting

The Hermitage Hotel, A Tribute Portfolio Hotel,

Jakarta

INA-RESPOND Newsletter

Network Steering Committee Meeting

By: M. HELMI AZIZ, DEDY HIDAYAT, ANANDIKA PAWITRI

The Network Steering Committee (NSC) meeting was successfully held on 7–8 May 2018 at The Hermitage Hotel, Jakarta . Progress of INA-RESPOND studies, new regulations, and future INA-RESPOND studies were intensely discussed. The first topic discussed on the first day was the INA-RESPOND strategic plan by dr. M. Karyana. The involvement of Directorate of General of Health Services, Medical Faculty Deans, Hospital Directors, and NIHRD related to legal contract approval of INA-RESPOND studies in each site was intensely discussed during this session. Another discussion during this session was related to ownership of research equipment and funding flow.

Preliminary data from 33 subjects of PEER study updates was discussed first in the Study Updates section. The PEER study, which aims to develop an algorithm to distinguish viral and bacterial pediatrics pneumonia, has very interesting preliminary results. Mixed infection of viral and bacterial pneumonia occurred in 20 (60.6%) recruited subjects, and some of the subjects were infected with three or more pathogens during hospitalization.

Considering the low number of PEER subjects, the statistical analysis related to pneumonia biomarkers will be discussed in the next NSC meeting.

REPORT

The INA-PROACTIVE has started to recruit subjects at five INA-RESPOND sites, and four new sites have signed the contract to join INA-PROACTIVE study. Six new potential sites across Indonesia were discussed to achieve INA-PROACTIVE target (12 sites activation by the end of June 2018). The current and new potential sites of INA-RESPOND were asked to prepare HIV database and hospital permission to accelerate the site activation process.

TRIPOD study has 313 subjects from seven INA-RESPOND sites, and two sites are ready to be activated this year. Based on the preliminary result from TRIPOD study, the multi-drug resistance tuberculosis (MDR-TB) is quite high. Therefore, this phenomenon raises concern to increase the capacity on MDR-TB diagnosis in hospitals across Indonesia.

The INA-105, a schistosomiasis study, is aimed to validate and estimate the diagnostic accuracy of the circulating cathodic antigen (CCA) rapid test in 28 villages in Schistosoma endemic areas in Central Sulawesi, Indonesia. The result of this study is expected to aid the eradication of schistosomiasis in Indonesia by 2025. Three interesting future studies were proposed using AFIRE and SEA050 repository specimen, and one study related to rodent-borne disease was also proposed considering AFIRE study findings related rodent-borne diseases. The last session on the first day discussed the prosperity of INA-RESPOND Research Assistants (RAs); contracts of RAs will be switched to Ganesha (previously through Prodia).

The second day started with the updates of INA-RESPOND related manuscripts. One manuscript is currently on editorial review at BMC infectious diseases, and resubmission of the AFIRE main manuscript to another journal is in progress because it was declined by The New England Journal of Medicine. Two manuscripts are ready to be submitted by the end of this month and are waiting for confirmation from all involved authors. The NSC suggested to put manuscript updates on monthly newslet-

Fellow from Kirby Insitute, Dr Mark Polizzotto, talked about a Dolutegravir study titled **A phase IIIB/IV randomised open-label trial to compare dolutegravir with pharmaco-enhanced darunavir versus dolutegravir with predetermined nucleosides versus recommended standard of care antiretroviral regimens in patients with HIV infection who have failed recommended first line therapy (the D3FT)** which will be conducted at RSCM (Jakarta), RS Soetomo (Surabaya), RS Wahidin (Makassar), and RS Sardjito (Yogyakarta)**.**

Photo credit to Dedy Hidayat and Erry Algiffary

ter or create WhatsApp group to communicate on manuscript progress. The discussion continued with the presentation of the new policy on data sharing and publication guidelines. The policy was developed to assist any researchers inside and outside INA-RESPOND network to use our studies related data for any kind of publications. The IRB/Ethics training will be held in July 2018 (for further information see page 18), following that the INA-RESPOND seminar will be held on October 2018 in Bandung collaborating with the 1st annual Scientific Meeting of the Indonesian Society of Tropical and Infectious Disease and the 8th annual Bandung Infectious Disease Symposium.

INA-RESPOND Newsletter

The 28th European Congress of Clinical Microbiology & Infectious Diseases

By: PATRICIA M. TAURAN, DEWI LOKIDA

The 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) is one of the most important congresses in infectious diseases, infection control and clinical microbiology. The event took place from 21-24 April 2018 in Madrid, Spain. As many as 12,949 people from 128 countries attended the 28th ECCMID.

The congress featured more than 150 sessions with invited speakers covering the entire field of infectious diseases and clinical microbiology, including eight keynote lectures, more than 100 symposia and oral sessions, 22 educational workshops and 22 meet-the-expert sessions. The program offered sessions on crowd-drawing topics including antimicrobial resistance, susceptibility testing, antimicrobial stewardship and infection prevention and control as well as sepsis, novel diagnostic techniques, emerging infections, and the microbiome.

The highlights of this year's congress included keynote lectures, the late-breaker session on clinical trial results, the award lectures, and the popular year-in sessions.

Disease evolution specialists Colin A. Russell was the keynote speaker on influenza pandemics on the 100th anniversary of the 1918 "Spanish" flu. Another notable lecture was given by Nobel Prize winner Rolf M. Zinkernagel who discussed virus mechanisms that affect immunity in addition to explaining

the success and failures of vaccines. Otto Cars showed how collective global action is needed to manage the crisis of antimicrobial resistance by balancing innovation access and stewardship. Christian Drosten addressed the emergence of novel coronaviral diseases, and George L. Daikos provided an overview of new agents with potential activity against XDR Gram -negative bacterial infections. In her keynote speech, Nathalie Questembert-Balaban addressed how bacteria evolve different strategies to evade antibiotic treatments. On the final day of the congress Christopher Dye elaborated on the challenges we are facing to eliminate tuberculosis, while Colin Hill discussed the real meaning and applications of understanding microbiome data and the impact that it may have on future antimicrobial discoveries.

One educational workshop we followed is Antimicrobial Susceptibility Testing (AST) with EUCAST breakpoints and methods. As all microbiology laboratory in Indonesia use Clinical Laboratory Standard Institute (CLSI) guidelines for AST, it is nice to know about EUCAST from the expert. The workshop topics include: What is new in EUCAST, Carbapenem and aminoglycoside breakpoints revisited, Expert rules, Standardization of antimicrobial susceptibility testing of M. tuberculosis, Rapid AST with disk diffusion on direct inoculation from blood culture bottles, Implementing breakpoints outside Europe, and Susceptibility testing of anaerobic bacteria. Interesting point from this workshop is EUCAST has validated a method for direct plating of disk diffusion mueller hinton agar plates for reading after 4, 6 and 8 hours of incubation. This recommendation for rapid AST for blood cultures will publish on EUCAST website during 2018.

Another brain-provoking topic is about satellite versus central laboratory-based blood-culture diagnostics. There were two sessions talking about it, "Workflow optimization: methodologies and applications" and "The clinical microbiology laboratory in 2020". Although the background issues of the topic are different between Indonesia and European, but we can adapt their solution. For example, In Germany, the problem is limitation of space for incubation culture bottles while in Indonesia the problem is limited of funding and human resources, so not all hospital in Indonesia have culture facilities. The solution is decentralized placement of culture bottle incubators (BactAlert or BACTEC) in a satellite laboratory located in other hospitals in the same province with central laboratory in the referral hospital. Only positive bottles are transported to the central laboratory for further work-up (gran stain, subculture, identification and susceptibility testing). This step can support patient diagnosis in areas that do not have a culture facility without burdening the hospital's financial especially in Indonesia's National Health Insurance System (*BPJS*) era.

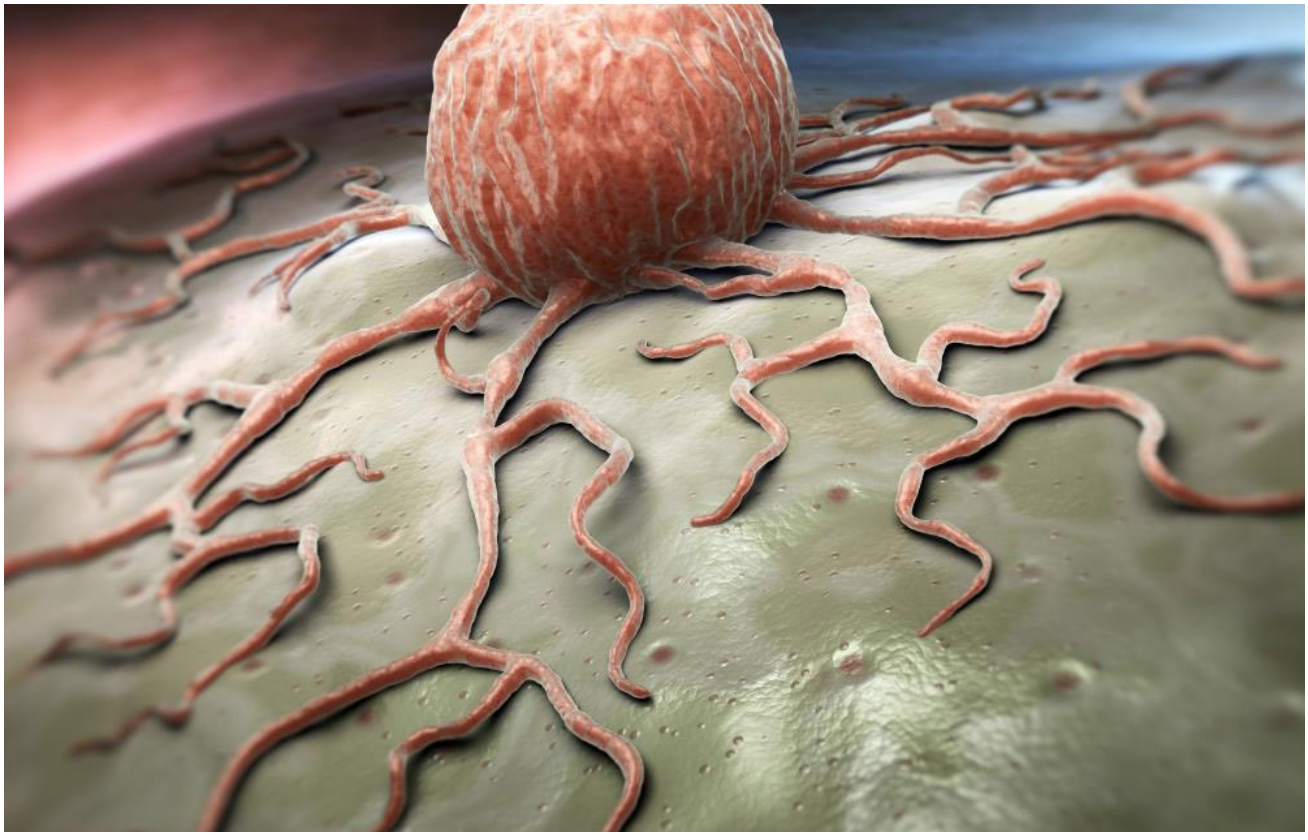
In conclusion, the 28th ECCMID presents not only cutting-edge knowledge and technology of infectious diseases and novel diagnostic techniques but also some interesting adaptable methods that could be used in Indonesia.

We thank INA-RESPOND for supporting us to attend the congress. It was indeed a valuable experience.

INA-RESPOND Newsletter

Saying Hello to Emerging Fungal Threat: Candida Auris

By: M.HELMI AZIZ



Candida spp. is a group of fungal species that can cause both superficial and bloodstream infections (BSI). The BSI caused by *Candida spp.* account for 400,000 cases in developed world, resulting in significant mortality, and has become a major threat for hospitalized patients in intensive care unit (ICU) [1, 2]. *Candida albicans*, the infamous among *Candida spp.*, is the most frequently isolated species in clinical setting [1]. However, recently there have been emerging cases of non-albicans Candida, such as *C. tropicalis, C. glabrata, C. parapsilosis, and C. auris* [1]. The last-mentioned Candida species, *C. auris*, is the emerging multidrug-resistant (MDR) yeast that was discovered in 2009 although the earliest known strain was found in 1996 from Korean isolate collection [1-3]. The emergence and health impact of *C. auris* will be discussed further in this monthly newsletter.

C. auris was first described from Japanese patient after its isolation from the external ear canal where the yeast name came from (Auris means "ear" in Latin) [1, 2]. *C. auris* has close phylogenetic relationship with *C. haemulonii*, and both are distinguished based on the sequence analysis of the D1/D2 domain of the large ribosomal sub-unit of 26S rRNA gene and the internal transcribed spacer (ITS) regions of the nuclear rRNA

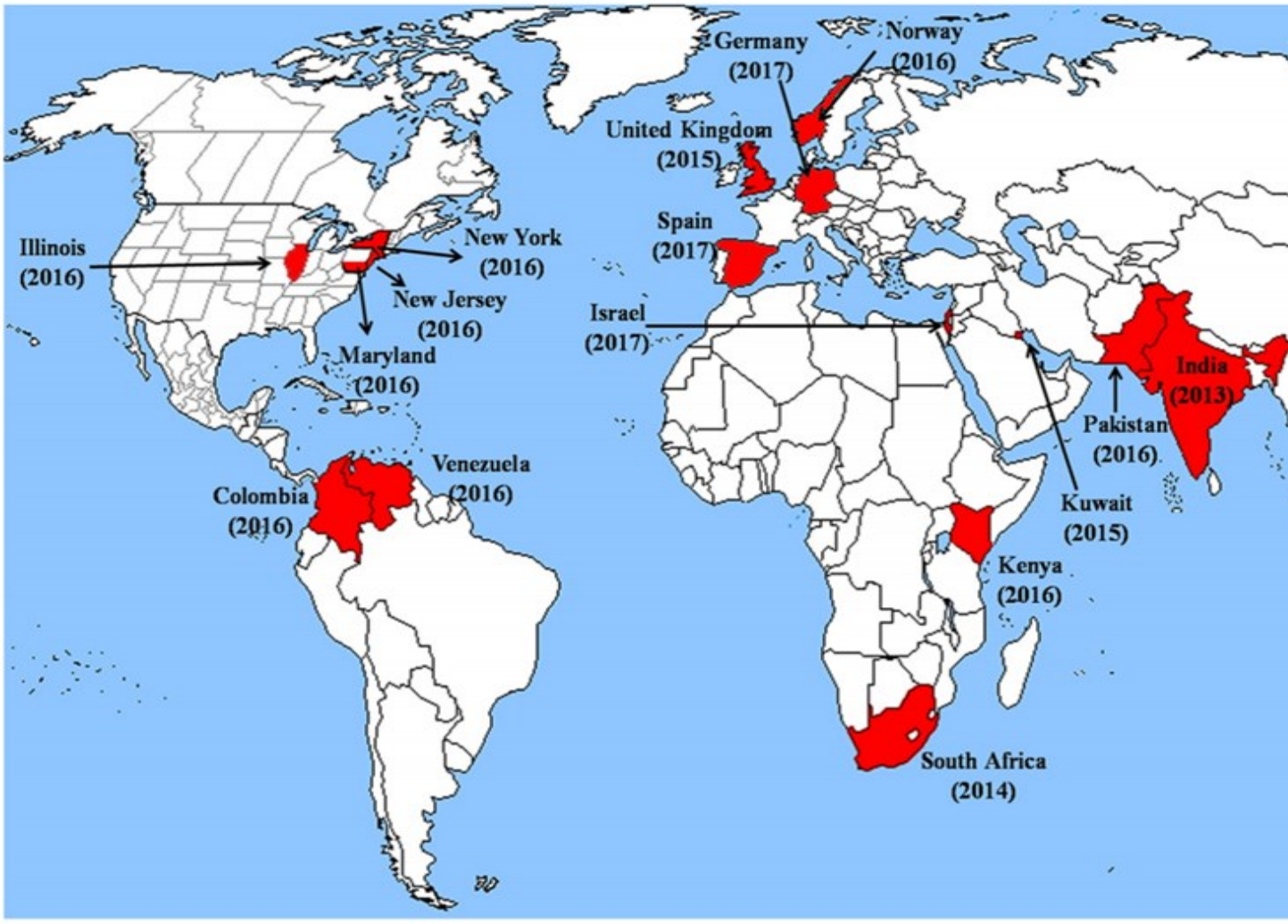


Figure 1. The global map of the emergence of *C. Auris* worldwide [1]

gene operon [1, 2, 4]. Due to the close genetic relationship, 3 cases of *C. auris* in South Korea are misdiagnosed as *C. haemulonii* and *Rhodotorula glutinis* using biochemical identification systems such as VITEK and API-20C AUX by BioMérieux. In addition, in India 102 clinical isolates are misdiagnosed as *C. haemulonii* and *C. famata* using VITEK system [1, 3, 4]. Following those two reports, there have been emerging cases of *C. auris* misdiagnosis worldwide using the biochemical identification system, which was later confirmed by ITS, D1/D2 region sequencing, or by the whole genome sequencing (WGS), or by the matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF MS) [1, 3]. The accurate identification of *C. auris* will be beneficial for the infected patient care due to the common MDR profile of this yeast.

C. auris has a genome size of approximately 12.3 Mb and a number of these genes are responsible for central metabolism and environmental adaptation that are also commonly found in other pathogenic *Candida spp.* [1]. Just like *C. albicans*, *C. auris* shares numerous virulence genes that are involved in cell wall modelling, biofilms forming, nutrient absorption, enzyme secretion, and drug efflux pump [1]. A significant amount of *C. auris* exhibit a single gene of ERG3, ERG11, FKS1, FKS2, FKS3, and encodes the ATP-binding cassette (ABC) and major facilitator superfamily (MFS) drug transporters that can cause resistance to antifungal classes [1, 2]. Another interesting fact is that *C. auris* also demonstrates thermotolerance, salt tolerance, and cell aggregation activity; which help *C. auris* survive in the hospital environment [1].

We have learned that *C. auris* carries several virulence

genes and factors, but how does *C. auris* infection impact human health? Back in 2009, 15 isolates of *C. auris* were isolated from ear canals of chronic otitis media patients in South Korea, and most of these isolates showed reduced susceptibility to Amphotericin-B (AMB) and azole antifungals [(1)]. Following the report, the first 3 nosocomial infection cases caused by *C. auris* emerged in South Korea and all 3 patients had persistent fungemia with 2 patients developing therapeutic failure to AMB and Fluconazole resulting in fatal outcome [(1)]. In India, the MDR strains of *C. auris* emerged in three hospitals during a study in 2013-2014, and the result from national ICUs survey in India showed that *C. auris* is responsible for >5% candidemia [(1)]. Following the reports, worldwide nosocomial infection reports of *C. auris* emerged from South Africa, United Kingdom, Venezuela, Colombia, United States, Pakistan, Israel, Kenya, and Spain (Figure1) [(1)]. Knowing these cases, US CDC conducted a multi-country project and reported that 93% isolates from 54 patients were resistant to Fluconazole, 41% were resistant to 2 antifungal classes, and 4% were resistant to 3 antifungal classes [(1)].

Another problem caused by *C. auris* is the nosocomial infection or transmission of this yeast in healthcare settings [(1, 3)]. Several reports highlighting persistent colonization of *C. auris* in multiple sites of the patients' body and hospital environments, including bed-space areas, mattress, bed rail, chair, and windowsill [(1)]. Surprisingly, from the outbreak in London, a healthcare worker who treated a *C. auris*-colonized patient had a positive nose swab of this yeast [(1)]. Although it is first reported to cause an ear infection, BSIs due to *C. auris* are recently reported more commonly, and other infection sites including urinary tract, skin, soft tissue, and lung infection are also reported [(3)]. Most of the nosocomial infected patients had multiple underlying disease such as diabetes mellitus, ICU administration, malignancy, chronic kidney disease, surgery, venous catheters installation, broad-spectrum antibiotic and antifungal administration [(1-4)]. When candidemia due to *C. auris* occurs, the crude in-hospital mortality rate is around 30-60% [(1, 3)].

Although *C. auris* colonizations or infections have not been documented in Indonesia, there is an urgent need to prepare for the upcoming threat of this MDR yeast. The need for early detection and rapid identification of *C. auris* in high-risk patients should be undertaken in hospitals by developing algorithm for the diagnosis of *C. auris*. Prevention and control measures such as applying standard precaution to all patients, hospital environmental cleaning, and hand hygiene could be the key to preventing the emergence of this yeast in our country.

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WHY DO I HAVE TO GO FIRST?
THERE'S NO I IN TEAM DAVE
SCOTTIE

INA-RESPOND Newsletter

Teamwork: My Battle To Survive

By: ALY DIANA

Nowadays, the importance of teamwork has been made a major point in job recruitment and real working environment. However, it is remarkable that we still have a strong individual-centric perspective considering the centrality of teamwork. This is probably because before we are a team, we are first and foremost individuals. Nevertheless, we have great faith that individuals thrown together into a team will be effective and successful.

Teamwork should help to promote deep learning through interaction, problem solving, dialogue, cooperation, and collaboration. When performed in a right way, teamwork should allow ordinary people to achieve extraordinary results. However, good teamwork is not a given condition when we work together in one workplace and call ourselves a team. We still have to perform wonderful teamwork.

We often spend most of our time with our teams. That's why our interactions as a team and their effectiveness are important to our well-being. There is over 50 years of psychological research—literally thousands of studies—focused on understanding and influencing the processes that underlie team effectiveness. These are some attributes required for successful/effective teamwork:

Commitment - Team members are committed to the success of their shared goals. Successful teams are motivated/engaged and aim to achieve the highest level of quality and performance.

Interdependence - Team members need to create a positive interdependent environment that brings out the best in each person, enabling the team to achieve its goals at a far superior level. Individuals promote and encourage their fellow team members to achieve, contribute, and learn.

Interpersonal skills – Team members must be honest, trustworthy, and supportive. They should develop ability to discuss issues openly with other team members and show respect and commitment to the team. Fostering a caring work environment is important.

Open communication and **positive feedback** – Team members listen to the concerns and needs of others and value their contribution. Team members should be willing to give and receive constructive criticism and provide authentic feedback.

Appropriate **team composition** is essential - Team members need to be fully aware of their specific team role and understand what is expected of them in terms of their contribution to the team and the project.

Contribution to team processes, **leadership** & accountability - Team members need to be accountable for their contribution to the team and the project. They need to be aware of team processes, best practice, and new ideas. Effective leadership is essential for team success including shared decision-making and problem solving.

So, could we do all of these based on our natural instincts? If not, would any teamwork intervention help us improve our teamwork and performance?

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INA-RESPOND Newsletter

UPCOMING EVENT

International Research Ethics Workshop

By: NENENG AINI, MILA ERASTUTI, T. ALICIA HENNY, ANTONIUS PRADANA

Currently, growing knowledge and technology in the field of health is supported by various number of health research, both interventional and observational, involving one or many research centers (multicenter). Some researchers have also started examining human genetics or genomes or carried out further research of stored biologic materials.

The human genome contains personal health information among other things. Human genome research can facilitate significant discoveries and scientific achievements, including mapping the complete sequence of human genome and identification of genetic markers of disease. However, sensitive ethical issues may arise before, during, or after research.

For research that analyzes the human genome, issues such as informed consent process, participants' privacy protections, and situations in which research results can be specified need to be considered. Storage of human biological materials or the use of leftover specimens for future follow-up studies also requires deep ethical considerations, particularly concerning informed consent and confidentiality.

One of the main tasks of health research ethics committee is to ensure that research ethics are conducted in accordance with nationally and internationally accepted standards of health research ethics, ensuring the safety and well-being of humans subjects as well as the privacy and dignity of the study participants. Implementation of these ethical obligations is at the core of health research ethics. To avoid violations, a deep understanding of the ethics of health research is required.

The World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS) have developed a guide that encourages researchers and members of HREC to obtain both basic and advanced training courses on research ethics guidelines involving human participants. Training in health research for members of the ethics committee is a key element to strengthen the capacity of research institutions. With the support from multi-sector partnerships and national or international networks, capacity building can lead to better ethical review mechanisms.

With this note, NIHRD through the Indonesia Research Partnership on Infectious Diseases (INA-RESPOND) and the United Stated - National Institutes of Health (US-NIH Department of Bioethics) will organize an International Standard of Health Research Ethics Training. The training will use an international module developed by US-NIH that has been done in several countries to increase multinational capacity building.

This training will be very useful for health research institutions to improve their ability in the study or ethical review of a research protocol. The goals to be achieved in this activity are:

- Improving participants' knowledge and understanding on various aspects of Health Research Ethics.
- Improving participants' ability in ethical review process through case study completion exercises.
- Improving the capacity and ethical standards of health research for ethical research committees of national and international health levels.

The training will be held from 17-19 July 2018 in Jakarta and is facilitated by speakers from Indonesia and United States—National Institutes of Health.

For further information, read the poster on the next page or contact us via email (INAMonitoring@ina-respond.net) or phone (+62 21 42879189).

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

NIH National Institutes of Health

PARK LANE HOTEL, JAKARTA 17-19 Juli 2018

INA RESPOND
INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

Menyelenggarakan

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FASILITATOR

Prof. Dr. M. Sudomo
(Ketua Komisi Etik Badan Penelitian dan Pengembangan Kesehatan)

Prof. Dr. dr. Suryani As'ad, M.Sc., Sp.GK(K)
(Ketua Komisi Etik Penelitian Kesehatan Fakultas Kedokteran Universitas Hasanuddin Makassar)

Prof. R. Sjamsuhidajat Ronokusumo, dr., Sp.B., KBD
(Departemen Bedah Fakultas Kedokteran, Universitas Indonesia)

David S Wendler, PhD
(*Senior Investigator, Head Section on Research Ethics. NIH Clinical Center Department of Bioethics*)

Liza Dawson, PhD
(*Research Ethics Team Leader, Division of AIDS, NIAID/NIH/DHHS*)

Reidar K. Lie, MD, PhD
(*Head and Professor of Department of Philosophy, University of Bergen, Norway; Bioethicist, Clinical Center Department of Bioethics, NIH.*)

Joseph R. Millum, PhD
(*Bioethicist, Clinical Center Department of Bioethics & Fogarty International Center, NIH.*)

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Anggota/Staf:

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- Fakultas Kedokteran yang terlibat dalam jejaring INA-RESPOND
- Komisi Etik yang terlibat dalam jejaring INA-RESPOND
- Komisi Etik Penelitian dan Pengembangan Nasional Kementrian Kesehatan Indonesia (KEPPKN)
- Komisi Etik Penelitian Kesehatan diluar jejaring INA-RESPOND

INFORMASI & PENDAFTARAN

Sekretariat INA-RESPOND
Badan Penelitian dan Pengembangan Kesehatan
Kementrian Kesehatan Republik Indonesia
Gedung 4 (Laboratorium Terpadu), Lantai 5

Jl. Percetakan Negara No. 29, Jakarta 10560
Email : **INAMonitoring@ina-respond.net**
Phone : +622142879189 (Aini/ Mila / Henny)

Website: **https://ina-respond.net/news/**

Segera daftarkan perwakilan Anda
TERBATAS 75 PESERTA

pendaftaran terakhir
5 Juli 2018

INA-RESPOND Newsletter

The Indonesia Research Partnership on Infectious Disease newsletter is an internal bulletin of INA-RESPOND research network intended to disseminate information related to the network's studies, activities, and interests to all members of the network as well as its sponsors and related parties.

The INA-RESPOND newsletter welcomes all network members and stakeholders to contribute by submitting articles related to the network's studies and interests. Send your articles or subscribe to our latest newsletter by sending an email to INA.Secretariat@ina-respond.net