

INA-RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE



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ASTMH
AMERICAN SOCIETY OF TROPICAL MEDICINE & HYGIENE
ADVANCING GLOBAL HEALTH SINCE 1903

2022 October 30 – November 3

ANNUAL MEETING

Washington State Convention Center | Seattle, Washington, USA

**HEALTH POLICY AGENCY
MINISTRY OF HEALTH REPUBLIC OF INDONESIA**

2022

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THANK YOU

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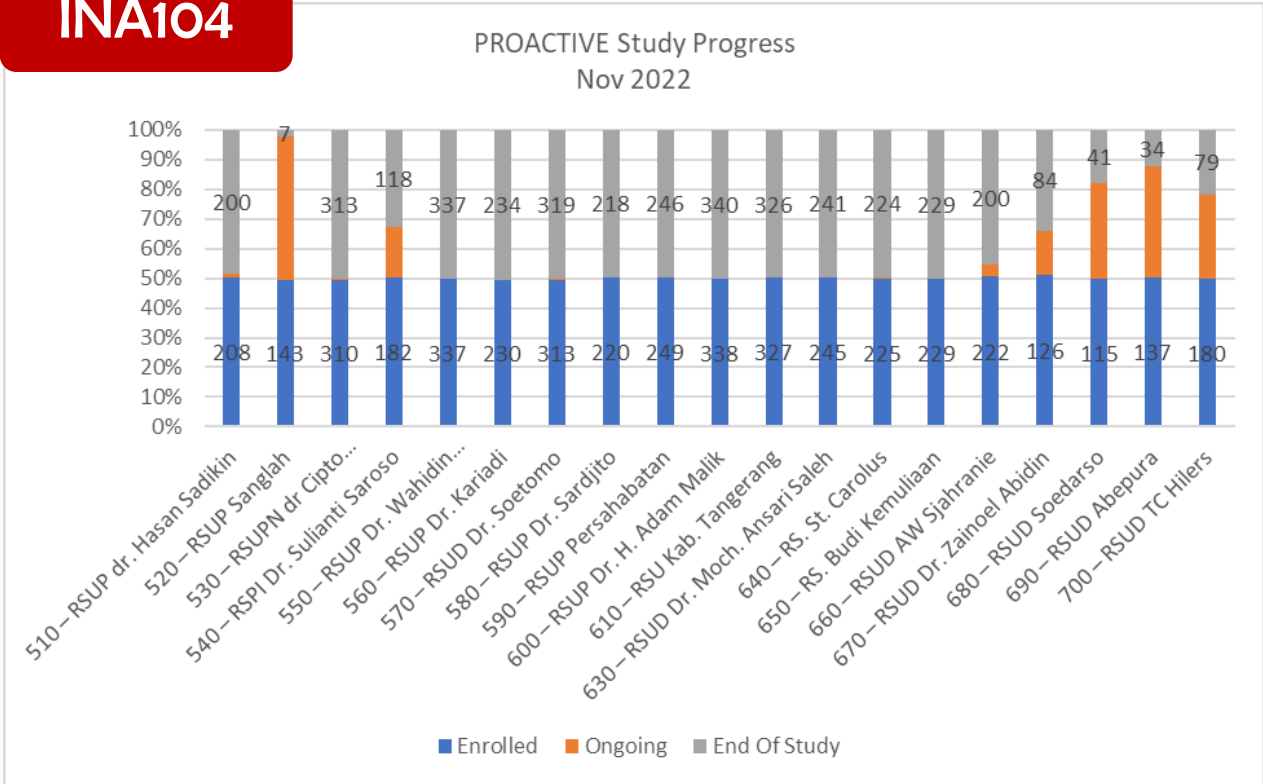
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PROACTIVE Study Updates

By: Eka Windari R., I Wayan Adi Pranata, Lois E. Bang, Melinda Setiyaningrum, Nur Latifa Hanum, Retna Mustika Indah, Riza Danu Dewantara

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STUDY UPDATES

As of 1 November 2022, out of the 4,336 subjects enrolled, 3,790 (87.4 %) subjects have ended their study, and 546 (12.6 %) subjects are still ongoing. For the end-of-study subjects, 3,112 subjects completed the study until follow-up visit month 36, 359 subjects were lost to follow-up, 246 subjects died, 33 subjects moved to the city without a PROACTIVE site, 32 subjects withdrew their consent, 5 subjects were HIV negative, and 3 subjects were suspended (imprisoned). The study progress from each site is described in Figure 1, while detailed information on the end-of-study participants is available in Table 1.

Following the completion of the follow-up at site 610 - RSU Kabupaten Tangerang in September 2022, some sites have already finished the follow-up for all of their subjects, such as sites 550 and 560, 580, 590, 600, 630 dan 650. The previously mentioned sites will have a site monitoring visit conducted by appointment with the site and site close-out visits within six months from the last follow-up before archiving the document in the next month. For the monitoring activity, two on-site monitoring visits are scheduled for November 2022, namely site 660 – RSU A. Wahab Sjahranie on 23-25 November 2022 and site 580 – RSUP Dr. Sardjito on 22-24 November 2022.

No	Site	End of Study Duration/Complete	Withdrew Consent	Participants with HIV negative	Moved	Death	Investigator Discretion	Lost to Follow Up	Other	Total
1.	510 – RSUP Dr. Hasan Sadikin	188	1	0	2	5	0	4	0	200
2.	520 - RSUP Sanglah	4	0	0	0	3	0	0	0	7
3.	530 – RSUPN Dr. Cipto Mangunkusumo	283	0	0	0	17	0	13	0	313
4.	540 – RSPI Dr. Sulianti Saroso	98	0	0	2	8	0	10	0	118
5.	550 – RSUP Dr. Wahidin Sudirohusodo	240	0	0	5	25	0	67	0	337
6.	560 – RSUP Dr. Kariadi	199	1	3	0	15	0	16	0	234
7.	570 – RSUD Dr. Soetomo	261	13	0	4	21	0	20	0	319
8.	580 – RSUP Dr. Sardjito	168	1	0	5	6	0	38	0	218
9.	590 – RSUP Persahabatan	186	0	1	0	37	0	22	0	246
10.	600 – RSUP Dr. H. Adam Malik	253	3	0	2	21	0	61	0	340
11.	610 – RSU Kabupaten Tangerang	272	6	0	4	20	0	22	2	326
12.	630 – RSUD Dr. M. Ansari Saleh	215	1	0	1	7	0	17	0	241
13.	640 – RS St. Carolus	210	0	0	0	1	0	13	0	224
14.	650 – RSU Budi Kemuliaan Batam	179	3	0	5	9	0	33	0	229
15.	660 – RSU A. Wahab Sjaranie	177	0	0	2	6	0	15	0	200
16.	670 – RSUD Zainoel Abidin	68	0	0	0	11	0	5	0	84
17.	680 – RSUD Soedarso	29	0	0	0	11	0	0	1	41
18.	690 – RSUD Abepura	22	2	1	1	7	0	1	0	34
19.	700 – RSUD TC Hillers	60	1	0	0	16	0	2	0	79
	Total	3112	32	5	33	246	0	359	3	3790

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BRIEF REPORT FROM 2022 ASTMH ANNUAL MEETING

By: Nurhayati, Wahyu Nawang Wulan



REPORT

The American Society of Tropical Medicine & Hygiene (ASTMH) Annual Meeting is the premier international forum for the exchange of scientific advances in tropical medicine, hygiene, and global health. The meeting draws tropical medicine and global health professionals representing academia, foundations, government, non-profit organizations, non-governmental organizations, the private sector, the military, and private practice. Participants include researchers, professors, government and public health officials, military personnel, travel clinic physicians, practicing physicians in tropical medicine, students, and all healthcare providers working in the fields of tropical medicine, hygiene, and global health.

The 2022 ASTMH Annual Meeting was held on October 30 – November 3, 2022, in Seattle, WA, USA. This is the first in-person conference since the pandemic. During the meeting, the live stream option provided access to 50 curated sessions and the electronic-Poster Hall Gallery.

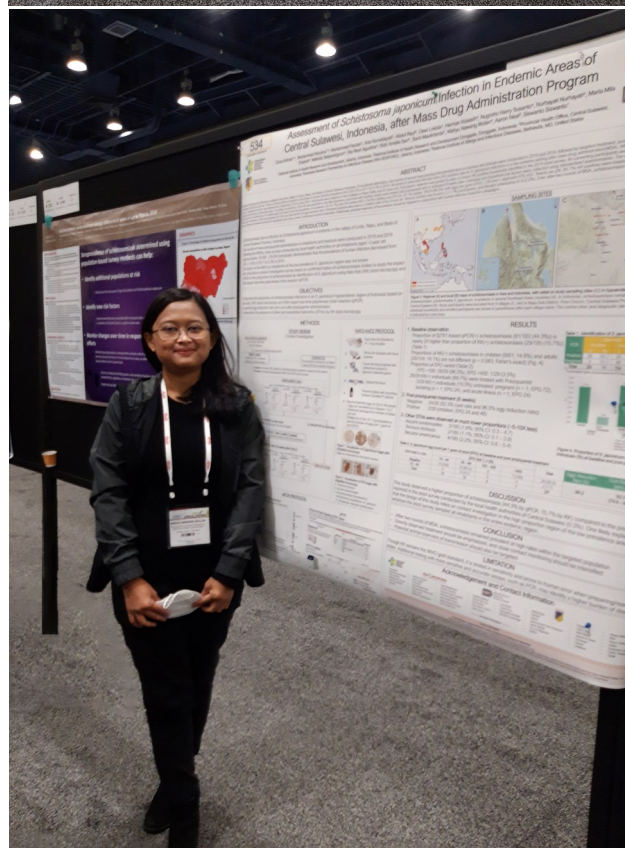
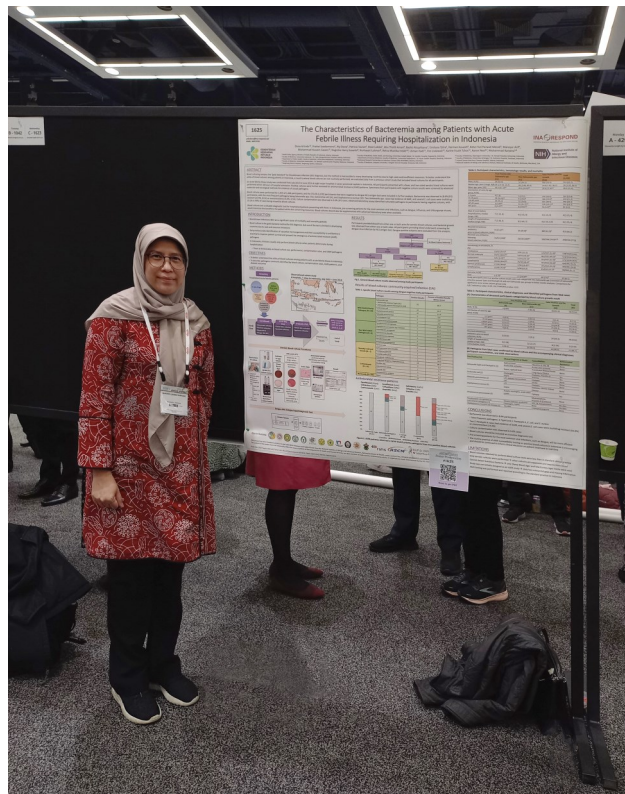
The five-day educational conference was attended by more than 4,000 attendees from more than 115 countries, who shared their updates in abstracts that were presented as oral talks or posters. A total of 2,706 presentations, including symposium presentations, late breaker abstract presentations, oral abstract presentations, and poster presentations, were presented during the event. Presented updates covered diseases that carry a major burden in tropical medicine, in particular, malaria and other tropical parasites (such as onchocerciasis), arbovirus infection, enteric bacterial infection, the neglected tropical diseases / NTDs (including schistosomiasis, soil-transmitted helminthiasis, filariasis, leishmaniasis), as well as reports on modernized diagnostics technologies such as proteomic-based diagnostic biomarkers or multiplex serologic diagnostics. Not to be left behind are updates on contemporary issues, including SARS-CoV2, Hepatitis E, Zika, cholera, and the monkeypox outbreak and enduring pneumonia/respiratory infections/

tuberculosis and global health (water, sanitation, hygiene, and environments). Works that are presented include drug/vaccine development and clinical trials, mass drug administration (MDA), molecular/cellular immunoparasitology, and also molecular genetics of pathogens/host/vectors.

The representatives from INA-RESPOND, Wahyu Nawang Wulan and Nurhayati, presented two posters on the latest update from the INA105 Validation of the Schistosomiasis Point-of-Care Circulating Cathodic Antigen (POC-CCA) Rapid Urine Test for Qualitative Detection of *Schistosoma japonicum* and INA101 Acute Febrile Illnesses Requiring Hospitalization (AFIRE) studies. Wahyu Nawang Wulan reported the proportion of schistosomiasis from a contact investigation survey in low prevalence regions of *Schistosoma japonicum* endemic area in Central Sulawesi Province, based on Kato Katz (KK) microscopy and qualitative real-time polymerase chain reaction (PCR), whereas Nurhayati reported a new analysis on pathogen identification based on blood culture from the INA101 study. In brief, the INA105 study shares an updated finding of a high schistosomiasis proportion (44.3% by qPCR, 15.7% by KK) within the targeted population. On the other hand, from the INA101 study, we reported that bacteremia was observed in 8.9% of participants. The top 3 (blood culture) pathogens identified were *S. typhi* and *S. paratyphi A*, *E. coli*, and *S. aureus*. Two *S. paratyphi A* cases had evidence of AMR, and several *E. coli* cases were multidrug-resistant (42.9%) or monoresistant (14.3%). It concluded that the routine practice of AMR susceptibility testing on positive blood cultures in Indonesia is encouraging and should be continued to inform clinical decisions on patient treatment in real time.

During the events, we had a chance to talk and share our study results with others and had a good opportunity to meet experts on schistosomiasis that have been in close communication with the INA-RESPOND team in conducting the INA105 study, i.e. Dr. W Evan Secor and Dr. Ann Straily from Centers for Disease Control and Prevention (US CDC). We also had a good conversation on prospective collaboration on peptide-based detection with Dr. Sukwan Handali, also from Dr. Secor's lab.

Overall, the meeting is interesting and valuable. Much of the latest information and results from various studies were shared, which broadened our knowledge of infectious diseases.



Top: Nurhayati and INA101 poster
 Bottom: Nawang and INA105 poster

INA-RESPOND Newsletter

DCR PHARMACY TEAM UPDATES FOR INA-RESPOND: DIFFERENCES BETWEEN OTAC PROTOCOL VERSION 1.0 AND VERSION 2.0

By: David Vallee, Lucy Chung, Nayon Kang

Introduction to DCR Pharmacy Team

The mission of the Collaborative Clinical Research Branch (CCRB) within the Division of Clinical Research (DCR) at National Institutes of Allergy and Infectious Diseases (NIAID) is to “facilitate clinical research in infectious diseases to inform public health through engagement in sustainable domestic and international collaborations”. The DCR pharmacy team is responsible for supporting CCRB special project sites, facilitating pharmacy research capacity building, rapidly mobilizing pharmacy operations for emergency clinical research during outbreaks, and consulting on pharmacy aspects of clinical trial development.

The DCR pharmacy team is comprised of three pharmacists: David Vallee, Lucy Chung, and Nayon Kang. All members of the DCR pharmacy team can be contacted by emailing DCRPharmacy@mail.nih.gov. The team can also be contacted by WhatsApp. The DCR pharmacy team can help with core SOP development for site pharmacies, study specific training, sterile compounding guidance, training on research pharmacy principles, and cold chain capacity building. We look forward to collaborating on clinical research capacity building and clinical trial implementation, such as the OTAC study.

Pharmacy Updates to OTAC for INA-RESPOND

As INA-RESPOND sites prepare for Version 2.0 of the protocol, DCR Pharmacy wanted to share some supplemental pharmacy information that highlights the differences between Version 1 and Version 2.

The Version 2.0 update includes two changes to the protocol:

- Removal of the Emergent hIVIG IP
- New lots of high-titer Grifols hIVIG

As such, the randomization scheme has been updated to only include Grifols hIVIG V2.0 lots vs placebo, as shown in Figure 1.

Design for v2.0

Adults ≥ 55 years of age or adults (≥ 18 years) who have an underlying immunosuppressive condition who recently tested positive for SARS-CoV-2 infection

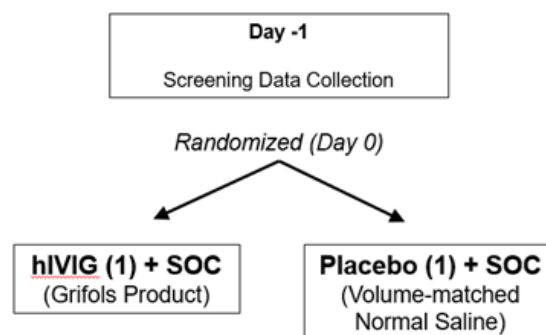


Figure 1. OTAC ICC Trainings, V1.0 Re-opening and V2.0 Update (10 Aug 2022), slide 18

As a review, the investigational product (IP) being tested (hIVIG) in OTAC Version 2.0, is manufactured by Grifols. As the diagram shows (Fig. 2), hIVIG is a polyclonal product obtained from multiple donors and offers a broader range of passive immunity, targets multiple antigenic epitopes and delivers consistent potency compared to non-hyperimmune convalescent plasma. The OTAC Study Overview slides provide more details about how hIVIG is collected and formulated (https://insight-trials.org/official_documents/I12/promotion/OTAC_Study_Overview.pdf)

FROM OUR PARTNER

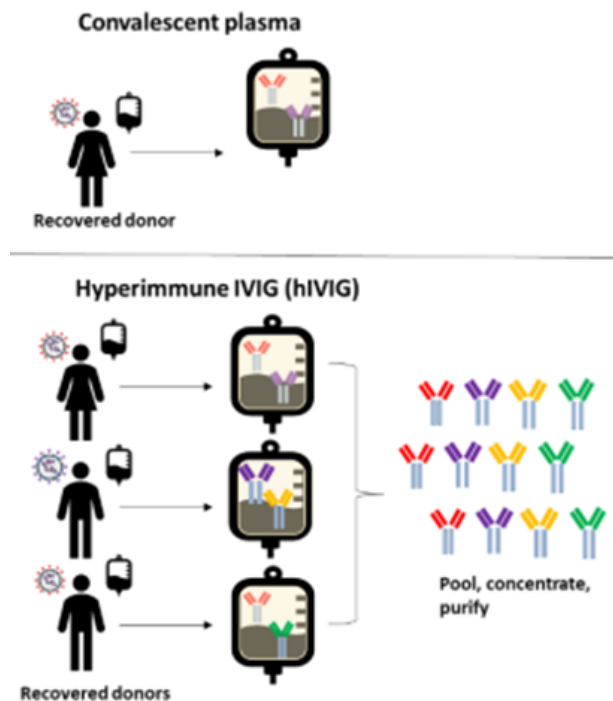


Figure 2: OTAC Study Promotion, FAQ: Hyperimmune IVIG in OTAC (06 May 2021) Page 1.

The new Grifols hIVIG lots used in V2.0 are made with donor convalescent plasma but donors have following COVID-19 infection and vaccination. Due to higher neutralizing antibodies, V2.0 lots are 3-4x more potent (with same IgG and protein concentration per unit of volume) and will be dosed at 35 mL.

Below is a summary table (Table 1) showing key differences between V1.0 and V2.0 that are pertinent to pharmacists.

Item	V1.0	V2.0
Grifols hIVIG	40 mL bags (0.1g/mL)	10 mL vials (0.1g/mL) Keep vials original carton until use
Qty Needed for Prep	8 bags	4 vials
Final prepared volume	300 mL (30 gm)	35 mL (3.5 gm)
Empty bag for pooling	500 mL	50 mL or 100 mL
Syringe pump	Not allowed	Permitted per institutional policy
Needle gauge for pooling	Not specified	18-gauge needle (recommended) Alternative larger gauge can be used only if recommended gauge is not available

Table 1

The entire required pharmacy training can be found on the INSIGHT website under the “INSIGHT 012 OTAC” page à “Protocol Materials” à “Training” à “hIVIG / Placebo Preparation (Protocol Version 2.0)” (Fig. 3)). Review of this training is required in order for pharmacists to participate in the OTAC protocol.

As seen in Table 1., pooling of V2.0 Grifols hIVIG requires 4 vials. Each vial contains a volume of 10 mL but only 35 mL are required. Therefore, the entire 10 mL from the first three vials will be withdrawn from each vial and pooled into an empty bag. However, for the fourth vial, only 5 mL will be withdrawn and pooled into an empty bag. The 5 mL that remains in the vial can be discarded per institutional policy.

Also new with Version 2.0 is the ability to utilize a syringe pump for administration. Since the final volume to be administered is rather small (35 mL), a syringe pump may be the ideal equipment for this purpose. If your site wishes to use a syringe pump for administration, please follow your institutional procedures. In addition, please follow your institutional procedures for providing the information that would be on an infusion bag label to study staff administering the infusion. And remember, if a syringe pump is used for active product, it must also be used for placebo.

The placebo for Version 2.0 is the same as it was for Version 1.0, 0.9% normal saline. The final volume is the same as for active (35 mL) as well as the bag size (50 mL or 100 mL).

Protocol Materials
Protocol
PIM
Study Forms
Pharmacy
IBs
Training
Laboratory
FAQ
Participant Brochure
Device Manuals

[Follow-up](#)
[Safety Reporting](#)
[Stored Specimen Collection Overview](#)
[Laboratory - Procedures](#)
[Pharmacy - General](#)
[Pharmacy - Web Applications](#)
[hIVIG / Placebo Preparation \(Protocol Version 1.0\)](#)
[hIVIG / Placebo Preparation \(Protocol Version 2.0\)](#)
[Using Barcode Scanner \(zoom recording; Courtesy WDC ICC\)](#)
[Q & A Case Examples](#)

ICC Trainings (PowerPoint)

[V1.0 Re-opening and V2.0 Update \(10 Aug 2022\)](#)

ICC Trainings (zoom recordings)

[WDC, CPH, LON, NIH-DCR \(27 May 2021\)](#)
[SYD \(27/28 May 2021\)](#)

Figure 3. OTAC Protocol Materials, Training page

If pharmacy is priming the bag in the pharmacy, the line must be primed using the contents of the prepared infusion. If the nursing staff primes the line, please remind them of this as well.

The initial infusion rate is the same for Version 2.0, which is 1.0 mg/kg/minute. If the participant tolerates this well, the rate can be increased to 2.0 mg/kg/minute. When the infusion is complete, the line must be flushed with 0.9% NS to ensure that any IP remaining in the tubing is administered to the participant.

Finally, all the pharmacy SOPs and materials can be found on the INSIGHT website at:

<https://insight-trials.org/i12/index.php?study=i12&page=&menu=materials&submenu=pharmacy>

Some additional best practice tips!

- Be consistent with which bag size will be used from the start of the study to the end.
 - ◊ If it becomes necessary to switch bag sizes, remember that the bag size used for placebo must be the same bag size as used for active.
- The preparation time for placebo should mimic the preparation time for active in order to maintain the blind.
- Questions? Ask DCR Pharmacy: DCRPharmacy@mail.nih.gov

Thank you again for the INA-RESPOND team support of the OTAC protocol. If there are any questions/concerns, the DCR pharmacy team is here to assist. Feel free to reach out to us anytime.

Protocol Materials
Protocol
PIM
Study Forms
Pharmacy
IBs
Training

Grifols Therapeutics Study Drug Procedures (OTAC VERSION 2.0)		
Procedure	Description	Version
OTAC-Pharm-Procedure-GRF-2	Preparing and Dispensing Grifols Therapeutics hIVIG (including required materials)	2.0
OTAC-Pharm-Procedure-10	Preparation and Dispensing Placebo (including materials required)	2.0
Accountability Log	Accountability Log for Grifols Therapeutics hIVIG (MS Word)	1.0
Infusion Bag Label	Template for hIVIG/Placebo Infusion Bag Label (MS Word) - print on Avery label stock 5264	1.0
Temperature Excursion	Form to Report Temperature Excursion (MS Word)	1.0
Product Technical Complaint Form	Additional Form to Report Temperature Excursion (MS Word)	1.0

Figure 4. OTAC Protocol Materials, Pharmacy

INA-RESPOND Newsletter

PCOS AND ITS MANAGEMENT FOR WOMEN

By: Ria Lestari

SPORTS & LIFESTYLE

Polycystic Ovary Syndrome (PCOS) is one of the most common gynecological problems in women of reproductive age. Based on the European Society for Human Reproduction and Embryology/American Society for Reproductive Medicine, the prevalence of PCOS is 15-20%. The diagnosis of this syndrome is based on two of the three from Rotterdam 2003 criteria: oligo-anovulation or chronic anovulation, clinical and/or biochemical signs of hyperandrogenemia, and polycystic ovary features. The prevalence of PCOS varies widely depending on the population and diagnostic criteria.^{1,2}

The proposed pathophysiology of PCOS is a synergistic relationship between perturbed gonadotrophin-releasing hormones (GnRH) pulsatility and hyperandrogenism, probably accompanied by hyperinsulinemia, insulin resistance, and inflammation. However, the nuances of these relationships are yet to be fully elucidated.³

In their study in Greece, Diamanti Kandarakis, et al. (1999) found that the average age of PCOS women was

(24.6 ± 1.8). Research by Knochenhauer et al. (1998) in the USA in white and black PCOS women was (29.4 ± 7.1 and 31.1 ± 7.8, respectively). In contrast, in Indonesia, in a study conducted by Sumapraja et al. (2011), the highest frequency was found in the age range of 26-30 years, which was 45.7%.⁴⁻⁷

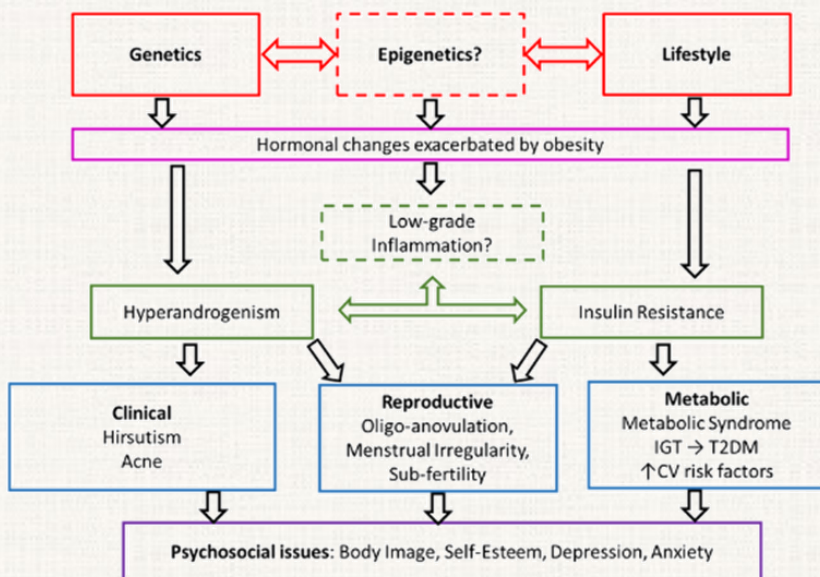
The most common reasons why patients with this syndrome come to the doctor are disturbances in the menstrual cycle (85-90% with oligomenorrhea and 30-40% with secondary amenorrhea), infertility (90%-95%), and other abnormalities such as hirsutism (70%) and acne (15-30%). Based on the results of Sumapraja's study, 44.8% of PCOS patients had ovulation disorders and polycystic ovaries phenotype.^{7,8}

How to deal with it?

Lifestyle modification is the first-line therapy of PCOS, which includes dietary interventions and physical activity. Dietary modifications in women with PCOS have the effect of improving hormonal and metabolic profiles. Diet

arrangements must be based on a balanced diet considering the glyce-mic index of the amount of carbohydrates consumed. Limitations of nutritional intake and exercise are the main foundations for the management of PCOS with obesity.⁹

It is hoped that it can reduce levels of fat in the body and increase insulin sensitivity by making lifestyle modifications. With exercise, glucose levels can be improved, and it can reduce the risk of cardiovascular disorders. The combination of exercise and limiting the number of calories consumed will reduce waist circumfer-



Picture 1. Proposed pathophysiology and features of Polycystic Ovary Syndrome (PCOS).³

ence and fat mass in the liver faster than just nutritional restrictions.¹⁰

According to WHO, the initial management of weight loss is by changing food patterns, limiting calorie intake, and increasing physical activity. Changes in visceral fat cannot be achieved with dietary changes alone. WHO recommends losing weight with moderate-intensity exercise 3-5 times a week, ideally every day, including walking/running, swimming, doing housework, and gardening. Exercise duration can be done in 30-45 minutes/day or more than 150 minutes/week.¹¹

Exercise for patients follows the rules of FITT (Frequency, Intensity, Time, Type). The type of exercise that should be done is an exercise with moderate intensity, such as brisk walking, running, swimming, cycling, and aerobics. The exercise is carried out for a minimum of 30 minutes. To lose weight, the recommended frequency of exercise is 3-5 times/week. It is better if strength training is added 2-3 times per week. The training involves the big muscle group for three sets with 12-15 repetitions for each muscle group.¹²

Palomba et al. (2008) compared the effectiveness of exercise versus a low-calorie diet. There was an increase in the ovulation rate (65% vs. 25%) and pregnancy rate (6.2% vs. 1.7%), which was greater in the exercise group than in the diet group. Both groups showed improvements in body weight, androgen levels, fasting glucose, and insulin resistance. The diet group showed a greater reduction in body weight (10% vs. 5%) and androgen levels than the exercise group. Furthermore, the exercise group showed a greater increase in SHBG levels, decreased testosterone, free androgen index, and insulin resistance compared to the diet group (9% vs. 41%).¹³

Conclusion

In the end, lifestyle modifications provide improvements in the anthropometric profile, hirsutism symptoms, and fasting insulin levels. WHO recommends moderate-intensity exercise 3-5 times/week, ideally done every day with a duration of 30-45 minutes/day or more than 150 minutes/week. Exercise has been shown to increase ovulation and pregnancy rates and improve body weight, androgen levels, fasting glucose, and insulin resistance in PCOS women.

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INA-RESPOND Newsletter

ATTENTION DEFICIT HYPERACTIVE DISORDER IN ADULTS – DO WE HAVE IT?

By: Aly Diana

COMIC CORNER



Source: https://www.boredpanda.com/comics-about-adhd-mostly-adhd/?utm_source=google&utm_medium=organic&utm_campaign=organic

Attention-deficit hyperactivity disorder (ADHD) has long been described in children who demonstrate developmentally inappropriate symptoms of inattention, impulsivity, and motor restlessness. However, it is probably adults' most common chronic undiagnosed psychiatric disorder. ADHD begins in childhood and can continue into the teen years and adulthood. Moreover, without proper treatment, ADHD continues to produce chronically impaired functioning and pain. ADHD can harm an individual's social relationships and school/work performance. However, effective treatments are available, and adequate treatment/management can be dramatically effective.

Have you or people near you experienced challenges with concentration, impulsivity, restlessness, and organization throughout life? Have you or people near you ever wondered whether you/they might have ADHD?

People with ADHD experience an ongoing pattern of the following types of symptoms: 1) Inattention—having difficulty paying attention; 2) Hyperactivity—having too much energy or moving and talking too much, and 3) Impulsivity—acting without thinking or having difficulty with self-control. Some people with ADHD may mainly have symptoms of inattention or hyperactivity-impulsivity or both. However, hyperactivity symptoms can be minimal or even none in adults.

Some adults who have ADHD don't know they have it. These adults may find it impossible to get organized, stick to a job, or remember to keep appointments. Daily tasks such as getting up in the morning, preparing to leave the house for work, arriving at work on time, and being productive on the job can be especially challenging for adults with undiagnosed ADHD. These adults may have a history of problems with school, work, and

relationships. Adults with ADHD may seem restless and try to do several things simultaneously—most of them unsuccessfully. They sometimes prefer quick fixes rather than taking the steps needed to gain greater rewards.

If you or people near you feel that you fit with the descriptions above or if you often lose things necessary for tasks and activities (e.g., wallets, keys, mobile phones, paperwork), are easily distracted, fidget with or tap hands/feet, talks excessively, has trouble waiting for your/their turn, or often interrupts/intrudes on other – please take your time to check the list of criteria for ADHD (<https://www.cdc.gov/ncbddd/adhd/diagnosis.html>). It might be a real game-changer!

Once you or people near you think they might have ADHD after looking at the criteria and conditions for ADHD, please seek help. Stress, other mental health conditions, and physical conditions or illnesses can cause similar symptoms to those of ADHD. Therefore, a thorough evaluation by a health care provider or mental health professional is necessary to determine the cause of the symptoms and identify effective treatments.

Treatment for ADHD includes medication, therapy, and other behavioral treatments or a combination of methods. In addition to these treatments, other strategies may help manage symptoms: 1) Exercise regularly, especially when you're feeling hyperactive or restless; 2) Eat regular, healthy meals; 3) Get plenty of sleep - try to turn off screens at least 1 hour before bedtime and get between 7 and 9 hours of sleep every night; 4) Work on time management and organization - prioritize time-sensitive tasks and write down assignments, messages, appointments, and important thoughts; 5) Connect with people and maintain relationships - schedule activities with friends, particularly supportive people who understand your challenges with ADHD; and 6) Take medications as directed, and avoid the use of alcohol, tobacco, and drugs.

Hopefully, you or people near you don't have it; but if someone does – I wish that person may get adequate help. Please remember that ADHD has many differential diagnoses, so if it's not ADHD, I hope that person may get good help/support.

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