INA-RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

NEWSLETTER

September 2021

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Mixing COVID-19 Vaccines: A Promising Yet Challenging Strategy to The Pandemic Exit

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MINISTRY OF HEALTH REPUBLIC OF INDONESIA
2021

MASTHEAD

INA-RESPOND newsletter

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THANK YOU

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INA-RESPOND Newsletter

TRIPOD, PROACTIVE, & ORCHID Study Updates

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

STUDY UPDATES

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Per 06 May 2021, all 490 enrolled participants in the TRIPOD study have finished the study. Two hundred and fifty-four participants have completed the study while 236 participants are terminated early (including death). From the uploaded CRFs, all participants from sites 520, 550, 560, 570, 580, 590, and 600 have been completed the study. The Source Document Worksheet has completed upload from sites 520, 550, 560, 570, 580, 590, and 600.

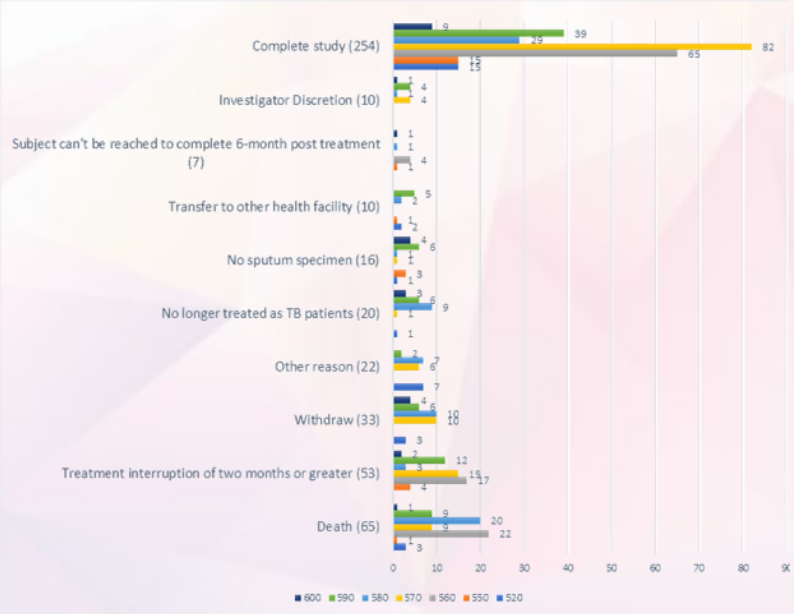
The database Quality assurance (except for TB Treatment pages) has been conducted for sites 520, 550, 560, 570, 580, 590, and 600. The Quality Assurance of critical fields for site 580 was conducted on 19 Jul – 18 August 2021 and the Quality Assurance for subject random was conducted on 20 August – 13 Sep 2021.

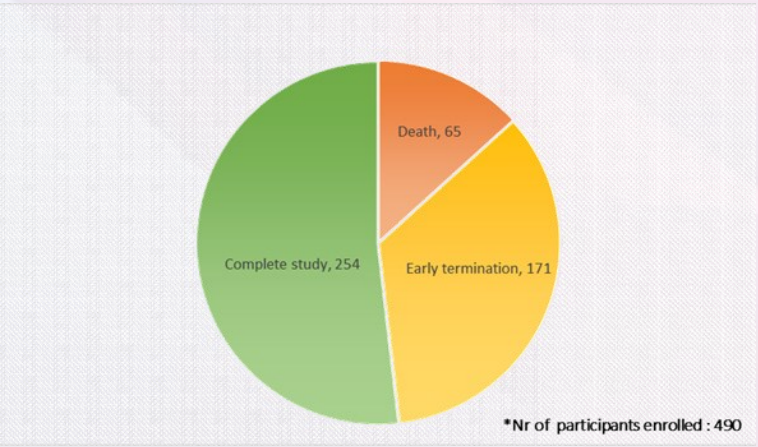
The Site Close-out Visit (SCV) was conducted for site 520 on 30 November – 1 December 2020, site 570 on 15-16 December 2020, site 590 on 19-20 January 2021, site 560 on 20-21 April 2021, site 550 on 22-23 June 2021, and site 600 on 20-21 Jul 2021. All Site Close-out Visit (SCV) action items from site 520, 570, 590, 560, and 550 have already been resolved. The upcoming SCV will be conducted at site 580 on 14-15 September 2021. All essential documents, CRF, SDW and laboratory test results are available in the EDMS for all sites. The study documents from these sites will be archived at IndoArsip for long term archival, at least 5 years after the study is closed.

The INA-RESPOND secretariat has announced an official letter and a final report on site closure to the hospital director and the local ethics commission. For sites 520, 570, 590, they were reported on 14-Apr 2021 and for site 560 on 18 May 2021. This procedure will be done for site 550, 600, and 580 as soon as the SCV is completed at each site.

The TRIPOD isolates were sent to Central Laboratory in Padjajaran University, Bandung on 12 April 2021 for subculture. Subculture will be prepared for several tests regarding TB, including TB strain examinations, which is one of the TRIPOD secondary objectives. Out of the 301 isolates sent, 54 were subcultured. Unfortunately, 3 of them did not grow. A total of 38 from 51 isolates that grew have been successfully extracted to obtain the DNA.

Per protocol, there are 8 types of specimens collected on TRIPOD study for future use. Status for repository specimens is provided in figure 4.





Site	Site Closed Out Visit	Current Status/Awaiting Items
520 (n=32)	Done, 30 November – 1 December 2020	Study documents has been sent to Indo Arsip
550 (n=25)	Done, 22-23 June 2021	• Final report has been finalized, the cover letter will need to be fully signed by the Head of Centre 2, NIHRD. • Study document still being prepared by the local RA, then all study documentations will be sent to INA-RESPOND for inventory purpose.
560 (n=108)	Done, 20-21 April 2021	• Study documents has been sent to Indo Arsip • DST result for 1 subject
570 (n=128)	Done, 15-16 December 2020	Study documents has been sent to Indo Arsip
580 (n=83)	Planned, 14-15 September 2021	SCV preparation but not limited to QA Process by DM, File Review by CRSS and Specimen Management Review by CRA
590 (n=89)	Done, 19-20 January 2021	Study documents has been sent to Indo Arsip
600 (n=25)	Done, 21-22 July 2021	• Final report has been finalized, the cover letter will need to be fully signed by the Head of Centre 2, NIHRD. • Study document still being prepared by the local RA, then all study documentations will be sent to INA-RESPOND for inventory purpose.

Site	Specimen Type	Whole blood (EDTA) - DNA	Whole blood (Heparin) - PBMCs	Whole blood (Heparin) – Plasma	Whole blood (PAXgene) - RNA	Urine	Saliva	Sputum	MTB Isolate
520 (n=32)	**BL (32)**	90	22	91	27	125	62	19	36
	M1 (24)	NA	18	64	21	99	NA	16	12
	M2 (24)	NA	22	68	24	93	NA	11	0
	EOT (15)	NA	28	45	15	60	30	2	0
560 (n=108)	**BL (108)**	382	204	328	102	440	216	131	272
	M1 (95)	NA	188	285	94	381	NA	107	60
	M2 (87)	NA	172	261	86	348	NA	91	20
	EOT (73)	NA	142	219	73	292	146	75	20
570 (n=128)	**BL (128)**	438	177	380	121	519	254	119	192
	M1 (104)	NA	162	311	103	416	NA	43	92
	M2 (97)	NA	162	294	98	392	NA	22	38
	EOT (80)	NA	162	243	81	320	160	4	12
580 (n=83)	**BL (83)**	235	130	210	67	308	147	26	42
	M1 (44)	NA	70	102	38	156	NA	18	6
	M2 (38)	NA	54	81	36	148	NA	16	0
	EOT (29)	NA	50	71	27	124	61	8	0
590 (n=89)	**BL (89)**	340	170	255	84	344	147	78	55
	M1 (59)	NA	98	147	49	196	NA	17	8
	M2 (56)	NA	80	120	41	164	NA	8	0
	EOT (40)	NA	46	72	24	96	46	9	0
600 (n=25)	**BL (25)**	100	50	75	25	100	50	50	30
	M1 (13)	NA	26	39	13	52	NA	26	4
	M2 (11)	NA	22	33	11	44	NA	22	4
	EOT (9)	NA	20	30	10	40	20	20	0
550 (n=25)	**BL (25)**	95	48	72	24	100	51	10	27
	M1 (20)	NA	36	54	19	68	NA	7	7
	M2 (20)	NA	36	54	17	72	NA	6	4
	EOT (15)	NA	26	39	13	52	25	0	2

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According to the data on 24 September 2021, from the 4,336 subjects enrolled, 701 subjects have ended their participation (End of Study) due to the following reasons: 427 subjects completed the study, 175 subjects died, 40 subjects moved away to the city where no PROACTIVE site is available, 30 subjects withdrew, 17 subjects were lost to follow up, and 5 subjects have negative HIV test result. As of 24 September 2021, there are 3,635 active subjects in this study. Below is the Chart of Enrolled and Active Participants per Sites:

Meanwhile, Onsite SMV (Site Monitoring Visit) was conducted at Site 640 (St Carolus Hospital) on 14-16 September 2021.

No	Site# / Name	1st Enrollment	Enrollment stop	# Enrolled			Active Participants (%)	
				Ped	Adult	Total		
1	510 – Hasan Sadikin	7-Feb-19	31-Dec-19	10	198	208	201	96,63
2	520 – Sanglah	7-Nov-19	30-Jun-20	5	138	143	142	99,30
3	530 – Cipto M.	3-May-18	31-Aug-19	36	274	310	238	76,77
4	540 – Sulianti Saroso	25-Feb-19	31-Dec-19	20	162	182	176	96,70
5	550 – Wahidin	14-Mar-18	31-Aug-19	10	327	337	236	70,03
6	560 – Kariadi	14-Aug-18	31-Aug-19	12	218	230	198	86,09
7	570 – Soetomo	26-Apr-18	31-Aug-19	6	307	313	199	63,58
8	580 – Sardjito	14-Sep-18	30-Sep-19	4	216	220	216	98,18
9	590 – Persahabatan	19-Jul-18	31-Aug-19	10	239	249	218	87,55
10	600 – Adam Malik	12-Mar-18	31-Aug-19	2	336	338	241	71,30
11	610 – Tangerang	10-Jan-18	31-Aug-19	17	310	327	208	63,61
12	630 – Ansari Saleh	17-Jul-18	31-Aug-19	9	236	245	202	82,45
13	640 – St. Carolus	13-Aug-18	30-Sep-19	0	225	225	221	98,22
14	650 – Budi Kemuliaan	2-Aug-18	31-Aug-19	4	225	229	203	88,65
15	660 – AW Sjahranie	3-Oct-18	30-Sep-19	17	205	222	216	97,30
16	670 – Zainoel Abidin	9-Apr-19	31-Dec-19	5	121	126	115	91,27
17	680 – Soedarso	4-Jul-19	31-Dec-19	8	107	115	107	93,04
18	690 – Abepura	2-Jul-19	30-Jun-20	4	133	137	129	94,16
19	700 – TC Hilers	8-Jul-19	30-Jun-20	10	170	180	169	93,89
Total				189	4147	4336	3635	86,78

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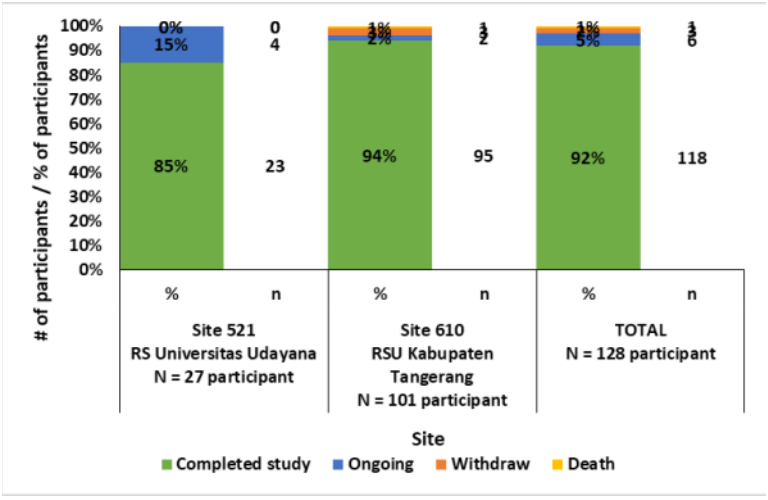
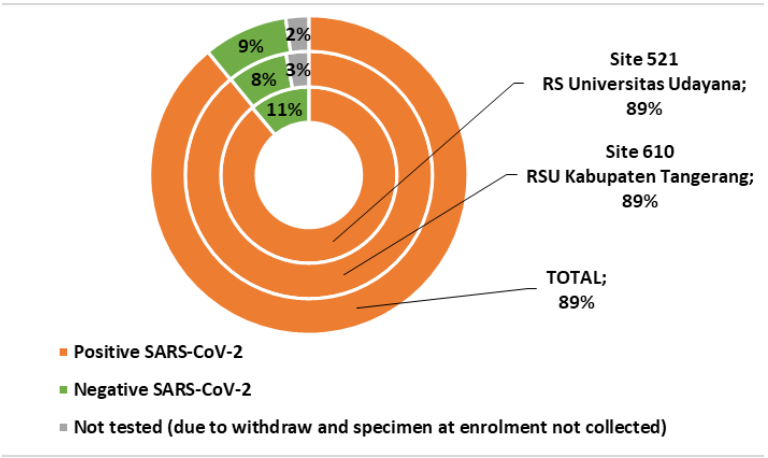
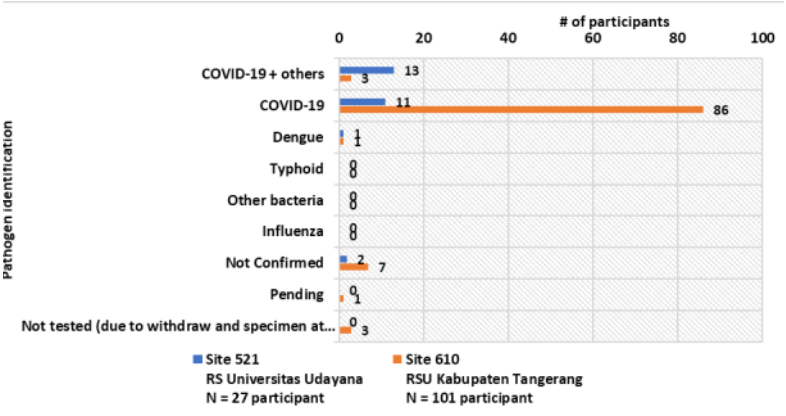
Based on uploaded CRFs, as of 7 September 2021 a total of 121 participants were enrolled in ORCHID study, which consisted of 101 participants from site 610 (RSU Kabupaten Tangerang, Tangerang) and 27 participants from site 521 (RS Universitas Udayana, Denpasar). 118 participants (92%) already completed this study, 1 participant passed away during the study, 3 participants withdrew, and 6 participants are still ongoing with the study (figure 1).



Up to 7 September 2021, a total of 114 participants (89%) were identified as positive SARS-CoV-2, and only 11 participants (9%) identified as negative SARS-CoV-2. 3 participants were not tested due to withdrawal. In site 610, the number of participants identified as positive SARS-CoV-2 was 90 participants (89%), 8 participants as negative SARS -CoV-2, and 3 participants were not tested due to withdrawal. While in site 521, there were 24 participants (89%) identified as positive SARS-CoV-2 and 3 participants (11%) identified as negative SARS-CoV-2 (figure 2).



Based on pathogen identification data, in site 521, 13 participants (48%) pathogen identified as COVID-19 with others and 11 participants (41%) were identified as COVID-19 only. While in site 610, 86 participants (85%) pathogen identified as COVID-19 only, following 3 participants (3%) identified as COVID-19 with others. Within 9 participants not confirmed for any pathogen, 2 participants were in Site 521 and 7 participants were in site 610. Only one participant was identified a single infection of Dengue in both sites. One participant in site 610 was still pending due to waiting for other lab test results and examination cannot be performed for 3 withdrawn participants (figure 3).



Ethical approval from NIHRD IRB was notified to Site Udayana. Site Udayana has started to continue its enrolment since August 24th, 2021. Meanwhile, the newest document approved by NIHRD IRB was submitted to the local Tangerang IRB on August 26th, 2021. The new Research Assistant (RA) at Site 610 (Tangerang) conducted the training on 6 and 8 September 2021; the RA will be involved in the study after the registration documents are completed i.e., GCP certificate, hospital ID card.

INA-RESPOND Newsletter

SITE 521: RS UNIVERSITAS UDAYANA, BALI

By: Ni Made Tika Herayanti

Udayana University Hospital was born from the need for a medical education vehicle for Udayana University Medical Students and other health workers within Udayana University. Udayana University Hospital is located at Jalan Hospital Unud No. 1 Jimbaran – Badung, Bali. It is about 16 km from Sanglah Hospital and can be reached in about 30 minutes by car. Built on an area of 41,000m2 starting in 2010, Udayana University Hospital started operating in 2013 by opening health services for the general public as a first-level health service provider. In 2018 it improved its operational status to Type C Hospital with four major services including Obgyn, Pediatric, Surgery and Internal Medicine.

Udayana University Hospital was selected as one of the 11 referral hospitals for COVID-19 patients in Bali. It is also one of the active sites (Site 521) for Orchid Study. It is expected that by participating in this INA -RESPOND study, Udayana University Hospital can gain experience and knowledge in conducting health research for the development of science

and can participate in more health research in the future. So far, the study process at Site 521- Udayana University Hospital has been running fluently from the screening and enrollment process until End of Study. Some of the problems that we have on the site are immediately conveyed to the secretariat, and we receive good responses and solutions for them. We have a very solid team that helps the research process running fluently. The following are some brief introductions for our team members:

Principal Investigator

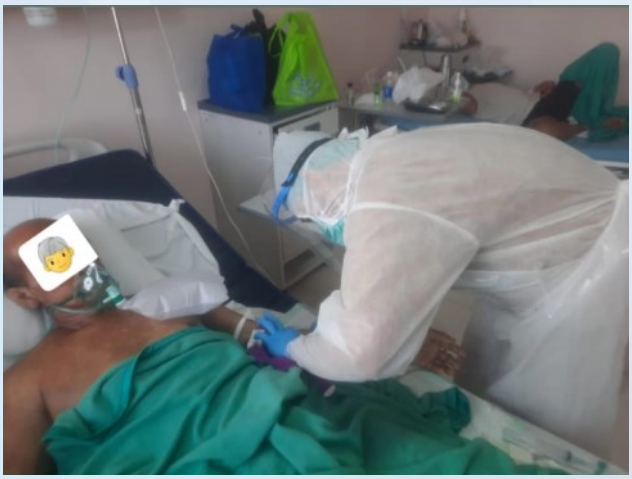
dr. Cokorda Agung Wahyu Purnamasidhi, M. Biomed, Sp.PD, FINASIM was born on 4 April 1985. dr. Cok Wahyu, who is an Internist graduated from Udayana University, is the Principal Investigator of the Orchid study. He is friendly and humorous, which makes it easier for us to communicate and discuss study-related issues with him.

Co-Principal Investigator 1

Dr. dr. Ni Kadek Mulyantari, Sp.PK(K) was born on April 26, 1979. dr. Kadek is a clinical pathology specialist at Udayana University Hopital and a Co-Principal Investigator of the Orchid study. She is very friendly, therefore, she is liked by many people.

Co-Principal Investigator 2

Dr. dr. I Ketut Agus Somia, SpPD, K-PTI, FINASIM was born in Denpasar 1968. He is an Internist Consultant for Tropical Diseases and Infections, Internal Medicine Department FK UNUD. Known for being friendly and humble, he has a unique hobby of filling his spare time with painting.



Ns. N P Arysta Kusuma Dewi, S.Kep, the research nurse, is taking sample from a study participant

Research Assistant 1

dr. Ni Made Suandewi born in December 1985, dr. Suandewi a.k.a dr. Suan, is the first RA from Site 521. She is 35 years old and has a lot of experience in various studies. Her hobbies are cooking and watching movies.

Research Assistant 2

Ni Made Tika Herayanti, S.KM a.k.a Tika Hera is the 2nd RA of Site 521. She is fully dedicated to the Orchid study. Born in January 1992, she is a graduate of public health from Udayana University. Her hobbies are cooking and cycling. Being well-connected with dr. Suan has made it easy for her to communicate in this Orchid Study.

Laboratory Technician 1

Ni Nyoman Triyani, Amd. AK is a Laboratory Staff at Udayana University Hospital. She is a Diploma III graduate from *Politeknik Kesehatan Denpasar*. She was born in 16 April 1992. She is very friendly and has good expertise in taking samples from patients.

Laboratory Technician 2

Kadek Ayu Lestariani, Amd.AK is a Laboratory Staff at Udayana University Hospital. She is a Diploma III graduate from *Politeknik Kesehatan Denpasar*. She was born on 17 January 1994. She has many experiences with patients, so she is an expert in taking samples from patients.

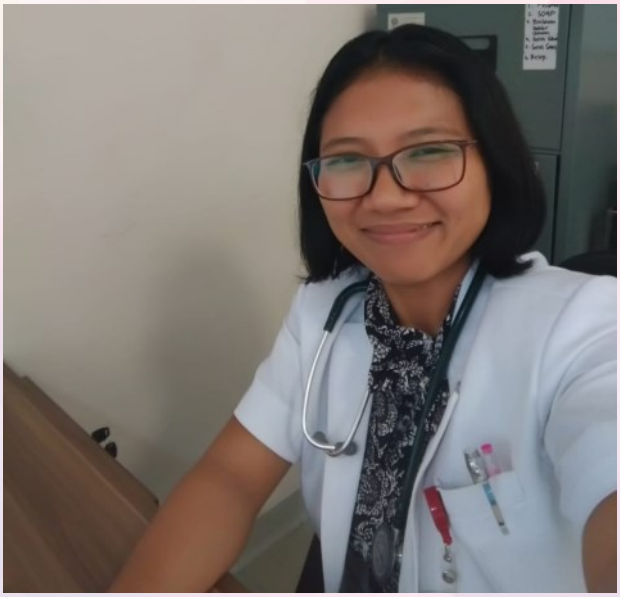
Laboratory Technician 3

I Gusti Lanang Agung Yoga Santika, S.Si is a Head Laboratory Staff at Udayana University Hospital. He graduated from Indonesian Hindu University. Born on 22 April 1991, he is very friendly and has a good expertise in running the equipment and supervising the implementation of sample inspection.

Research Nurse

Ns. N P Arysta Kusuma Dewi, S.Kep is a nurse who heads the inpatient care at Udayana University Hospital. She helps provide information on patients who will be participating in the research.




From left to right, top to bottom:

dr. Cokorda Agung Wahyu Purnamasidhi, M. Biomed, Sp.PD, FINASIM; Dr. dr. Ni Kadek Mulyantari, Sp.PK(K); Dr. dr. I Ketut Agus Somia, SpPD, K-PTI, FINASIM

dr. Ni Made Suandewi; dr. Ni Made Tika Herayanti, S.KM; Ns. N P Arysta Kusuma Dewi, S.Kep

Lab Technicians team (I Gusti Lanang Agung Yoga Santika, S.Si, Ni Nyoman Triyani, Amd. AK; Kadek Ayu Lestariani, Amd.AK)

INA-RESPOND Newsletter

SCIENCE CORNER

MIXING COVID-19 VACCINES: A PROMISING YET CHALLENGING STRATEGY TO THE PANDEMIC EXIT

By: Adhella Menur, Izhar Muhammad Arif

A: "Hey, where are you from?"

B: "Indonesia"

A: "Ah, Sinovac?"

B: "Yeah, where are you from?"

A: "United States"

B: "Ah, Pfizer?"

A: "Nope, Moderna"

For almost two years, we have fought against the SARS-CoV-2, and the conversation above may be familiar nowadays. Various COVID-19 vaccine platforms have been rolled out and got emergency use approval. Ranging from the whole inactivated viral platforms (Sinovac-CoronaVac, Sinopharm), adenovirus vectored platforms (ChAdOx1-S nCoV-19/ AstraZeneca, Janssen, Sputnik-V, CanSino), to the prestigious one; mRNA platforms (BNT162b2/Pfizer and mRNA-1273/ Moderna). Most of them (except Janssen) need two-dose which provided high efficacy (50-95%) and are believed to prevent severe COVID-19 in the real-world setting.1 Hence, every country around the world gives their best effort to vaccinate their civils. Up to the end of September 2021, more than 6.12 billion doses have been administered across 184 countries. The latest jab rate was around 29.1 million doses a day, enough to fully vaccinate 39.8% of the global population.2

The world started COVID-19 vaccination around December 2020 and January 2021. While the public is excited to see the end of the pandemic, the governments and scientists face the complexity of vaccine issues. First, even with the robust vaccines' development, production, and distribution; shortages and delay still occur. Those might result in delayed administration of the second dose. Second, as vaccine post-marketing covered communities as a whole with a more variable population, a new safety issue may arise. Some people may have serious adverse events after the first vaccination, such as anaphylaxis and other rare events of thrombosis with thrombocytopenia syndrome (TTS) related adenovirus-vector vaccine, changed vaccine policies in some countries. Third, the more updated knowledge about vaccine immunogenicity opens a wider horizon. Special population such as immunocompromised patients have a difficulty to mount the expected immune response. Immunogenicity in response to adenovirus-vectored vaccines is limited by pre-existing neutralizing antibodies to common adenovirus serotypes to which humans are exposed, and may compromise the ability to mount an immune response to the SARS-CoV-2 spike protein. Moreover, subsequent doses in adenovirus-vectored vaccines also have a risk of developing an immune response against the adenovirus vector, thereby dampening its effectiveness. Finally, the immune response from vaccination wanes faster than expected, along with the emerging variants of concern that give a new nightmare. As a result, several breakthrough infections and a surge of cases have been reported.3

Mixing or giving heterologous COVID-19 vaccines bid the potential answers to those issues. Scientists think that combining different vaccine platforms could strengthen immune responses by optimizing the best features of each, and it is likely tolerable. Royal Melbourne Institute of Technology (RMIT) vaccine researcher Dr Kylie Quinn has described Covid-19 vaccines as vehicles delivering cargo – the vehicles may be different, and they may drop off their payloads by different means, but the spike protein cargo is the same. Because the cargo is similar, the vaccines should, in theory, work well together. Mixing vaccines has been practically used for multiple infectious diseases, including HIV, malaria, Ebola, and

influenza. The trial of mixing vaccines in the Ebola vaccine showed safety and long-lasting immunity. The first dose of the Ebola vaccine used the same adenovirus vector as in the AstraZeneca COVID-19 vaccine, while the second dose used a Modified Vaccinia Ankara vector (modified poxvirus). It has shown that mix and match vaccination is feasible in low-income and middle-income countries. Sputnik-V adopted the strategy using a recombinant adenovirus 26 and 5 vector based heterologous prime–boost COVID-19 vaccine, and showed 91.6% efficacy in a phase 3 trial.3,4,5

In mixing COVID-19 vaccines strategy, the purposes are to elicit higher and broader protective immune responses (both humoral and T cell responses), provide better efficacy to combat COVID-19 variants, and improve safety profile. Humoral responses, specifically neutralizing antibodies (NAbs), are believed to prevent viral infection and correlate with clinical protection. Besides NAbs, innate immunity, a robust cytotoxic CD8 + T cell response, and a TH1 cell-biased CD4 + T cell effector response protect against severe disease by killing cells that have already been infected. Currently available vaccines are effective against COVID-19, but their underlying immune mechanisms seem to be different. For example, mRNA vaccines produce extremely high neutralizing and binding antibody titers, but the CD8 + T cell responses are relatively not remarkable. In contrast, adenovirus-vectored vaccines elicit lower neutralizing and binding antibody levels but produce polyclonal antibodies after vaccination and potent T cell responses with the production of TNF and IFNγ from CD4 + T cells. Thus, mixed vaccination may elicit the immunological benefits of different platforms, similar to what occurs in COVID-19 survivors who receive a vaccination known as 'hybrid vigour immunity,' a phenomenon that happened as a combination of natural immunity and vaccine-generated immunity. The concept of 'hybrid vigour immunity' is derived from plants. When different plant lines breed together, the hybrid line produces a stronger plant. Furthermore, it is observed that pre-existing trained innate cells and antibodies to the same vaccine and adjuvant tend to impair antigen presentation in individuals who receive

No	Study name/ authors/ country/ participants	Vaccine combination and group	Humoral immune response	Cellular immune response	Impact on the variants of concern	Safety Issues
1	CombiVacS/ Borobia et al./ Spain/ randomised, phase II trial, n=663	Trial arm: Prime: ChAdOx1 nCoV-19 Boost: Pfizer-BNT162b2 Control arm: received only one dose and not received any second dose of vaccine	- SARS-CoV-2 anti-RBD at day 14 after mixed booster	- Functional spike-specific T-cell response at day 14 after mixed booster	Not evaluated	Similar in both groups (mild to moderate)
2	Groß et al./ Germany/ prospective, observational study, n=26 [pre-print]	Prime: ChAdOx1 nCoV-19 Boost: Pfizer-BNT162b2 No control group	- Neutralizing antibodies 2 weeks after mixed booster	- Functional spike-specific T-cell response 2 weeks after mixed booster	Good neutralising activity against B.1.1.7 after mixed booster	Similar in both groups (mild to moderate)
3	Com-COV trial/ Shaw et al./ UK/ participant-blind, randomised, non-inferiority phase II trial, n=830	Trial arm: Arm 1: Prime: ChAdOx1 nCoV-19 Boost: Pfizer-BNT162b2 Arm 2: Prime: Pfizer-BNT162b2 Boost: ChAdOx1 nCoV-19 Control arm: Homologous schedules Arm 1: Prime and boost: Pfizer-BNT162b2 Arm 2: Prime and boost: ChAdOx1 nCoV-19	- SARS-CoV-2 anti-spike IgG and neutralizing antibodies at day 28 after mixed booster	- Functional spike-specific T-cell response at day 28 after mixed booster	Not evaluated	Greater systemic reactogenicity in mixed booster

4	EICOV-COVIM Study/ Hillus et al./ Germany/ prospective, observational study, n=380	Arm 1: Prime: ChAdOx1 nCoV-19 Boost: Pfizer-BNT162b2 10–12 weeks apart Arm 2: Prime and boost: Pfizer-BNT162b2	- Neutralizing antibodies and S1-IgG avidity 3 weeks after mixed booster	- Functional spike-specific T-cell response 3 weeks after mixed booster	Good neutralising activity against Alpha and Beta variants after mixed booster	- Local reaction in mixed booster. No potentially life-threatening event
5	Benning et al./ Germany/ prospective, observational study, n=166	1. Prime and boost: ChAdOx1 nCoV-19 2. Prime and boost: Pfizer-BNT162b2 3. Prime: ChAdOx1 nCoV-19 Boost: Pfizer-BNT162b2	- SARS-CoV-2 anti-S1 IgG and neutralizing antibodies after mixed booster	Not evaluated	Not evaluated	Reactogenicity among mixed booster more bearable than homologues group
6	Normark et al./ Sweden/ prospective, observational study, n=88	1. Prime and boost: ChAdOx1 nCoV-19 2. Prime: ChAdOx1 nCoV-19 Boost: Moderna-mRNA-1273	- SARS-CoV-2 anti-spike and RBD IgG antibodies at day 7-10 after mixed booster	Not evaluated	Good neutralising activity against B.1.351 after mixed booster	- Frequent reports of fever, headache, chills, and muscle aches in mixed booster
7	Barros-Martins et al./ Germany/ prospective, observational study, n=87	1. Prime and boost: ChAdOx1 nCoV-19 2. Prime: ChAdOx1 nCoV-19 Boost: Pfizer-BNT162b2	- SARS-CoV-2 anti-spike IgA and IgG antibodies after mixed booster	- Functional spike-specific T-cell response after mixed booster	Good neutralising activity against B.1.1.7, B.1.351. and P.1 after mixed booster	Not evaluated
8	Wanlapakorn et al./ Thailand/ cross sectional study, n=236 [pre-print]	1. Prime and boost: CoronaVac 2. Prime and boost: ChAdOx1 nCoV-19 3. Prime: CoronaVac Boost: ChAdOx1 nCoV-19	- SARS-CoV-2 anti-spike RBD IgG and neutralising antibodies after mixed booster	Not evaluated	Good neutralising activity against B.1.1.7 and B.1.351 mixed booster	Not evaluated
9	Kant et al./ India/ cross sectional study, n=98 [pre-print]	1. Prime and boost: Covaxin (whole inactivated viral) 2. Prime and boost: CoviShield (India version of AstraZeneca) 3. Prime: CoviShield Boost: Covaxin	- SARS-CoV-2 anti-S1-RBD IgG, anti-N, and neutralising antibodies after mixed booster	- Cytotoxic T activity in the CoviShield and mixed booster group	Good neutralising activity against Alpha, Beta, Delta variants after mixed booster	Similar in both groups. None of the participants enrolled in the study had any serious adverse event
10	Li et al./ China/ a randomized, controlled, observer-blinded trial, n=300 [pre-print]	1. Prime and boost: Convidecia (Cansino) 2. Prime: CoronaVac (one dose and full dose) Boost: Covaxin	- SARS-CoV-2 anti-RBD IgG, anti-N, and neutralising antibodies at day 14 after mixed booster	- Th1 cellular immune responses	Not evaluated	- Local reaction in mixed booster. The adverse reactions were generally mild to moderate

homologous boosters. Conversely, when an unrelated heterologous vaccine is administered, trained innate cells, hematopoietic stem, progenitor cells, and resident memory T cells may produce subsequent robust responses of naïve cells via epigenetic reprogramming.6

AstraZeneca's ChAdOx1 nCoV-19 (ChAd) vaccine rare TTS triggered a temporary cessation of its use in several European countries. It is followed by the recommendation of the UK that people younger than 40 y.o should seek an alternative vaccine by May 2021. Germany took a brave yet brilliant step to boost persons under 60 y.o who got the ChAd as the first vaccination with an mRNA vaccine (Pfizer or Moderna). An observational investigation of the event by Schmidt et al. in 96 healthy adult individuals showed that the heterologous vaccine led to a strong induction of both antibodies and T cells. IgG levels were similar in magnitude to those following homologous mRNA vaccination, and approximately tenfold higher than those after homologous vector vaccination.7 Emerging immunogenicity studies indicate robust immune responses after heterologous vaccines in adults receiving ChAd/mRNA vaccines against variants of concern in adults.8 That's because people mounted the adequate T cell responses to the mutated version of the virus despite some loss of epitopes. It is along with high neutralizing antibodies titers providing a significant extra layer of protection against disease.8 More extensive trials and long-term monitoring for the benefits and side effects in mixing COVID-19 vaccines are urgently needed.

Fully vaccinated person is a person who has received his/her first 2 vaccinations (full dose) or "prime-boost" course. The implementation of a third dose of COVID-19 booster is likely to happen in the future to provide added protection. In Israel, a national third-dose of COVID-19 booster campaign initiated per August 24, 2021 for those aged 30 and over as well as for high-risk populations with homologue vaccine (Pfizer-Biontech). In England, since May 2021, the COV-BOOST study, led by University Hospital Southampton UK-NHS (National Health Services) Foundation Trust and the government's Vaccines Taskforce, started a trial of seven different COVID-19 vaccines as potential third-dose COVID-19 boosters. Vaccines being trialled include Oxford/AstraZeneca, Pfizer/BioNTech, Moderna, Novavax, Valneva, Janssen, and CureVac. It will give scientists from around the globe and the experts behind the UK's COVID-19 vaccination program a better idea of the impact of a booster dose of each vaccine in protecting individuals from the virus. In early September 2021, the COV-BOOST investigators reported the unpublished interim report from the study to JCVI (The Joint Committee on Vaccination and Immunisation) regarding the UK third dose COVID-19 booster program. JCVI advises that those living in residential care homes for older adults, all adults aged 50 years or over, frontline health and social care workers, all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19, and adult household contacts (aged 16 or over) of immunosuppressed individuals should be offered a third dose COVID-19 booster vaccine. The JCVI advises a preference for the Pfizer-BioNTech vaccine for the booster program, regardless of which vaccine brand someone received for their primary doses due to its well-tolerated profile and provides a strong booster response. Alternatively, clinicians may offer a half dose of the Moderna vaccine. If the mRNA vaccines cannot be offered due to allergies, the Oxford-AstraZeneca vaccine may be considered for those who received it previously.[19,20]

Early August 2021, Indonesia Ministry of Health decided to give the third vaccination dose or booster with mRNA vaccine platform (Moderna) for fully Sinovac vaccinated health-workers as the front liner in the COVID-19 pandemic. Approximately 900,000 from total 1,5 million health workers (60%) already got the Moderna booster. Indonesia National committee of Immunization Adverse Events reported that the adverse events in Moderna booster were more pronounced than Sinovac administration before. The most common adverse events are pain and tenderness at the injection site, fever, and fatigue. The reactions were usually mild or moderate. No serious adverse event has been reported.[21] A small observation in four naïve health workers (no history of COVID-19) who received two doses of Sinovac in March 2021 and were boosted with Moderna in early August 2021 revealed an interesting result. Using chemiluminescence immune assay (CLIA) serology platform, the median IgG S-RBD before booster was 17,1 (2-163,2) U/mL. Two weeks

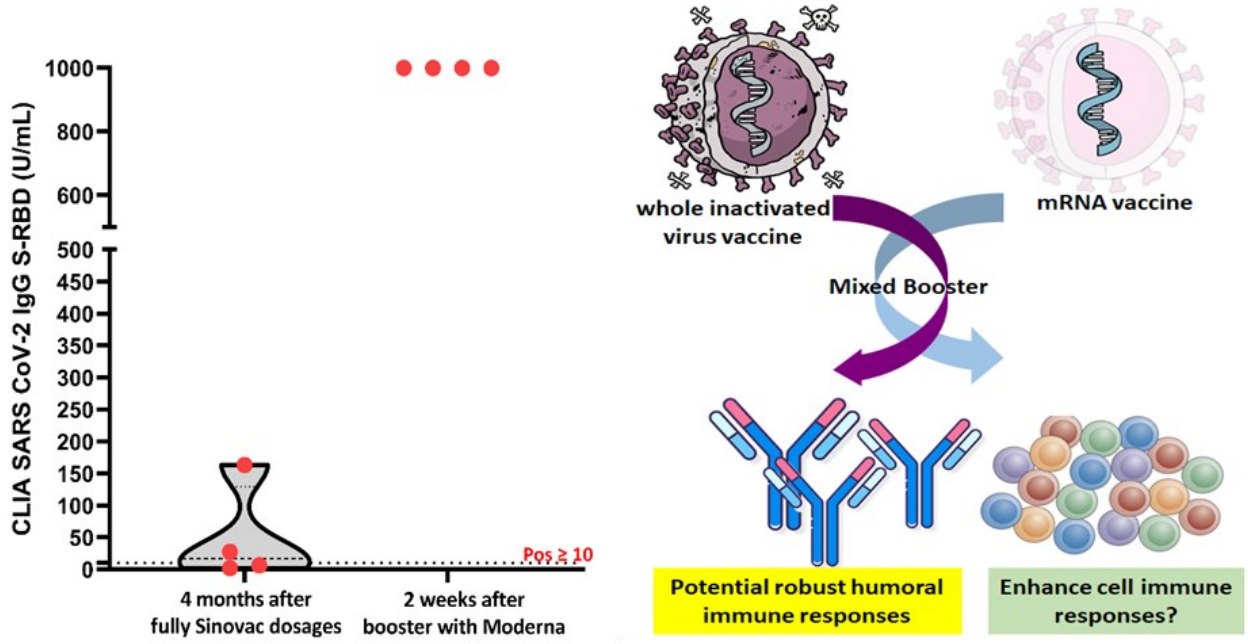


Figure 1. Violin plot of SARS-Cov-2 IgG S-RBD from four persons before and after Moderna booster (acknowledged to the INA-RESPOND Reference Laboratory Team for the testing)

after Moderna booster, the antibodies response significantly increased to the maximum assay detection limit for all subjects (unpublished data). International study on COVID-19 Vaccine to assess Immunogenicity, Reactogenicity and Efficacy (InVITE) is a collaborative study lead by the National Institute of Allergy and Infectious Diseases (NIAID) in six countries around the globe. This study will assess the COVID-19 vaccine immunogenicity and durability, and severe acute respiratory syndrome coronavirus -2 (SARS-CoV-2) infections in people who receive a COVID-19 vaccine through their country's national vaccination programs. Indonesia through INA-RESPOND also participates in the study, where the health-workers who got Moderna booster after Sinovac fully vaccine dosages will be enrolled. It will be interesting to see the results and give the beneficial information to the world.

Despite of all promising results of mixing vaccines, the lingering possibility of the rare side effects is one of the reasons why some scientists still recommend to stick with the homologous plan. Combining two different vaccines, both of which might have their own profile of adverse events and effects, could amplify any problems. The studies so far have enrolled only a few hundred people. This means that they are too small to pick up rare events such as the clotting conditions or any others.

The number of people who are immune to the SARS-CoV -2 is increasing every day. This includes people getting vaccinated and, unfortunately, a lot of people getting COVID-19. Some countries reported good news about the decline of COVID-19 cases, while others still struggle to combat this virus. The emergence of new variants and the in-equality of COVID-19 vaccines also shadowing our population's effort to build enough immunity. Scientists are still endeavouring to find a way out to exit this pandemic, and mixing vaccines might be one of the promising ways.

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Important Announcement!

The **Network Steering Committee (NSC) meeting** will be held on the first week of October (6-7 October 2021) at J.S. Luwansa Hotel, Kuningan, Jakarta. This NSC meeting will be the first one we have after a couple of years of online meetings. Surely, all participants are expected to follow and adhere to the applicable health protocols to keep everyone safe.

INA-RESPOND Newsletter

FROM OUR PARTNER

INTRODUCTION TO GOOD PARTICIPATORY PRACTICES

By: Yvette Delph, MBBS, DA

The goal of good participatory practices (GPP) is to strengthen and facilitate quality research that meets local needs. It makes research better through respectful, meaningful engagement with stakeholders.

What is GPP?

GPP is a process that involves building collaborative partnerships between researchers and stakeholders. It is not just an informational campaign or one-way communication. There is no single approach to GPP; it is different for each study. GPP depends on the country and community setting and must addresses differences in cultures and communities.

GPP applies across research types and settings and at all stages of research. It starts during pre-trial planning and goes through dissemination of study results.

Why is GPP Important?

GPP makes research more acceptable and relevant to the communities in which it is conducted. Through respectful stakeholder engagement, GPP demonstrates understanding and appreciation, builds trust, and empowers communities. With increased knowledge and understanding of research processes, stakeholders are able to contribute more effectively to the process of guiding research. Their input strengthens the design, acceptability, and quality of research, including considerations such as feasibility assessments for site selection and use of trial procedures that are culturally sensitive and appropriate. It also strengthens the alignment of the research questions and approach with the collaborating population's priorities.

GPP helps ensure that the power imbalance between research teams and community stakeholders is addressed.

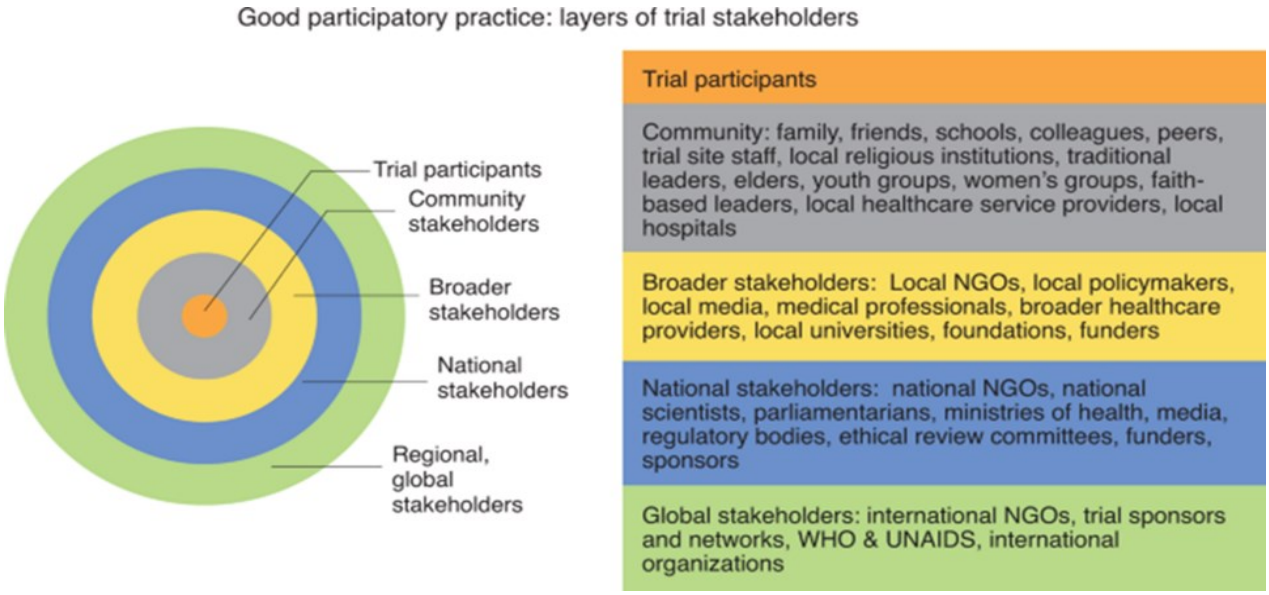

Figure 1. The multiple layers of stakeholders in clinical research center on the trial participants. Researchers often pay too much attention to the two outer circles and not enough to the three inner circles. NGOs, non-governmental organizations; WHO, World Health Organization; UNAIDS, Joint United Nations Programme on HIV/AIDS. From Nat Med 27, 369–371 (2021) https://doi.org/10.1038/s41591-021-01271-3 that was adapted from UNAIDS/AVAC 2011.

Figure 2. The basic principles of GPP are essential to respectful, meaningful engagement with stakeholders that builds mutual understanding and trust.

It may heighten the sensitivity of research staff to the needs of marginalized populations and guard against reinforcement of inequalities that already exist.

GPP can strengthen recruitment and informed consent processes, identify and minimize physical or social risks (e.g., stigma) that may result from enrollment, and improve recruitment, retention, adherence, and data quality. It promotes successful research conduct and increases the likelihood that trial results will be disseminated and implemented in communities with greater uptake of proven products and interventions. GPP can strengthen trust and increase the credibility of researchers, with implications for current and future research.

Mechanisms for Stakeholder Engagement

Before the study starts, it is important to develop a stakeholder engagement plan that maps different stakeholder groups in communities where the study will be implemented and proposes consultations with key groups. Throughout the process, utilize a variety of channels to communicate and engage effectively using local languages and clear wording. All stakeholders should have an opportunity to learn, raise concerns, and provide input into study planning and implementation. This may require formation of a Community Advisory Board (CAB) if none exists.

Figure 3. Actively maintain communication channels and honor GPP principles to build collaborative partnerships with stakeholder groups.

Enable stakeholder contributions and build local capacity. Keep track of community priorities and concerns raised, and if and how they have been responded to by the research team. Carefully plan and follow through with collaborator agreements.

The mutual understanding and trust built through collaborative partnerships with stakeholders will pay dividends in facilitating quality research that addresses local needs.

Further Reading

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INA-RESPOND Newsletter

KEEPING IT SANE IN AN INSANE TIME

By: Caleb Leonardo Halim

The COVID-19 pandemic has struck the world for almost 2 years, and to date there is no effective treatment for this infection. Various prevention measures such as frequent hand washing, keeping physical distance, and wearing face masks have been widely implemented. For most countries, implementing lockdown is one of the policies.[1]

The consequence of the disruptive routine changes due to the COVID-19 pandemic is experienced by most individuals. Some common impacts include disturbed eating behaviours such as increased food consumption, eating in response to stress and boredom, snacking after dinner, decreased physical activity, and increases in substance abuse.[1]

One of the important consequences is global psychological distress. Multiple researchers have found increased prevalence of pandemic-related psychiatric morbidity and psychological distress. Overwhelming fear and anxiety toward the disease causes strong emotions to emerge out.[2]

The stress can manifest as fear and worry about their health, changes in sleep and eating patterns, trouble sleeping and concentrating, worsening of chronic health problems, and increased intake of alcohol, smoking, or other substances.[2] One systematic review of mental health problems during pandemic stated that the most prevalence mental health issues are depression, anxiety, distress, and insomnia.[3] Frontline workers such as doctors,

nurses, and ambulance drivers are exposed to additional stress during the COVID-19 pandemic because of higher demands during work, fear of spreading COVID-19 onto their families, high physical strain they have had to endure while wearing protective equipment, and the physical isolation to which they have had to submit themselves in order to protect their families. Children are also impacted by the pandemic. They may feel fear and sadness because they cannot socialize and must adjust to a new routine at home. Children and adolescents who are physically active will find it difficult to confine their activities at home. For elder people, confinement has detrimental effect both on physical and psychological because the feeling of loneliness could accelerate physical and cognitive decline.[4]

Healthy coping mechanisms toward stress will create a stronger society and communities Fortunately, we have guidelines from the Indonesian Psychiatric Association for the community on maintaining mental health during the COVID-19 pandemic. The guidelines include the following:[5]

Limit exposure to excessive information and cut down time spent on watching, reading, or listening to news about COVID-19, including social media such as Instagram or Twitter especially those whose news does not have any proper evidence. WHO recommends checking the news only once or twice during the day.

Perform relaxation by engaging in meditation and exercise, such as physical workout, yoga, or pilates. Getting enough rest and eating food with balanced nutrition are also important.

Do various relaxing and fun activities to vent the stress away. Looking after oneself mentally and physically during the pandemic, as well as providing a safe environment for children and the elderly, are of utmost importance.

During the pandemic, the community can serve as a valuable source of support in helping manage difficulties faced by individuals and families.

Try talking and connecting with people who can be trusted about all the fears and worries that one is experiencing, which can be done through technology applications.

One of the most common coping strategy during pandemic is through exercise. Exercise have shown to give a lot of benefit both for physical and psychological health. WHO recommend all adults should conduct at least 150 to 300 minutes per week of any moderate intensity activity and for additional health benefits people should do more than 300 minutes per week. On top of that is to conduct resistance training to gives benefit to our muscle and ultimately our health, fitness, and mental wellbeing. Beside of doing regular physical activity/ exercise is to have a balanced nutrition throughout the day. Keep our macro and micro nutrition in checked is one of the very important aspect in keeping our mental health.

A feeling of connectedness is one of the key factors to overcoming adversities and developing resilience to emerge victorious in this pandemic era. Keep your social relationship, stay active throughout the day, and supply your body with healthy balanced diet. Hopefully we all can overcome this tough situation together.

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INA-RESPOND Newsletter

WAHOO, PUNCTUATION, WHAT A FUN TOPIC!

By: Aly Diana

COMIC CORNER

"Punctuation establishes the cadence of a sentence, telling readers where to pause (comma, semicolon, and colon), stop (period and question mark), or take a detour (dash, parentheses, and square brackets). Punctuation of a sentence usually denotes a pause in thought; different kinds of punctuation indicate different kinds and lengths of pauses." However, punctuation mistakes often remain unnoticed and unaddressed by researchers themselves, peer reviewers, and journal editors. There are several factors causing an overlooked of punctuation mistakes. Firstly, punctuation is often viewed as a less important subject when compared to other areas of writing difficulties, such as organization of scientific ideas, choice of persuasion strategies, and grammar. Furthermore, there is a wide variation in the use of punctuation due to insufficient attention to its main rules in language classes or scientific writing courses.

Here some overview of some punctuation: comma, semicolon, and colon. The rules here are based on the American Psychological Association (APA) style Publication Manual (7th edition). Most of the statements below are the direct quote of their rules and examples.

Comma is used in the following cases:

1. Between elements in a series of three or more items, including before the final item. Example: height, width, and depth

2. After an introductory phrase (if the introductory phrase is short, the comma after it is optional. Example: After the nurses administered the medication, patients rated their pain.
3. To set off a nonessential or non-restrictive clause – that is, a clause that embellishes a sentence but if removed would leave the grammatical structure and meaning of the sentence intact. Example: Strong fearful faces, which are rarely seen in everyday life, convey intense expression of negative emotions.
4. To set off statistics in the text that already contains parentheses, to avoid nested parentheses. Example: Sleep amount was not significantly different between the three groups (nap: M = 7.48 hr, SD = 1.99; wake: ...)
5. To separate two independent clauses joined by a conjunction. Example: Facial expressions were presented, and different photo models were chosen randomly.
6. To set off the year in exact dates in the text or in a retrieval date. Example: Retrieved April 24, 2020, from ….
7. To set off the year in parenthetical in-text citations. Example: (Horowitz, 2019, discovered …)
8. To separate groups of three digits in most numbers of 1,000 or more.

Semicolon is used in the following cases:

1. To separate two independent clauses that are not joined by a conjunction. Example: Student received gift card for participation, community members received money.
2. To separate two independent clauses joined by a conjunctive adverb such as “however”, “therefore”, or “nevertheless”. Example: The children studied the vocabulary words; however, they had difficulties with recall.
3. To separate items in a list that already contain commas. Example: The colour groups were red, yellow, and blue; orange, green, and purple; or black, grey, and brown.
4. To separate multiple parenthetical citations. Example: (Gaddis, 2018; Lai et al., 2016; William & Peng, 2019)
5. To separate different types of information in the same set of parentheses, to avoid back-to-back parentheses. Example: (n = 33; Fu & Ginsburg, 2020)
6. To separate sets of statistics that already contain commas. Example: (age, M = 34.5 years, 95% CI [29.4, 39.6]; year of education, …)

Colon is used in the following cases:

1. Between a grammatically complete introductory clause (one that could stand alone as a sentence, including an imperative statement) and a final phrase or clause that illustrates, extends, or amplifies the preceding thought (if the clause following the colon is a complete sentence, begin it with a capital letter). Example: There are three main patterns of mother-infant attachment: secure, avoidant, and resistant/ambivalent (Ainsworth et al., 1978).
2. In ratios and proportions. Example: The proportion of salt to water was 1:8.

That’s all for now!

The challenge: How many mistakes of punctuation I have made in the first paragraph of this article?

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INA-RESPOND website: www.ina-respond.net

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.

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