INA-RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

NEWSLETTER

October 2022

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HEALTH POLICY AGENCY
MINISTRY OF HEALTH REPUBLIC OF INDONESIA
2022

MASTHEAD

INA-RESPOND
newsletter

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THANK YOU

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FEATURES

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

INA102

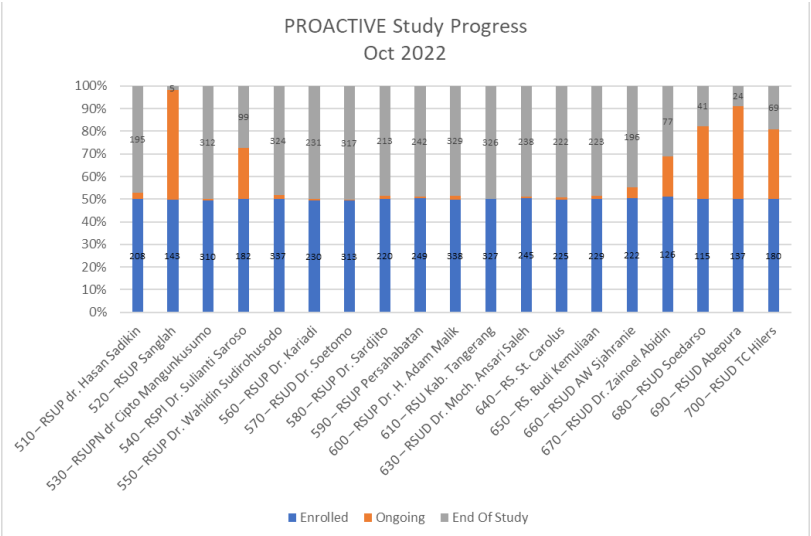
The submitted TRIPOD manuscript titled "The Characteristics of Drug Sensitive and Drug-Resistant Tuberculosis Cases in Indonesia" was accepted by the American Journal of Tropical Medicine and Hygiene on 18 August 2022, and it is available online since 17 October 2022 **on this link** or you can see the latest post at www.ina-respond.net.

The manuscript article will be scheduled to appear in volume 107 issue 5 of AJTMH. The team has also sent the response to the 3rd reviewer for the other paper, "Performance of Xpert TB/RIF and Sputum Microscopy Compared to Sputum Culture for Diagnosis of Tuberculosis in Seven Indonesian Hospitals," submitted to the Frontiers in Medicine - Infectious Diseases - Surveillance, Prevention, in October 2022. After the completion of mTB DNA extraction, the protocol core team is preparing the concept plan for Whole Genome Sequencing for a local funding opportunity

The RePORT network through CRDF Global announced a funding opportunity and encouraged the RePORT Consortium to apply on the grant proposal with the scope of activities include: scientific proposal, website development and site or laboratory capacity building for future clinical trial opportunities. The grant application should be submitted before 1 December 2022. The core team will setup a meeting to formulate proposal for grants to RePORT.

INA104

By 11 Oct 2022, from 4,336 subjects enrolled, 15% were still ongoing, and 85% of subjects had ended their study. The picture on the right shows the study progress from each Site.



For the end-of-study subjects, 83% subject had already completed the study until follow-up month 36, 8% were lost to follow-up, 7% died, and the rest is due to withdrawn consent, moving away to a city without PROACTIVE Site, HIV Negative test, and were suspended (imprisoned). The list of participants end of study status from each Site is shown in the table below:

The study visit was completed at Site 610 in September 2022. This completion visit, also known as Last Participant Last Visit (LPLV), is the date on which the last participant made the final visit to the Site. The Site Close Out Visit will follow this LPLV. The LPLV and Site Close-Out Visit plan has been discussed with the Sites to generate a common target, timeline, and coordinated preparation between the Secretariat and Sites. Table 2 shows the timeline of the LPLV and Site Close-Out Visit until the study documents archiving.

For the monitoring activity, one on-site monitoring visit was done at Site 630 on 11-13 October 2022.

Table 1. Subjects' end of study reasons

No	Site	End of Study Duration/ Complete	Withdrew Consent	HIV negative	Moved	Death	Investigator Discretion	Lost to Follow Up	Other	Total
1.	510 – RSUP Dr. Hasan Sadikin	184	1	0	2	5	0	3	0	195
2.	520 - RSUP Sanglah	2	0	0	0	3	0	0	0	5
3.	530 – RSUPN Dr. Cipto Mangunkusumo	282	0	0	0	17	0	13	0	312
4.	540 – RSPI Dr. Sulianti Saroso	80	0	0	2	8	0	9	0	99
5.	550 – RSUP Dr. Wahidin Sudirohusodo	236	0	0	5	25	0	58	0	324
6.	560 – RSUP Dr. Kariadi	198	1	3	0	15	0	14	0	231
7.	570 – RSUD Dr. Soetomo	261	13	0	4	21	0	18	0	317
8.	580 – RSUP Dr. Sardjito	168	1	0	5	5	0	34	0	213
9.	590 – RSUP Persahabatan	186	0	1	0	37	0	18	0	242
10.	600 – RSUP Dr. H. Adam Malik	252	3	0	2	21	0	51	0	329
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	14	0	238
13.	640 – RS St. Carolus	208	0	0	0	1	0	13	0	222
14.	650 – RSU Budi Kemuliaan Batam	178	3	0	5	9	0	28	0	223
15.	660 – RSU A. Wahab Sjahranie	173	0	0	2	6	0	15	0	196
16.	670 – RSUD Zainoel Abidin	61	0	0	0	11	0	0	5	77
17.	680 – RSUD Soedarso	29	0	0	0	11	0	0	1	41
18.	690 – RSUD Abepura	13	2	1	1	7	0	0	0	24
19.	700 – RSUD TC Hillers	52	1	0	0	16	0	0	0	69
Total		3050	32	5	33	245	0	310	8	3683

Table 2. Timeline

Site No	Enrollment	Current Active Participants (as of 11 Oct 2022)	LPLV Timeline from Secretariat	Last SMV prior to Site Close out Visit	Site Close Out Visit (6M from LPLV) - real contract	Document for Archiving sent to Secretariat
520 – RSUP Sanglah	143	140	Apr 23	2-4 May 23	Oct-23	Nov-23
530 – RSUPN dr Cipto Mangunkusumo	310	4	Apr-23	30May- 01Jun 23	Oct-23	Nov-23
540 – RSPI Dr. Sulianti Saroso	182	81	Jan 23	27Feb- 01Mar 23	Jul-23	Sep-23
550 – RSUP Dr. Wahidin Sudirohusodo	337	13	Oct 22	30Nov-02Dec22	Apr-23	May-23
560 – RSUP Dr. Kariadi	230	3	Oct 22	17-19 Jan 23	Apr-23	May-23
570 – RSUD Dr. Soetomo	313	3	Oct 22	25-27 Oct 22	Apr-23	May-23
580 – RSUP Dr. Sardjito	220	5	Oct 22	21-23Nov22	Apr-23	May-23
590 – RSUP Persahabatan	249	4	Oct 22	27-29 Dec 22	Apr-23	May-23
600 – RSUP Dr. H. Adam Malik	338	11	Oct 22	4-6 Oct 22	Apr-23	May-23
610 – RSU Kab. Tangerang	327	0	Aug-22	13-15Sep22	Feb-23	Mar-23
630 – RSUD Dr. Moch. Ansari Saleh	245	3	Oct 22	8-10 Nov 22	Apr-23	May-23
640 – RS. St. Carolus	225	5	Nov-22	6-8 Dec 22	May-23	Jun-23
650 – RS. Budi Kemuliaan	229	6	Oct 22	9-11Nov 22	Apr-23	Jun-23
660 – RSUD AW Sjahranie	222	21	Nov-22	22-24 Nov 2022	May-23	Jun-23
670 – RSUD Dr. Zainoel Abidin	126	44	Jan 23	13-15Feb 23	Jul-23	Aug-23
680 – RSUD Soedarso	115	74	Jan 23	1-3 Feb 23	Jul-23	Aug-23
690 – RSUD Abepura	137	112	Jan 23	20-24 Feb 23	Jul-23	Aug-23
700 – RSUD TC Hilers	180	111	Apr 23	16-18 May23	Oct-23	Nov-23

INA107

The data management team have completed the data audit for random sample subject in all sites. Meanwhile, the data audit for the critical data field on all subjects for site 521 is already done, while site 610 is still ongoing. All the study process close out at site RS Universitas Udayana has already finished since the site close-out visit (SCV) on 22 and 23 September 2022. The screenshot of the remote SCV is shown in Figure 1. The SCV of site RSU Kabupaten Tangerang was arranged on 13 and 14 October 2022. The site is still preparing the pending/ incomplete documents to be filed in the study's regulatory binders before archiving. Figure 2 shows the study team at RSU Kabupaten Tangerang preparing for the SCV. We express our deepest gratitude for the efforts and good cooperation of the two sites during the research. We hope to continue to collaborate on INA-RESPOND research in the future.

Figure 1. Remote Site Close-Out Visit at RS. Universitas Udayana

Figure 2. Study Team at RSU Kabupaten Tangerang

Currently, the reference laboratory team is doing PCR SARS-CoV-2 test on all collected specimens (saliva, nasopharyngeal swab, oropharyngeal swab, urine, feces, and serum) from all COVID-19 cases. Some specimens that were positive SARS COV-2 at visit 1 (enrolment) will continue for another PCR SARS-CoV-2 testing on samples collected at follow-up visit 2 (7- 14 days after enrolment). Meanwhile, the study team will determine the target pathogen to do molecular and serology testing for non-COVID-19 cases based on clinical symptoms.

Moreover, the study team is preparing two manuscripts (Overall study result and FLU PRO data), and it is discussing the tables and figures for the manuscript's overall study results.

INA-RESPOND Newsletter

SITE CLOSE OUT VISIT

By: Eka Windari Rusman, Lois Eirene Bang

Currently, preparations for a Site Close Out Visit are carried out in one of the INA-RESPOND studies, the PROACTIVE INA104 study. What is a Site Close Out Visit, and what preparations should be made before a Site Close Out?

Site Close Out Visit (SCV) is a visit and procedure scheduled by the Research Sponsor to ensure that all research activities have been reconciled, recorded, and reported at the end of the study in accordance with the Protocol, SOP, GCP, and applicable regulatory requirements. SCV can be done as a stand-alone visit or in conjunction with a monitoring visit. In general, SCV is the last visit to the research site. Ideally, SCV is done when the study is complete, enrollment and follow-up visits have been completed or have stopped, all subjects have completed all study activities, and the data is complete and verified. However, SCV can also occur for several other reasons; for example, the overall enrollment target has been achieved so sites that have not reached their target can be closed, the statistical criteria for study termination that have been determined previously in the protocol have been met, termination from sponsors, enrollment targets that are not possible to achieve, or the PI loses interest in the research. In addition, for clinical trials with interventions, SCV can also be caused because the test product is found unsafe, the test product is ineffective, or the Sponsor decides the test drug is unfit for marketing.

SCV preparation

Before conducting the SCV, the Sponsor represented by the monitor will schedule a visit with the PI and the research team according to the time availability of the entire team. Invitations will be sent via email. Several things that need to be prepared by the Site before SCV are as follows: ensure that all Case Report Forms have been completed in accordance with the source documents, ensure that safety reports such as adverse events (AE), serious adverse events (SAE) and Unanticipated Problems (UP) have been reported and reconciled, complete essential documents contained in the Site Regulatory Binder, inventory of tools, laboratory & office supplies and research drugs (for interventional clinical trials), ensure that specimens have been analyzed or stored according to protocol, and complete outstanding/pending action items from previous monitoring.

SCV process

During SCV, the Monitor will conduct a final review and verification that all PI obligations have been carried out and all applicable clinical trial provisions and regulations have been completed at the end of the study. The following things will be checked during SCV:

Case Report Form

The monitor will ensure that all CRFs have been reviewed per the monitoring plan and that improvements to the CRF have been completed.

Drug Accountability (specifically for Intervention research)

If there are any research drugs on the premises, a final inventory will be performed at the time of SCV. The remaining medication can then be destroyed at the site or returned to the Sponsor in accordance with the study's terms.

Research Sample

The monitor will ensure that all research samples have been collected according to the protocol, the inspection has been carried out according to the protocol, the samples are stored in appropriate locations following storage standards, and that the samples sent to the repository have been sent following the provisions in the protocol and applicable regulations.

Site Regulatory Binder

The SRB will be reviewed to ensure that all essential documents are completely stored in the SRB.

Investigator Final Report to IRB

The investigator is required to make a final study report to IRB. This report should include an enrollment summary, including the number of subjects entered, those who completed, those who dropped out and their reason of dropping out. It will also include the information of adverse events and any other information relative to the trial at that Site and specifically requested by the IRB. The investigator must also notify the institution that the study is complete, if applicable.

Final Report to Regulatory

The final report to the regulatory agency, namely BPOM, applies to clinical trial research and does not apply to observational studies because no permit from BPOM is required. The final report includes the same information as the IRB report, as well as information on the use of clinical trial drugs.

Administrative Issues

Since this visit is the Sponsor's last visit or monitoring of the research site, any outstanding business or issue should be resolved before the study closeout is complete. Administrative matters such as site team service fee payments must be resolved soon. If there are unused study materials (unused laboratory kits, investigational products), they should be disposed of or returned according to the sponsor's direction. Any outstanding issues from previous visits or issues that arose during sponsor review should be resolved before the study is closed at the investigative site.

During the SCV, there will also be a discussion about record retention, how long the research document will be stored on the Site, and who will be in charge of the document from the Site and the Sponsor. Such records are maintained in a secure, limited-access location and are retained in accordance with all applicable regulatory and sponsor requirements. For easy management, documents can be stored in a 3rd party (archiving vendor).

After the monitor ensures that there are no pending action items from SCV and all activities and responsibilities of researchers for the study have been completed at the site, the Authorized Site Signature and Delegation Log (ASDL) document will be completed with a final signature by the PI and then stored in the SRB. Final ASDL can also be completed after the SCV if there are still action items that need to be followed up after the SCV.

The investigator will also be informed about any publication terms for the study and notify the Sponsor of any impending Audit or Inspection. In addition, during the SCV, there will be a discussion about the responsibilities of the equipment and goods provided by the study, where the site is responsible for ensuring all the equipment and goods are maintained and can be reused in the next study.

After SCV

After SCV, the monitor will send a follow-up letter. The follow-up letter summarizes significant items reviewed and discussed during the visits and any action that require follow-up. The sponsor will follow up on any outstanding issues or action items until they are closed by telephone and/or emails after SCV.

Any significant objective findings noted during the SCV, which may have an impact on human subject protection or the outcome of the clinical trial, are reported to the sponsor in a timely manner.

Reference:

S-INA-CRM-003.02 Site Closeout Visits, effective date: 22 June 2020

Clinical Research Site Specialist (CRSS) Guideline version 3.0 dated 10 November 2021

The CRA's Guide to Monitoring Clinical Research, Thomson Centerwatch, 2003

Reference:

1. S-INA-CRM-003.02 Site Closeout Visits, effective date: 22 June 2020
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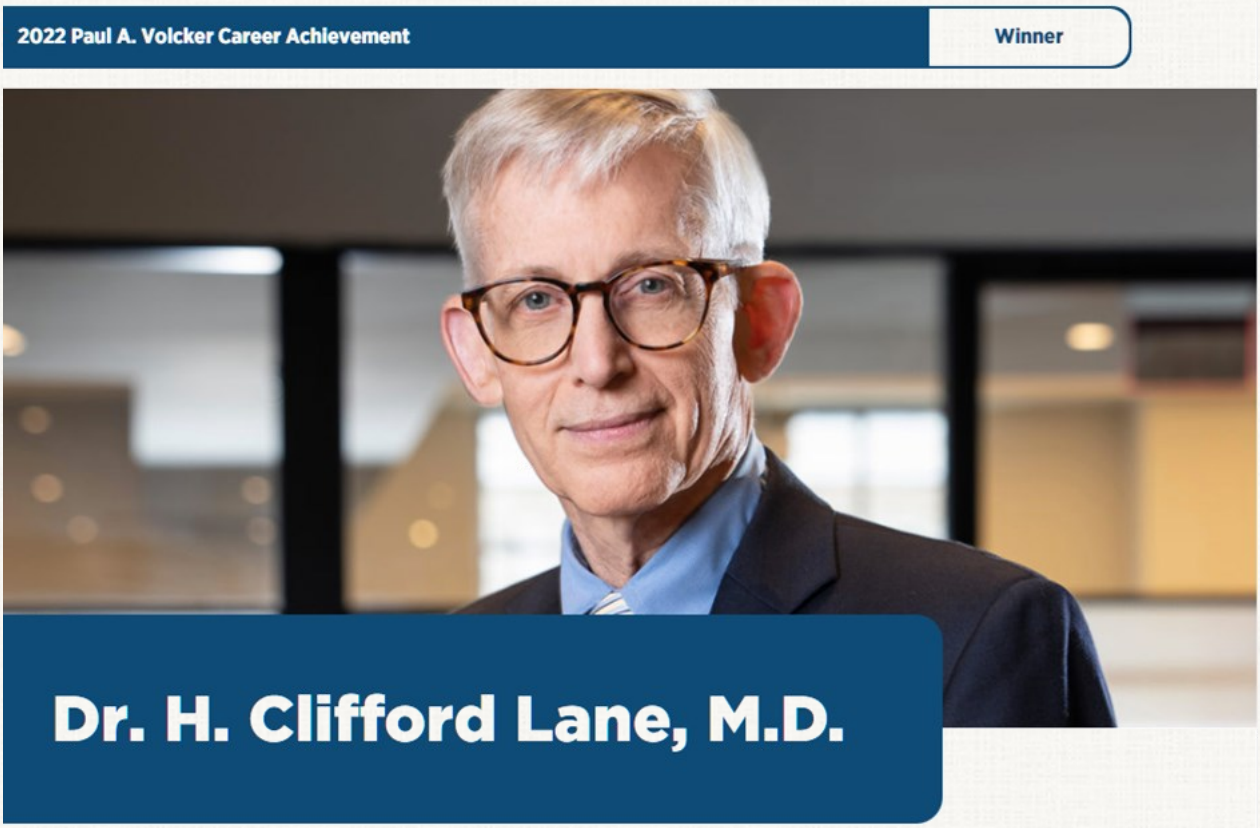
INA-RESPOND Newsletter

NEWS

THE WINNER OF 2022 PAUL A. VOLCKER CAREER ACHIVEMENT

By: Dedy Hidayat, Herman Kosasih, M. Karyana



Source: https://servicetoamericamedals.org/honorees/h-clifford-lane-m-d/

The Career Achievement Medal is named for the late Paul A. Volcker in recognition of his nearly three decades of distinguished federal service. This honor, made possible through the generous support of Ray and Barbara Dalio, recognizes career federal employees who have led significant and sustained achievements during 20 or more years of service in government.

While finance and the economy dominated much of Volcker's career, he was outspoken about the importance of an effective government and the need to restore faith in government. In 2018, Volcker told the Financial Times he would like his legacy to be his "attention to public service" rather than his economic achievements.

Dr. H. Clifford Lane has spent four decades at the National Institutes of Health conducting research that has saved the lives of people with HIV/AIDS, making significant contributions to the international fight against and treatment of infectious diseases like Ebola, and assisting in the development of national COVID-19 treatment guidelines.

The NIH AIDS research program was started by Dr. Lane and Dr. Fauci two years after Dr. Lane first joined the NIH. Dr. Lane initiated investigations examining the rela-

tionship between HIV and the immunological weakness underlying AIDS.

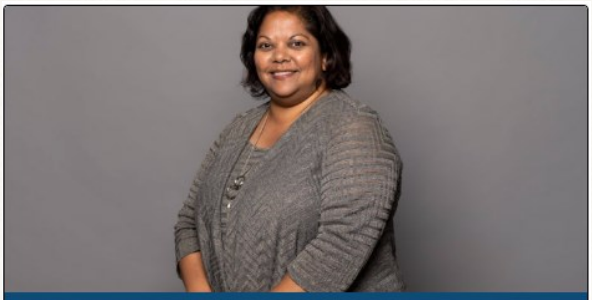
"Cliff is an exemplar of a physician-scientist who does many things well: conducting research, running clinical trials, and teaching, all with the highest levels of ethics and integrity. His work at home and globally has had an enormous impact," said Dr. Anthony Fauci, the director of NIH's National Institute of Allergy and Infectious Diseases.

Over 30 clinical trials under Dr. Lane's direction have produced vital data about how HIV causes disease, the best ways to treat patients, and the ideal times to begin antiretroviral therapy. His work was essential in transforming an HIV diagnosis from a terminal illness into a controllable chronic condition. He oversaw the first American trial of a still-elusive HIV vaccine in 1988.

During Liberia's ongoing Ebola outbreak in 2014, Dr. Lane established a clinical research relationship with the country. When Lane urged that the design be the gold standard—a randomized, controlled clinical trial—the initial objective, to begin clinical trials of potential Ebola vaccines and treatments, met strong opposition from individuals outside of Liberia. From all the logistical difficulties and the unpredictability of the healthcare system to the requirement for training researchers who could carry out the study in a specific way—all the obstacles.

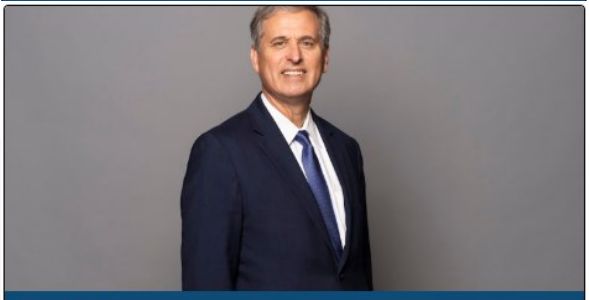
"I don't know if there's anybody else on the planet who could have pulled that off," said Dr. Francis Collins, the former NIH director and now acting science adviser to President Joe Biden. "Cliff is the perfect role model of a highly trained physician-scientist who is capable of responding in an emergency situation by the skill of his diplomatic abilities and his determination to get scientific answers that are going to save lives."

As an Ebola outbreak arose in a region of the country that was heavily affected by conflict in 2018, the Democratic Republic of the Congo asked Lane's assistance to set up a cooperative research partnership. Despite the difficult conditions, the partners carried out a crucial clinical experiment that revealed the first two Ebola medications, ultimately winning approval from the Food and Drug Administration.



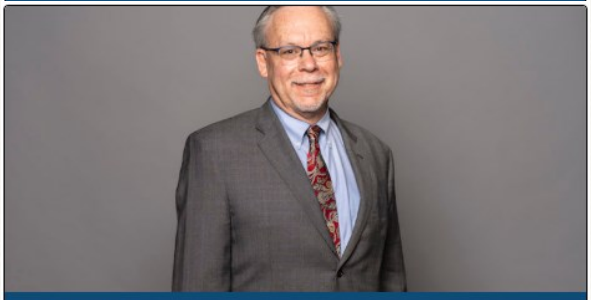
2022 Finalist

Rupa Bhattacharyya



2022 Finalist

Scott Busby



2022 Finalist

Mitchell Zeller, J.D.

2022 Finalist

Craig McLean

Paul A. Volcker Career Achievement

When working in developing nations, Lane "never gets discouraged by things like technical or bureaucratic obstacles," Fauci said. "He figures out ways of getting the people in-country to appreciate that it's their show as opposed to his. He leaves them with a sustainable intellectual and principled infrastructure to continue long after he's gone."

Most recently, Lane worked to create a public-private partnership overseen by the NIH that established COVID-19 clinical research priorities and oversaw several clinical trials using patients who were hospitalized with the virus. He also serves as co-chair of the NIH COVID-19 Treatment Guidelines Panel, which has given medical professionals, patients, and policy experts access to the most recent information on the best practices for treating and managing COVID-19 patients. The often-updated online recommendations have received more than 30 million page views overall.

When reflecting on his professional life, Dr. Lane remarked that his work researching and caring for HIV/AIDS patients made him the proudest. It has been tremendously fulfilling to be able to provide leadership on the treatment guidelines for HIV and to have the opportunity to watch how the medical world steadily improved in dealing with HIV/AIDS.

When Dr. Lane began working at the NIH more than 42 years ago, he claimed he was simply seeking a place to study immunology and infectious diseases. However, he quickly understood that there were numerous chances to enhance both domestic and international public health. In addition, when asked why he chose a government service when he could take a job as a doctor in any other institution/organization, Dr. Lane answered that the focus is the mission and nothing else. It is not how many relative value units you generate in a day. What matters most is what you achieve and how it advances general health and, indirectly, the individual patient's health.

Dear Dr. Lane,

Congratulations on winning the "2022 Paul A. Volcker Career Achievement" award from the US Partnership for Public Service.

You have always worked hard and gone above and beyond. It's hard to find someone who puts their whole heart into everything they do. I know you are one of them.

Your patience, perseverance, and dexterity have carved a path for a better, more conducive research environment in Indonesia through our robust network, which in turn provides valuable inputs for developing health policies to enhance the well-being of its people. Also, I appreciate all the efforts you have made to help build our capacity, both infrastructure and human resources. I genuinely love and appreciate your work, and I couldn't have done it better myself.

Congratulations on your outstanding achievement!

Sincerely,
Dr. M. Karyana
Chair of INA-RESPOND

Sources:

- https://servicetoamericamedals.org/about/paul-volcker-career-achievement/
- https://servicetoamericamedals.org/honorees/h-clifford-lane-m-d/
- https://www.youtube.com/watch?v=JO10PHN3O9o&t=334

INA-RESPOND Newsletter

NIH SCIENTIFIC DATA SHARING

By: Louis Grue

The National Institutes of Health (NIH) issued the final NIH Policy for **Data Management and Sharing (DMS Policy)** to promote the management and sharing of scientific data generated from NIH-funded or conducted research. The Policy establishes the requirements of submission of Data Management and Sharing Plans and compliance with NIH Institute, Center, or Office (ICO)-approved Plans. It also emphasizes the importance of good data management practices and establishes the expectation for maximizing the appropriate sharing of scientific data generated from NIH-funded or conducted research, with justified limitations or exceptions. The Policy applies to research funded or conducted by NIH that results in the generation of scientific data.

"The NIH encourages the sharing of data whenever possible."

As the **DMS Policy** is released, the world is amid the COVID-19 pandemic. The recognition that more open data sharing can lead to faster advances and treatments has led to an unprecedented worldwide effort to openly share publications and data related to both SARS-CoV-2 (the novel coronavirus that causes COVID-19) and coronaviruses more generally. While this is a specific example of an urgent public health need, patients, families, and patient advocacy groups consider the diseases and conditions that affect them to be of equal urgency, as do

those who research these diseases and conditions and treat affected patients. With public input, NIH has worked to develop and refine this DMS Policy, the goal of which is to increase the sharing of scientific data generated from NIH-funded research to ultimately enhance health, lengthen life, and reduce illness and disability.

The NIH looks forward to working with applicants and the funded community as they prepare to meet the DMS Policy's requirements and expectations, as we all move toward a future in which data sharing is a community norm.

Data Management & Sharing Policy Overview

The NIH has issued the DMS Policy to promote the sharing of scientific data. Sharing scientific data accelerates biomedical research discovery, in part, by enabling validation of research results, providing accessibility to high-value datasets, and promoting data reuse for future research studies.

Under the DMS Policy, the NIH expects investigators and institutions to:

- Plan and budget for the managing and sharing of data
- Submit a DMS plan for review when applying for funding
- Comply with the approved DMS plan

Research Covered Under the 2023 Data Management & Sharing Policy

The NIH DMS Policy applies to all research, funded, or conducted in whole or in part by NIH, that results in the generation of scientific data.

This includes all NIH-supported research regardless of funding level, including:

- Extramural (grants)
- Extramural (contracts)
- Intramural research projects
- Other funding agreements

The DMS Policy does not apply to research and other activities that do not generate scientific data, for example: training, infrastructure development, and non-research activities.

Scientific Data is defined as data commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications.

Scientific data includes any data needed to validate and replicate research findings.

Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens.

Foreign Collaboration

Policies related to data sharing vary across countries. Investigators from foreign institutions and U.S. investigators collecting data in other countries should familiarize themselves with the policies governing data sharing in the countries in which they plan to work and to address any specific limitations in the plan in their application.

Considerations for Proprietary Data

The NIH understands that some scientific data generated with NIH funds may be proprietary. Under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Policy Directive, effective May 2, 2019, SBIR and STTR awardees may withhold applicable data for 20 years after the award date, as stipulated in the specific SBIR/STTR funding agreement and consistent with achieving program goals. SBIR and STTR awardees are expected to submit a Data Management & Sharing Plan per DMS Policy requirements.

Issues related to proprietary data also can arise when co-funding is provided by the private sector (for example, the pharmaceutical or biotechnology industries). NIH

recognizes that the extent of data sharing may be limited by restrictions imposed by licensing limitations attached to materials needed to conduct the research. Applicants should discuss projects with proposed collaborators early to avoid agreements that prohibit or unnecessarily restrict data sharing. NIH staff will evaluate the justifications of investigators who believe that they are unable to share data.

Data Management

"Proper data management is crucial for maintaining scientific rigor and research integrity."

Data management is the process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the data for its users. Proper data management helps maintain scientific rigor and research integrity. Keeping good track of data and associated documentation lets researchers and collaborators use data consistently and accurately. Carefully storing and documenting data also allows more people to use the data in the future, potentially leading to more discoveries beyond the initial research.

The NIH emphasizes the importance of good data management practices and encourages data management to be reflective of practices within specific research communities.

FAIR Principles

The NIH encourages data management and sharing practices to be consistent with the FAIR (**Findable, Accessible, Interoperable, and Reusable**) data principles. These principles make it easier for computers to process and analyze datasets, which is important when reusing or repurposing datasets for secondary research.

Length of Time to Maintain Data

Per Section 8.4.2 of the NIH Grants Policy Statement, grantee institutions are required to keep the data for 3 years following closeout of a grant or contract agreement. Contracts may specify different time periods. Please note that the grantee institution may have additional policies and procedures regarding the custody, distribution, and required retention period for data produced under research awards.

Metadata and Other Associated Documentation

Metadata Definition: Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).

- Metadata and other documentation associated with a dataset allow users to understand how the data were collected and how to interpret the data. Importantly, this ensures that others can use the dataset and prevents misuse, misinterpretation, and confusion.
- The exact metadata or other associated documentation will vary by scientific area, study design, the type of data collected, and characteristics of the dataset.
- Methodology and procedures used to collect the data
- Data labels
- Definitions of variables
- Any other information necessary to reproduce and understand the data

Naming Conventions

Within a project team, agreement on naming conventions for multiple objects or files—or multiple versions of files—could be useful before embarking on a project that generates large amounts of data that need names or unique identifiers.

Common Data Elements

Common data elements (CDEs) are pieces of data common to multiple datasets across different studies. NIH encourages researchers to use CDEs, which helps im-

prove accuracy, consistency, and interoperability among datasets within various areas of health and disease research. The NIH maintains a repository of NIH CDEs.

Data Storage Format

There are many storage formats for different types and sizes of datasets. For instance, small and simple datasets can be managed in a spreadsheet program. More complicated or larger datasets may need to be managed in a database. Remember that some types of data storage incur costs, which may be part of the project budget.

Data Security

Maintaining multiple copies of data can help protect against unforeseen events. Similarly, version control can help maintain the integrity of data

Data Preservation and Sharing Timelines

Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first. Researchers are encouraged to consider relevant requirements and expectations (e.g., data repository policies, award record retention requirements, journal policies) as guidance for the minimum time frame that scientific data should be made available, which researchers may extend.

Methods for Sharing Scientific Data

Under the 2023 Data Management and Sharing (DMS) policy, NIH encourages investigators to use an established repository. When selecting a repository, investigators should choose based on factors such as the sensitivity of the data, the size and complexity of the dataset, and the volume of requests anticipated.

Sharing Data from Human Participants

For research involving human participants, NIH has specific requirements for research staff, and policies regarding research conduct, safety monitoring, and reporting of information about research progress. Applicants need to follow all applicable federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies that govern research involving human participants and the sharing and use of scientific data derived from human participants. The NIH also respects Tribal sovereignty, even in the absence of written Tribal laws or policies.

The DMS Policy is consistent with federal regulations for the protection of human research participants and other NIH expectations for the use and sharing of scientific data derived from human participants.

Data Management and Sharing Plans

Researchers planning to generate scientific data are required to submit a Plan to the funding NIH ICO as part of the Budget Justification section of the application for extramural awards, as part of the technical evaluation for contracts, as determined by the Intramural Research Program for Intramural Research Projects consistent with the objectives of this Policy, or prior to release of funds for other funding agreements. Plans should explain how scientific data generated by research projects will be managed and which of these scientific data and accompanying metadata will be shared. If Plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), Plans should be updated by researchers and reviewed by the NIH ICO during regular reporting intervals or sooner. Plans from NIH -funded or conducted research may be made publicly available and should not include proprietary or private information.[7]

Award recipients must comply with any applicable laws, regulations, statutes, guidance, or institutional policies related to research with human participants and that protect participants' privacy. The DMS Policy encourages respect for participants by encouraging researchers and award recipients to:

- Address data management and sharing plans during the informed consent process to ensure prospective participants understand how their data will be managed and shared;

- Outline steps they will take for protecting the privacy, rights, and confidentiality of prospective participants (i.e., through de-identification, Certificates of Confidentiality, and other protective measures);
- Assess limitations on subsequent use of data and communicate these limitations to the individuals or entities (e.g., repositories) preserving and sharing the data; and
- Consider whether access to shared scientific data derived from humans should be controlled, even if de-identified and lacking explicit limitations on subsequent use. Sharing via controlled access may be specified by certain funding opportunity announcements (FOAs) or the funding NIH Institutes or Centers.

NIH strongly encourages investigators to plan for how data management and sharing will be addressed in the informed consent process. Investigators should communicate with prospective participants about how their scientific data are expected to be used and shared. Investigators should also consider whether scientific data derived from humans, even if de-identified and lacking explicit limitations on subsequent use, should be controlled.

In addition, NIH expects that in drafting their DMS plans, researchers will attempt to maximize scientific data sharing, but may acknowledge that certain factors (i.e., ethical, legal, or technical) may necessitate limiting sharing to some extent. Foreseeable limitations should be described when drafting DMS plans. As outlined in NIH Guide Notice Supplemental Policy Information: Elements of an NIH Data Management and Sharing Plan, a compelling rationale for limiting scientific data sharing should be provided and will be assessed by NIH.

Examples of reasons that would generally not be justifiable factors limiting scientific data sharing include:

- Data are considered to be too small
- Data researchers anticipate will not be widely used
- Data are not thought to have a suitable repository

The NIH respects and recognizes Tribal sovereignty and American Indian and Alaska Native (AI/AN) communities' data sharing concerns, and NIH has proposed additional considerations when working with Tribes and AI/AN communities.

Plan Assessment: The NIH ICO will assess the Plan, through the following processes:

- Extramural Awards: Plans will undergo programmatic assessment by NIH as determined by the proposed NIH ICO. NIH encourages potential awardees to work with NIH staff to address any potential questions regarding Plan development prior to submission.
- Contracts: Plans will be included as part of the technical evaluation performed by NIH staff.
- Intramural Research Projects: Plans will be assessed in a manner determined to be appropriate by the Intramural Research Program.
- Other funding agreements: Plans will be assessed in the context of other funding agreement mechanisms (e.g., Other Transactions).

Managing and Sharing Scientific Data

The NIH expects that in drafting Plans, researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared. Any potential limitations on subsequent data use should be communicated to individuals or entities (e.g., data repository managers) that will preserve and share the scientific data. The NIH ICO will assess whether Plans appropriately consider and describe these factors.

Compliance and Enforcement

During the Funding or Support Period

During the funding period, compliance with the Plan will be determined by the NIH ICO. Compliance with the Plan, including any Plan updates, may be reviewed during regular reporting intervals (e.g., at the time of annual

Research Performance Progress Reports (RPPRs)).

- Extramural Awards: The Plan will become a Term and Condition of the Notice of Award. Failure to comply with the Terms and Conditions may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions.
- Contracts: The Plan will become a Term and Condition of the Award, and compliance with and enforcement of the Plan will be consistent with the award and the Federal Acquisition Regulations, as applicable.
- Intramural Research Projects: Compliance with and enforcement of the Plan will be consistent with applicable NIH policies established by the NIH Office of Intramural Research and the NIH ICO.
- Other funding agreements: Compliance with and enforcement of the Plan will be consistent with applicable NIH policies.

Post Funding or Support Period

After the end of the funding period, non-compliance with the NIH ICO-approved Plan may be taken into account by NIH for future funding decisions for the recipient institution (e.g., as authorized in the NIH Grants Policy Statement, Section 8.5, Special Award Conditions, and Remedies for Noncompliance (Special Award Conditions and Enforcement Actions)).

Repositories for Sharing Scientific Data

In general, NIH does not endorse or require sharing data in any particular repository, although some initiatives and funding opportunities will have individual requirements. Overall, NIH encourages researchers to select the repository that is most appropriate for their data type and discipline. See Selecting a Data Repository.

Browse through this listing of NIH-supported repositories to learn more about some places to share scientific data. Note that this list is not exhaustive. Select the link provided in the "Data Submission Policy" column to find data submission instructions for each repository.

NIH-supported Scientific Data Repositories*

If you have any questions, Frequently Asked Questions may help.

Policy Effective Date

The effective date for the DMS Policy is January 25, 2023. Specifically, the policy applies to:

- Competing grant applications that are submitted to NIH for January 25, 2023 and subsequent receipt dates.
- Proposals for contracts that are submitted to NIH on or after January 25, 2023.
- NIH Intramural Research Projects conducted on or after January 25, 2023.
- Other funding agreements (e.g., Other Transactions) that are executed on or after January 25, 2023, unless otherwise stipulated by NIH.

The **NIH 2023 Data Management and Sharing Policy** (Replaces the 2003 NIH Data Sharing Policy)

INA-RESPOND Newsletter

BEWARE... THE NEW ARISING PANDEMIC

By: Caleb Leonardo Halim

Currently, the world is entering the final end of the COVID-19 pandemic, or so they speak, but a new pandemic is emerging and does not appear to be over. In fact, the new pandemic is getting more prominent right now, and health problems due to Non-Communicable Diseases (NCDs) seem to be rising because of this COVID -19 pandemic. United Nations stated that "Every two seconds, one person under the age of 70 dies of an NCD". NCDs, including heart disease, stroke, cancer, diabetes, and chronic lung disease, are collectively responsible for 74% of all deaths worldwide. Eighty-six percent of those deaths occur in low and middle-income countries, including Indonesia.

NCDs can have devastating impacts on personal financial security and national economic growth. In low- and middle-income countries, NCDs often affect people during their most productive years. When individuals with NCDs face tremendous healthcare costs and a restricted ability to work, households struggle with increased financial risk. So, it's time for us to shift our focus from the COVID -19 pandemic to the NCDs pandemic, which even has a much higher global burden.

People of all age groups, regions, and countries are affected by NCDs. These conditions are often associated with older age groups, but evidence shows that 17 million NCD deaths occur before the age of 70. Children, adults, and the elderly are all vulnerable to the risk factors contributing to NCDs, whether from physical inactivity, sedentary behavior, insufficient fruit and vegetable consumption, carbonated soft drink consumption, fast food consumption, tobacco use, alcohol consumption, and overweight/obesity. One study data from 140 countries conducted by United Nations found that the most prevalent risk factor among adolescents in all regions are physical inactivity and lack of fruit and vegetable consumption. All these factors lead to a rise in blood pressure, increased blood glucose, elevated blood lipids, and obesity. These are called metabolic risk factors and can lead to cardiovascular disease, the leading NCD in terms of premature deaths. An important way to control NCDs is to reduce the risk factors associated with these diseases. To lessen the impact of NCDs on individuals and society, a comprehensive approach is needed requiring all sectors, including health, finance, transport, education, agriculture, planning, and others, to collaborate.

Along with the development of digital technology, people no longer have to move too much to complete certain activities, such as shopping for daily necessities or food. It makes people move less and less. The number of stalls where fast food that is high in calories and low in fiber is even more favored by our society nowadays. For example, if the food is less salty, it is considered less tasty, or if your drink is less sweet, it is not delicious. The impact of technological advances also makes people sit quietly in front of their computer screens or gadgets. The current digital era makes us busier and busier; from one meeting activity to another without stopping -sitting in front of the screen- making body movements minimal, which causes us to gain weight or be overweight. The accumulation of all these habits and lack of time to exercise lead to NCDs over time.

Let's see... when we are walking in public places, how many people are overweight compared to those who are not? This is not a body shaming problem. It is a health problem. Being overweight/obese is unhealthy, and we shouldn't accept it. Therefore, we must do something to prevent or reduce the incidence or severity of these NCDs.

Some simple things we can do to reduce the impact of these NCDs:

1. Food

Let's use the Ministry of Health's guidelines, "Isi Piring-ku." We need vegetables and fruits that make up half of what we eat each time. This will help us meet our daily fiber needs.

Try to reduce foods/drinks that contain fast-absorbing carbohydrates, such as sweet foods and drinks. Even fruits that are too sweet are actually not good. Look for foods that have a low Glycemic Index (GI). The lower the GI, the longer it will take us to digest, so you don't get hungry easily. The increase in blood sugar also doesn't spike right away and is ultimately good for maintaining the body's insulin sensitivity.

Moreover, our daily protein need is approximately 1 gram of protein/kg of body weight. This can be obtained from various types of meat, eggs, nuts, and milk. Make sure the daily protein needs are met. This is good for the body's metabolism and maintaining our body's muscle mass.

2. Other things through our mouth.

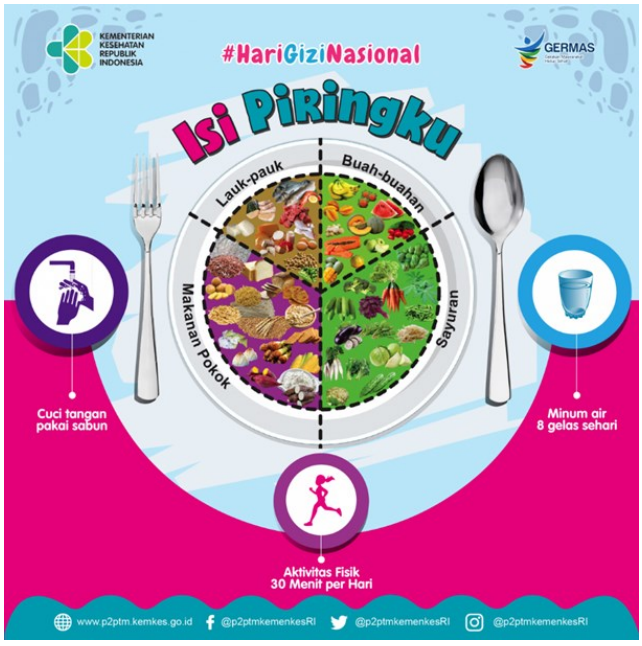
Consuming coffee daily can also be a risk of increased blood pressure, especially when the coffee is added with lots of sugar, increasing the risk of high blood pressure and diabetes mellitus. Limit daily coffee consumption to just one cup.

Consumption of alcoholic beverages in Indonesia is not as much as in western countries. However, keep in mind that alcoholic drinks also have high calories. For example, a whiskey/gin/tequila shot has ±100Kcal calories for a tiny glass, while a 330cc beer has around ±150kcal. We can still drink alcoholic beverages, but please be mindful.

Reduce cigarette consumption, conventional or modern-form cigarettes, because all smokers also have a higher risk of NCDs; Not only problems in the lungs but also in the blood vessels, and consequently increase the risk of heart disease later in life.

3. Be active.

Moving is always better than just sitting still, so try to move as often as possible in daily life according to our work and activities. Try to find a sport that we like and



can be done with family/friends. Even only once a week is still better than nothing.

Suppose you want to have an even more impact. In that case, you must take the time to engage in regular exercise, 2-3 times a week, that includes cardiorespiratory/ stamina training, which is good for our heart health and can reduce the risk of coronary heart disease, hypertension, and diabetes; and resistance training, which is good for our muscle and metabolism. You will get the benefit of reduced risks of all NCDs as well as improved quality of life.

So, what are you waiting for? Don't wait until you get sick. Start now and change your life today!

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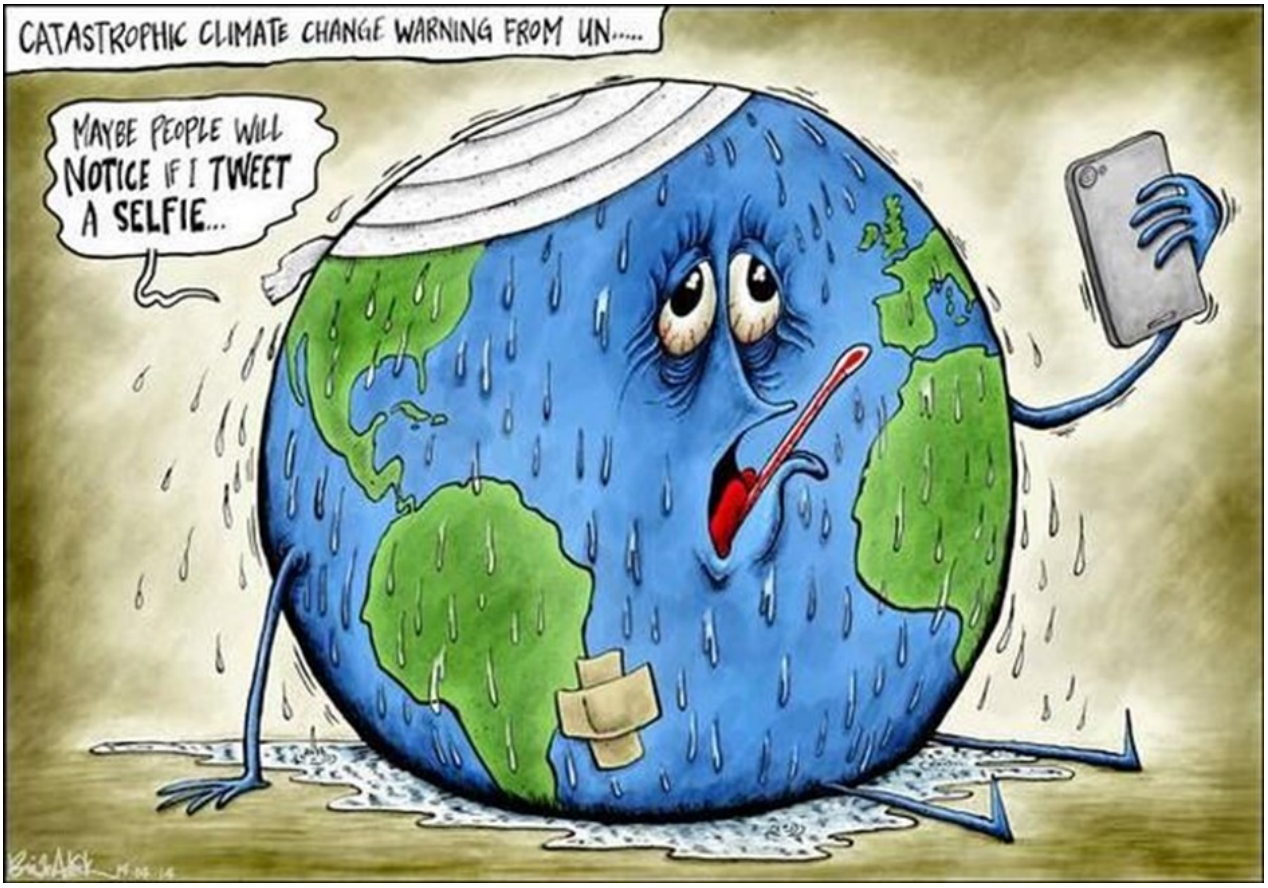
INA-RESPOND
Newsletter

CLIMATE CHANGE IS AN OLD ISSUE, BUT WE ARE NOT TOO OLD TO ACT NOW

By: Aly Diana

COMIC CORNER



Source: Source: Jasmine Vuong, https://www.thinglink.com/scene/883958326361063424

We have heard about climate change for a long time, but now we have heard it more and more often. The world has changed, we did not do enough in the past, and now we have to deal with the consequences. To summarize the global issue in a small nutshell, let's review the definition, main causes, some common jargon in climate change (mitigation, adaptation, resilience), and how we contribute to being kinder to our earth.

Climate change refers to long-term shifts in temperatures and weather patterns. These shifts may be natural, such as through variations in the solar cycle. But since the 1800s, human activities have been the main driver of climate change, primarily due to burning fossil fuels like coal, oil, and gas. Burning fossil fuels generates greenhouse gas emissions that act like a blanket wrapped around the Earth, trapping the sun's heat and raising temperatures. Climate change can affect our health, ability to grow food, housing, safety, and work. Conditions like sea-level rise and saltwater intrusion have advanced to the point where whole communities have had to relocate, and protracted droughts are putting people at risk of famine.

So, what will be the plan? Mitigation, adaptation, and resilience!

Mitigation refers to efforts to reduce or prevent the emission of greenhouse gases. Mitigation can mean using new technologies and renewable energies, making older equipment more energy efficient, or changing individual behavior to reduce carbon emissions. Adaptation refers to humans adapting to life in a changing climate and adjusting to the actual or expected future climate. Adaptation encourages everyone to think about our likely climate future and plan ahead, so we are not caught when, for example, the rate of sea level rise increases or more droughts or storms occur. The goal is to reduce vulnerability to climate change's harmful effects, such as higher sea levels, more extreme weather events, or food insecurity. Resilience is a measure of an area's ability to deal with the effects of climate change and 'bounce back' or recover from an event like a storm or an extreme high-tide if one occurs. Cities with urban green space that could absorb flooding, especially by rivers or along coastlines, would arguably be more resilient to flooding than those with businesses and homes in these areas. In brief: Mitigation can help minimize climate change, so we don't get increasingly severe storms. Adaptation helps prepare for the more severe storms we are already beginning to experience, and resilience helps us bounce back more quickly following these storms.

Yes, climate change is a complicated matter that needs action from so many levels from governments, businesses, and individuals. So this is only a sweet reminder that we can do something to positively contribute to handling climate change. United Nations Campaign for Individual Action introducing ten impactful actions for us to start:1) Save energy at home; 2) Walk, bike, or take public transport; 3) Eat more vegetables; 4) Consider your travel; 5) Throw away less food; 6) Reduce, reuse, repair, and recycle; 7) Change our home's source of energy to wind or solar; 8) Switch to an electric vehicle; 9) Choose eco-friendly products (local and seasonal products); and 10) Speak up for bold action by all sectors of society. Let's try to do our best!

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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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