INA-RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

NEWSLETTER

September 2024

Report

Updates from the 8th RePORT International Annual Meeting at Salvador, Brazil – to reflect and move forward against Tuberculosis using collaborative research

From Our Partner

The Partnership of Clinical Research in Guinea (Pregui)

Sport & Lifestyle

The Hidden Link Between Exersice and Academic Achievement in Children

HEALTH POLICY AGENCY
MINISTRY OF HEALTH REPUBLIC OF INDONESIA
2024

INA-RESPOND newsletter

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THANK YOU

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MASTHEAD

content

September 2024 Edition | issue #132

FEATURES

INA-RESPOND Newsletter

InVITE & PROACTIVE Study Updates

By: Eka Windari R., I Wayan Adi Pranata, Lois E. Bang, Melinda Setiyaningrum, Natalia Regina, Nur Latifa Hanum, Restu Amalia, Riza Danu Dewantara

InVITE

The Indonesia InVITE study is currently undergoing random quality assurance (QA) by the local Data Management team. Once this process is completed, the Sites team will prepare for a site close-out visit (SCV), which is expected to be conducted in February 2025. The Secretariat and Sites team are coordinating to ensure the completeness of study documents and the necessary supplies for SCV activities.

The InVITE study team has reached a critical milestone by successfully shipping the first batch of specimens to the Central Laboratory in the United States this month. The InVITE study, a multicountry initiative, aims to answer important public health questions about vaccines, such as comparing immune responses across different vaccines and populations. To ensure credible results, testing will be conducted in a central laboratory using standardized instruments, protocols, and technicians, minimizing variability. Additionally, the specialized equipment used in this study is unavailable in Indonesia. Thus, the INA-RESPOND Reference Laboratory will also gain valuable experience learning about the assay. For this international specimen shipping, the team had to secure approval from Indonesia's Ministry of Health through a Material Transfer Agreement (MTA) signed by the sending and receiving laboratories and the Ministry of Health representative.

The team diligently prepared the MTA documents following Indonesia's Ministry of Health Regulation No. 85 of 2020 and followed the submission procedures (https://www.badankebijakan.kemkes.go.id/layanan-mta-material-transfer-agreement/). The MTA Committee, under the Health Policy Agency (BKPK), reviewed the submission, and after productive discussions, granted approval for the InVITE study on June 3, 2024, with all documents finalized in January 2024. The approval covers the export of serum and mid-turbinate swab specimens, allowing for 1/3 of all collected serum and 1/2 of all mid-turbinate swabs to be shipped. The remaining specimens are stored at the INA-RESPOND Reference Laboratory for quality assurance and retention.

Initially, the team planned to ship both sera and mid-turbinate swab specimens. However, during shipment preparations, the US-NIAID team alerted them to the ongoing polio eradication requirements. Since the mid-turbinate (respiratory) swab specimens were collected between 2021 and 2023, during the presence of polioviruses in Indonesia (2021-2022), the specimens were classified as potentially infectious for poliovirus. According to the WHO's 2023 guidance on minimizing risks for facilities handling potentially infectious poliovirus material (WHO/POLIO/23.02), such specimens must either be destroyed, inactivated, or handled within a designated polio virus facility. As an alternative to the bio-risk management strategy, nucleic acid (such as RNA) extraction from the specimens can be performed using methods that inactivate poliovirus. The extracted RNA can then be handled outside of polio containment, provided it is not introduced into poliovirus-permissive cells or animals, unless under appropriate containment conditions, as recommended by the Containment Advisory Group in 2017. After discussions with the US-NIAID team, it was decided to

No.	Country or area	1. WPV/VDPV potentially infectious material dates			2. OPV2/nOPV2/Sabin2 potentially infectious material dates (Must mitigate now)
		WPV1/cVDPV1	WPV2/cVDPV2 (Must contain now)	WPV3/cVDPV3 (Must contain now)	
90.	**Indonesia**[1]	• Until Dec 1995[3] *(17)* • Jan 2004 – Dec 2006 *(1, 16, 32)* • *Nov 2018 – Feb 2019 (1)*	• Until Dec 1995[3] *(17)* • *Oct 2022 – **ongoing** (1)*	Until Dec 1995[3] *(17)*	Jan 1996 – Jul 2016

1 Last use of trivalent OPV: Apr 2016
3 Last clinically confirmed polio case; poliovirus type unknown
Figure 1. Country- and area-specific poliovirus circulation data, April 2023 update (source: WHO/POLIO/23.02).

extract RNA from the mid-turbinate swab specimens and ship the RNA extractions to the Central Laboratory. The team will notify the MTA Committee and consult with them on the next steps.

The InVITE Indonesia team valued the learning process involved in specimen management. It was clearly explained that identifying laboratory samples at risk of containing poliovirus is crucial for ensuring a polio-free world. The guidance outlines the timeline of poliovirus detection in each country (Figure 1). It emphasizes that samples collected during wild poliovirus (WPV)/ circulating vaccine-derived poliovirus (cVDPV) circulation are considered potentially infectious, posing a higher risk than those associated with oral polio vaccine (OPV), novel OPV (nOPV), or Sabin strains. Based on the Figure 1, the InVITE specimens collected in Indonesia may be classified as WPV2/ cVDPV2 potentially infectious (October 2022-present), given that the mid-turbinate swab collection took place from December 30, 2021, to December 28, 2023.

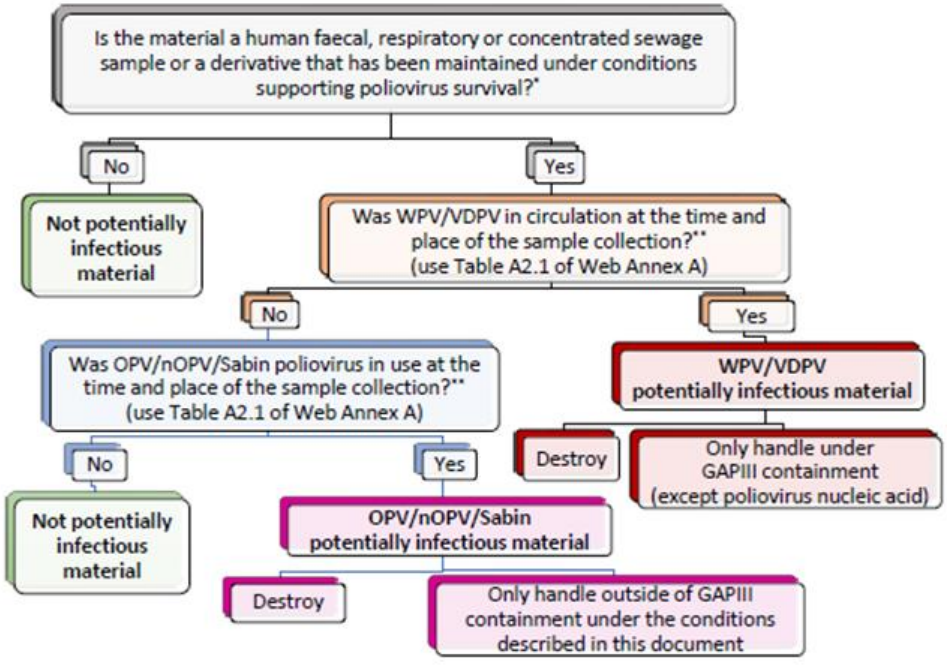


Figure 2. Determination process of poliovirus potentially infectious materials (source: WHO/POLIO/23.02).

Identifying, eliminating the risk through destruction, or mitigating the risk of handling such materials is essential, not only to maintain the safety of laboratory

WPV/VDPV potentially infectious material	Risk mitigation strategy
Faecal, respiratory, concentrated sewage samples or derivatives of such samples stored under conditions that maintain the viability of poliovirus	Destroy, inactivate or transfer materials to a poliovirus-essential facility
	Receive retention approval from the responsible national authority (e.g. Ministry of Health) and undergo containment certification
	Only handle or store[3] materials in a poliovirus-essential facility certified by the national authority for containment against GAPIII, following the CCS
Extracted nucleic acid from WPV/VDPV infectious or potentially infectious material	Declare holdings to the national authority (e.g. Ministry of Health) in the national poliovirus survey and maintain an accurate inventory
	Only perform transfections into poliovirus-permissive cells or animals under GAPIII containment
	Handle outside of GAPIII containment except for transfections into poliovirus-permissive cells or animals

[3] The storage of polioviruses (WPV/VDPV potentially infectious material) must be performed under appropriate containment conditions, as determined by a risk assessment approved by the competent authority (NAC), in line with the approach detailed in the CCS for an interim certificate of containment as well as for a certificate of containment assessment (see Report of the Second Meeting of the Containment Advisory Group, CAG2 November 2017 Meeting report. Geneva: World Health Organization; 2017 at http://polioeradication.org/wp-content/uploads/2018/02/poliovirus-containment-advisory-group-meeting-20171130.pdf, accessed 7 December 2020).

Figure 3. Risk Mitigation Strategy (source: WHO/POLIO/23.02).

workers and their communities, but also for the success of the global polio eradication effort. Facilities that may possess poliovirus potentially infectious materials include those working in diarrheal and respiratory disease research, nutritional research and other human research areas that involve using faecal and respiratory samples, and environmental research areas using concentrated raw sewage. Facilities at particular risk include (but are not limited to) those working with enterovirus, rotavirus, norovirus, hepatitis A and E, other viral enteric agents, and enteric bacterial agents including Escherichia coli, Shigella, as well as respiratory agents such as influenza, measles and other respiratory samples. The global strategy to minimize risks from the non-poliovirus facility is aligned to the one outlined for the poliovirus facility in the Global Action Plan (GAP) III (Figure 2):

1. Risk elimination by poliovirus potentially infectious materials destruction, inactivation or transfer to a poliovirus-essential facility (PEF) in the same or a different country/ region; and
2. Biorisk management by those facilities that retain poliovirus potentially infectious materials and meet the required safe-handling and containment requirements.

As mentioned before, RNA extraction is one mitigation strategy for potentially infectious samples since this process could coincidentally co-purify poliovirus RNA. Figure 3 outlines the mitigation strategies in detail.

In parallel, the INA-RESPOND Reference Laboratory has completed the 2024 Indonesia Ministry of Health survey on the inventory of potentially infectious poliovirus materials. RNA extraction from mid-turbinate swabs will begin once NIAID finalizes the SOP for technical procedures and the INA-RESPOND Reference Laboratory team completes the procedure validation. The first batch of specimens, comprising approximately 2,000 serum vials from Visits 1, 2, 3, and symptomatic visits (26 cryoboxes), was successfully shipped via World Courier on September 23, 2024. The second batch is scheduled for shipment on October 21, 2024. The team is currently preparing the required shipping documents, which are due two weeks before the shipment, along with the shipping request.

INA104

The INA-RESPOND Secretariat held a discussion on updating the manuscript and concept plan for the INA-PROACTIVE study with all INA104 sites and writing team on August 28, 2024. The following is a summary of the results of the meeting:

Manuscript Submission Updates

No.	Title	Status	Proposed site(s)	Manuscript writing lead
1.	A prospective observational cohort study of HIV infection in Indonesia: baseline characteristics and one-year mortality	Under peer review in the BMC Infectious Disease journal	All sites	Prof. dr. Tuti (Site 520)

Approved Concept Plan Updates

No.	Title	Status	Proposed site(s)	Manuscript writing lead
1.	Early analysis of three-years mortality in people living with HIV	Data analysis	All sites	Prof. Evy (Site 530)
2.	Late presentation of HIV infection in 18 referral hospitals in Indonesia: Trends and characteristics from INA-PROACTIVE cohort	Manuscript drafting	All sites	dr. Dona (Secretariat)
3	Characteristics and outcomes of children living with HIV: Findings from 3 years observation of the INA-PROACTIVE study	Data analysis	All sites	dr. Dina (Site 530)
4.	Analysis of genotypic resistance and phylogeny of HIV-1 in Indonesia	Data analysis	Reference Lab	Dr. Nawang/ dr. Dewi (Reference Lab)
5.	Comparison of immune system suppression between PLWH with and without Hepatitis B infection and profile of HBV-DNA and genotypes in HIV-Hepatitis B co-infected patients	Data analysis + specimen testing (for conference presentation)	Site 510	dr. Agnes
6.	Laboratory protocols to identify recent HIV infection	Manuscript drafting	Reference Lab	Dr. Nawang/ dr. Dewi (Reference Lab)

Proposed Concept Plan Updates

No.	Title	Status	Proposed site(s)	Manuscript writing lead
1.	Immune non responder (INR) at one year follow-up among outpatients with sustained HIV suppression at 19 hospitals in Indonesia	Concept plan revision (received input from US-NIAID team)	510, 580, 610, 640, 650, and 690	dr. Rudi/ dr. Nurul (Site 510)

2.	Investigating the role of HIV-infected cell populations in persistent immune activation during effective antiretroviral therapy	Concept plan drafting	Reference Lab	Dr. Nawang/ dr. Dewi (Reference Lab)
3.	Predictors of Tuberculosis in people living with HIV on antiretroviral therapy in Indonesia	Concept plan drafting	530, 580, 590, and 630	Prof. Evy/ dr. Arini (Site 530)
4.	Evaluating the impact of antiretroviral therapy on nutritional outcomes in pediatric living with HIV in Indonesia: a three-year study	Concept plan drafting	All sites	dr. Dina (Site 530)

Proposed ideas by Sites

**The Secretariat encourages Sites to start developing the concept plan*

No.	Idea	Proposed site(s)	Manuscript writing lead
1.	Immune response profile after initiation of ART amongst INA-PROACTIVE subjects	580, 610	610
2.	Survival among HIV patients with metabolic/ non-communicable disease comorbidities in 19 referral hospitals in Indonesia	520, 540, 570, and 580	520, 570
3.	Prevalence/ incidence of syphilis co-infections in INA-PROACTIVE subjects and its association with social behavior/ laboratory parameter/ mortality	530, 540, 580, 590, 600, 630 and 640	560
4.	Prevalence/ incidence of Hepatitis B/ Hepatitis C co-infection in INA-PROACTIVE subjects	560	560
5.	Adverse events of ART (tenofovir, etc.)	550, 580	580, 550

The Secretariat refreshed the audience about the manuscript writing procedure, beginning with developing and submitting a concept plan to be reviewed by the Approval Committee. They encouraged the prompt finalization and submission of proposed concept plans and welcomed new ideas for development. They reminded Sites planning to propose a concept plan to ensure that the idea does not overlap with the objectives outlined in the INA-PROACTIVE protocol.

The discussion was productive, with several site representatives, mainly from teaching hospitals with active warm-based research assistants, expressing enthusiasm for manuscript writing. The INA-PROACTIVE Core team emphasized the importance of solid collaboration and ensuring that non-teaching hospitals, which may be busy with clinical services, were not left out. The Secretariat will continuously update Sites on writing opportunities and invite all Sites to participate. Sites interested in contributing to available topics can contact the Secretariat to check the availability of manuscript writing members and coordinate with the writing lead. Additionally, the Secretariat will keep Sites informed about upcoming conferences to encourage abstract submissions.

INA-RESPOND Newsletter

UPDATES FROM THE 8TH REPORT INTERNATIONAL ANNUAL MEETING AT SALVADOR, BRAZIL – TO REFLECT AND MOVE FORWARD AGAINST TUBERCULOSIS USING COLLABORATIVE RESEARCH

By: Adhella Menur, Lidya Chaidir

If you read last year's newsletter about the 7th RePORT Annual Meeting in Goa, India (INA-RESPOND Newsletter Sept 2023), we now bring you an update on the 8th RePORT Annual Meeting held in Salvador, Brazil.

To refresh your memory, RePORT (Regional Prospective Observational Research in Tuberculosis (TB)) is an international consortium established by the National Institute of Allergy and Infectious Diseases (NIAID) in 2013 (https://reportinternational.org/). Member countries include Indonesia (coordinated by INA-RESPOND), India, South Africa, Brazil, China, the Philippines, South Korea, and Uganda. The consortium's international activities are managed by the RePORT International Coordinating Center (TB-RICC), chaired by Dr. Jerrold Elner. The project is structured into two phases: Phase I (2013-2023, now completed) and Phase II (2019-present). The RePORT consortia are linked by a common data and specimen collection protocol, supporting local TB data and specimen repositories and research efforts in each participating country. RePORT International follows a standardized common protocol for two study cohorts—Cohort A for active TB and Cohort B for household contacts—with countries choosing to conduct one or both based on available resources.

INA-RESPOND participated in Phase I, specifically Cohort A, through the TRIPOD study (Tuberculosis Research of INA-RESPOND On Drug Resistance, NCT02758236, 2017-2020). The RePORT International annual meetings provide a platform for participating countries to coordinate, share TB research updates, present junior investigator projects, and engage in high-level discussions. This year, the meeting was held over four days in Salvador, Brazil, starting with a data pre-meeting on August 20th, followed by the main meeting from August 21st to 23rd, 2024. INA-RESPOND was represented by Adhella Menur, a TRIPOD researcher, and Lidya Chaidir as a Junior Investigator.

The data pre-meeting brought exciting updates. Following the complex process of Phase I data harmonization across participating countries, the Global Data Harmonization team advanced to visualizing and analyzing the data. In this RePORT data harmonization project, the TRIPOD study contributed 312 bacteriologically TB-confirmed subjects. RePORT International has partnered with Frontiers Science Foundation for data management, developing a centralized database and creating portal dashboards for data visualization, monitoring, and tracking cross-network study progress. One key initiative is the portal dashboard named RADar (RePORT Specimen and Data Availability Dashboard), an interactive tool that allows users to explore aggregate counts and summaries of available data and specimens across RePORT. RADar aims to facilitate new concept proposals by enhancing RePORT's visibility and making investigators—both internal and external—more aware of the resources available within the network. Alex Benns from Frontiers Science presented a live demo of RADar, expressing enthusiasm about finalizing this tool in collaboration with RePORT member countries.

During the data pre-meeting, each RePORT country member presented how specimens and data are stored and linked at their respective sites. RePORT International also sought to understand the challenges each country faced. Adhel shared the complexities of biorepository management within

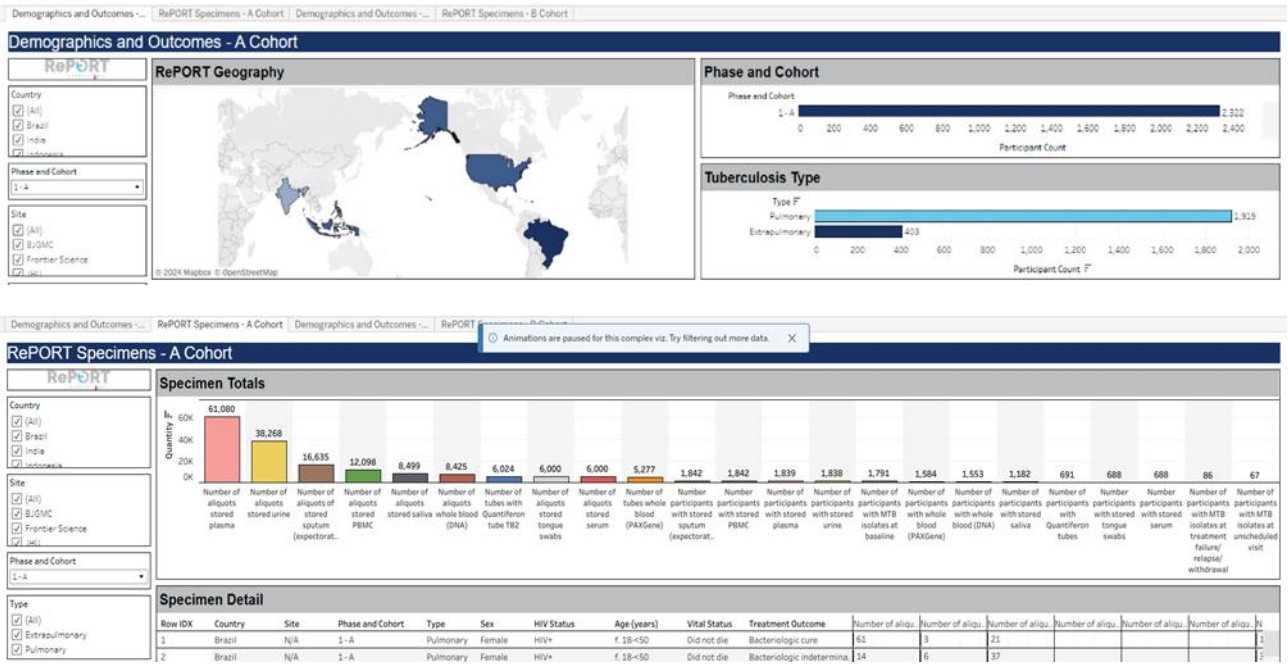


Figure 1. Examples of data visualization in the RADar.

INA-RESPOND, which handles thousands of specimens from sites across Indonesia, all centralized at the INA-RESPOND Reference Laboratory in Tangerang District Hospital. Fortunately, smooth operations were ensured through clear procedures and strong coordination between clinical researchers, laboratory staff, the data team, and the IT team. The key link between specimens and clinical data is the unique identifier assigned to each participant. However, INA-RESPOND currently uses a simple Excel-based system for biorepository management. RePORT International plans to support INA-RESPOND by implementing FreezerPro, a cutting-edge laboratory management software. FreezerPro offers user-friendly tools for labeling, tracking, and managing samples with precision, improving overall efficiency and accuracy.

The following three days of the main meeting were packed with updates from RePORT International, new insights into TB science, Junior Investigator presentations, and capacity-building discussions. Dr. Bruno Andrade, the Principal Investigator from Brazil, opened the session with enthusiasm, highlighting his excitement for a productive and enjoyable meeting. He emphasized RePORT Brazil's success in building networks, conducting extensive research, and publishing widely, attributing this to strong engagement with the Ministry of Health and TB-RiCC. RePORT Brazil also runs a career development program that offers funding to support young researchers who significantly contribute to their research achievements. Fatimah Jones from NIAID delivered sponsor updates, underscoring the importance of RePORT International as a research collaboration aimed at ending TB. She outlined NIAID's four priority areas in TB research: (1) advancing fundamental TB knowledge, (2) improving TB diagnosis, (3) developing better treatment and prevention strategies, and (4) accelerating vaccine development. She also emphasized RePORT's vision to strengthen the clinical and research capacities of regional networks, while fostering young and mid-career investigators and cultivating future RePORT leaders in partner countries.

The TB science update sessions featured key topics like the progression to active TB, treatment responses, and subclinical TB. One standout presentation was from Sarah Fortune of Harvard University, who discussed human-focused biological discovery in TB research. She explained that *Mycobacterium tuberculosis* (MTB) evolves under drug and host pressures, presenting findings from her study (Liu Q et al., Science 2022, doi: 10.1126/science.abq2787) on the transcriptional regulator

Figure 2. Lidya Chaidir presented the TRIPOD laboratory findings and received an acknowledgement from RePORT International (in photo: Amita Gupta and Bruno Andrade).

Rv1830, or *resR,* as a frequent target of positive (adaptive) selection. *resR* mutants do not show canonical drug resistance or drug tolerance but instead shorten the post-antibiotic effect, allowing MTB to resume growth faster after drug exposure. This "phenotype antibiotic resilience" can contribute to treatment failure and the acquisition of canonical drug resistance. She emphasized the enormous opportunity within the RePORT International consortium to share data, samples, and assays, as differences across regions could reveal critical variations in pathogenic strategies. She encouraged the consortium to explore MTB strains in each country. Adhel and Lidya nodded to this idea since they had discussed it before, particularly the prospect of studying TRIPOD MTB strains and their geographical distribution in blind-spot regions like Medan, Denpasar, and Makassar. They considered spoligotyping as a cost-effective alternative to whole genome sequencing for this purpose. The homework clearly consists of finding funding to support this project.

This year, INA-RESPOND proudly sent Lidya Chaidir, a highly regarded TB researcher in Indonesia, as a Junior Investigator. Lidya has been assisting the INA-RESPOND Reference Laboratory, mainly working with Gustiani on extracting MTB DNA and performing targeted sequencing to analyze molecular drug resistance. Lidya's abstract, titled "*Discordant rifampicin susceptibility results between Xpert MTB/RIF and phenotypic drug susceptibility testing: Experience from a prospective study of adult pulmonary tuberculosis patients in Indonesia*," was one of only six abstracts selected from 27 submissions across RePORT member countries. The abstract highlighted despite the widespread use of Xpert MTB/RIF in Indonesia, there is a lack of performance data and epidemiological information on rpoB mutations, highlighting a need for further research. Lidya envisioned further testing to increase scientific value, such as minimum inhibitory concentrations (MIC) tests using MYCOTB MIC plate, at least on isolates with disputed and unreported mutations. Other accepted abstracts included: 1). *Effects of missed anti-tuberculosis therapy doses on treatment outcome* – RePORT Brazil, 2). *Predictive metabolite signatures for risk of progression to active TB from QuantiFERON supernatants of household contacts of TB patients* – RePORT India, 3). *Insights into post-TB lung disease severity through PET-CT Imaging, lung function testing, and immune characterization* – RePORT South Africa, 4). *Subclinical TB in adults with household exposure to recently diagnosed pulmonary TB patients* – RePORT South Africa, and 5). *Transcriptomic and proteomic biomarkers for subclinical TB* – RePORT South Africa.

Each RePORT country member was provided 10 minutes to present their achievements, activities, and challenges. Adhel, on behalf of Prof. Dr. Erlina Burhan, Sp. P (K), and INA-RESPOND, presented updates on RePORT Indonesia. The highlight was the approval of the Material Transfer Agreement (MTA) for shipping specimens for the RePORT International Biomarker study after nearly a year of effort. Adhel appreciated the hard work of Hanum and the INA-RESPOND team, as well as the support from Sheetal Verma and the RePORT Biomarker team for this achievement. She also mentioned the upcoming TRIPOD publication on treatment outcomes and ongoing MTB laboratory capacity building. The biggest challenge for INA-RESPOND remains the lack of active funding for TB research. INA-RESPOND is also under significant reorganization in the Ministry of Health. Adhel emphasized INA-RESPOND's interest in pursuing external funding and collaboration opportunities. In response, the TB-RiCC leadership held a close gathering with Adhel and Lidya to brainstorm ways to boost opportunities for RePORT Indonesia, focusing on finding funding and assisting in writing research grants. They plan further discussions with INA-RESPOND and Indonesia TB researchers during the November UNION meeting in Bali, Indonesia.

Dr. Bob Bollinger from the capacity strengthening working group provided updates on last year's achievements, including the development and launch of TB courses and the enrollment of four RICC post-doctoral fellows from RePORT Brazil and India. He announced the next new recruitment for the post-doctoral fellowship program and shared his excitement about expanding access to TB courses through a QR code initiative, which everyone can access. The RePORT Scientific Review Committee also provided updates on their work, informed attendees about projects in the queue, and encouraged investigators to submit research proposals.

Dr. Jerrold Ellner concluded the meeting by celebrating its success, noting the high participation, engagement of external speakers, and excellent Junior Investigator presentations. He praised the demonstration of the RADar, research updates, and the community engagement plan. The inclusion of a TB survivor (a Brazilian clinician who worked in the ICU) talks and the environmentally friendly, paperless format, supported by an Annual Meeting website, were well-received. Reflecting on RePORT International's journey, Dr. Ellner thanked country members and supporting teams. He announced an upcoming supplement in the *Clinical Infectious Diseases* journal titled "*Advancing TB research: enhancing treatment outcomes, predicting disease progressions, and understanding subclinical TB*." This will include an article about RePORT International's milestones and prospects. The challenges ahead include promoting RePORT data and biospecimens, collaborating with other TB networks, seeking external funding, and moving toward interventional research.

You can scan this QR code to register and get TB courses invitation!

RePORT Indonesia, through INA-RESPOND, is committed to advancing TB research through collaborative efforts.

This meeting was truly memorable for me. First, I had the opportunity to travel with Lidya Chaidir, who I deeply admire. She is a role model for any woman interested in science, particularly in TB research. Second, I met and befriended Evangeline Ann Daniel, a junior investigator from RePORT India. She is such a lovely person and a passionate young TB researcher. A highlight of the meeting was when the three of us had the opportunity to chat with Prof. Bavesh Kana during lunch. Prof. Kana works at the University of the Witwatersrand in Johannesburg, South Africa. He shared inspiring stories about how he began his career, building his research lab from scratch, persistently seeking grants, and doing research creatively. Out of over 700 applicants worldwide, he received a prestigious grant from the Howard Hughes Medical Institute. He also translated his research into products used for quality assurance of TB diagnostic tools, which are now used in over 20 countries, including Indonesia.

Despite being such a renowned researcher, his humbleness and openness truly inspired me. He encouraged us to be resilient and never give up, no matter the challenges we face. He shared a piece of wisdom from his mentor: **"Whatever happens in life, just dance with it!"**

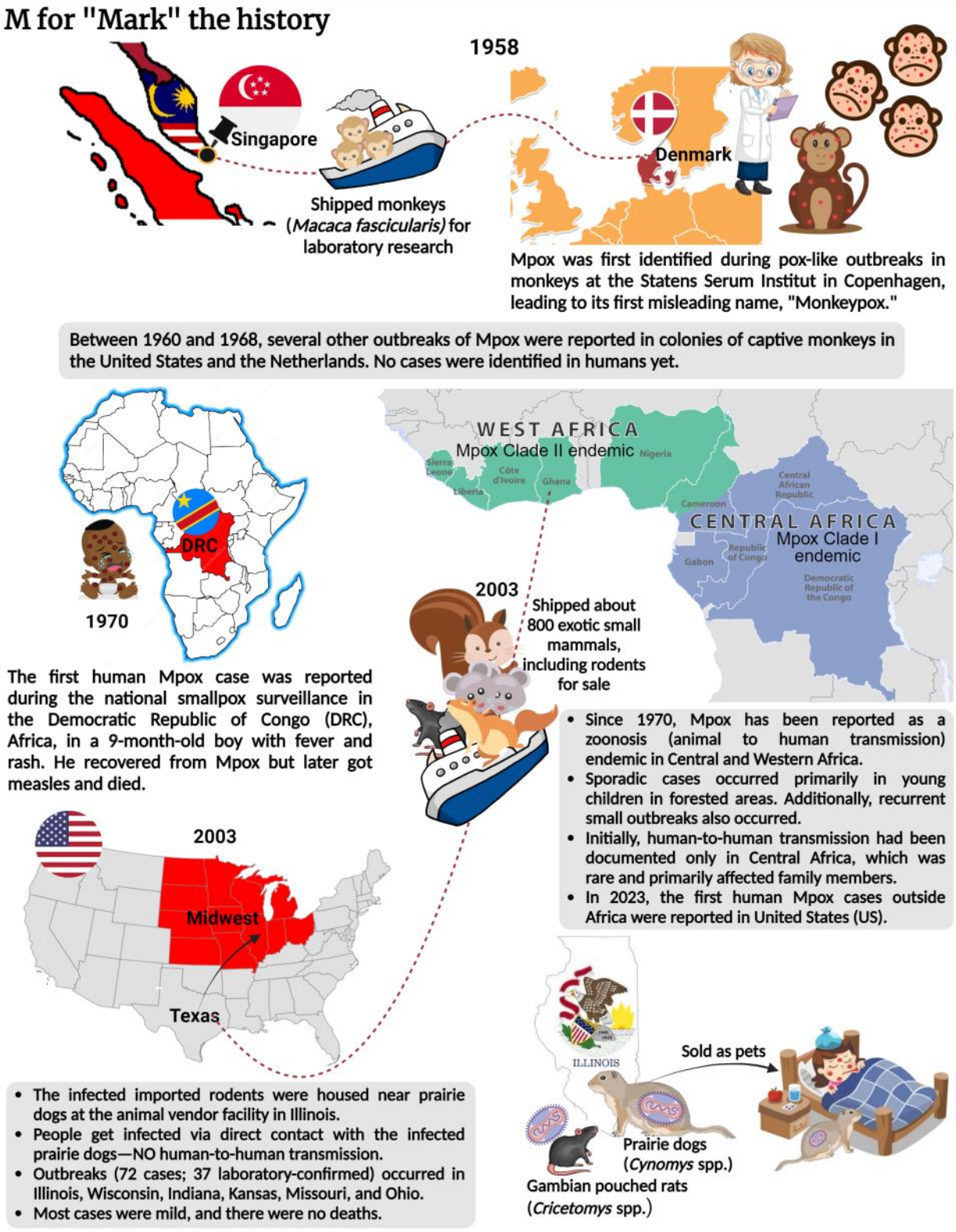
Thank you, INA-RESPOND, for this incredible opportunity – Adhel.

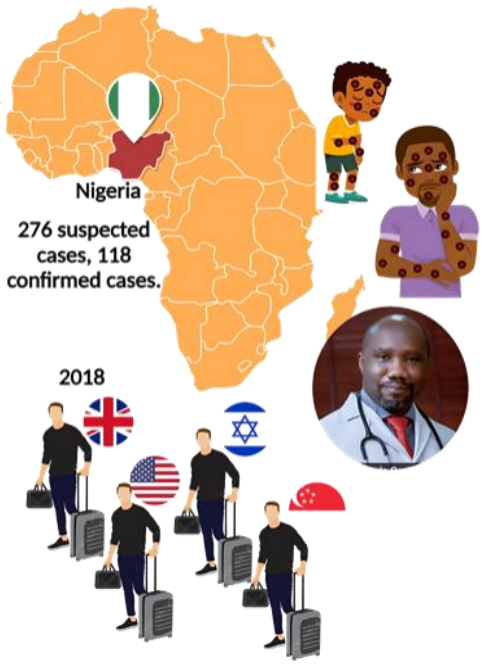
See you at the RePORT annual meeting in the United States next year!

INA-RESPOND
Newsletter

Mpox, M is for "Maybe..."

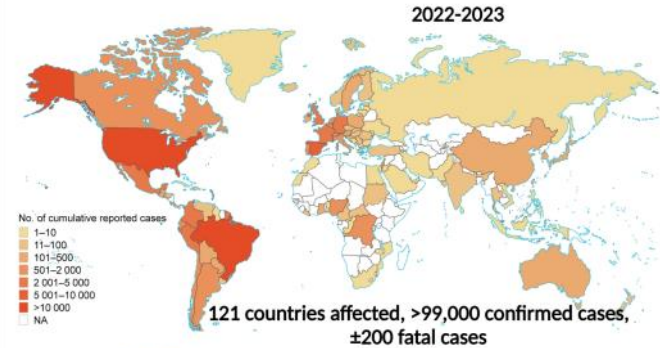
By: Adhella Menur





2017-2018

- The last reported human Mpox case in Nigeria was in 1978
- In 2017, an 11-year-old boy from Bayelsa was hospitalized with lesions resembling chickenpox, but also affected the soles and palms—areas not typically involved. His family members developed similar symptoms.
- The boy and his uncle had been in contact with a neighborhood monkey, and the uncle had other potential exposures, including visited slaughterhouses for the restaurant, and had visited a sex worker a week before becoming ill.
- Prof. Dimie Ogoina, an infectious disease specialist, suspected Mpox and alerted the Nigeria-CDC.
- 80% of cases involved young men with genital lesions, and there were signs of new patterns of transmission.
- Early on, Prof. Ogoina raised concerns about possible links to high-risk sexual behaviors, though these ideas initially faced skepticism. *A thoughtful story on the Mpox outbreaks in Nigeria by Jon Cohen and Abdullahi Tsanni can be found in Science (doi: 10.1126/science.z3d5uwl).*
- Between 2018 and 2021, the United Kingdom, the U.S., Israel, and Singapore reported nine human Mpox cases, all involving travel history from Nigeria. Three of the cases were men who had genital lesions.
- Mpox cases continue to be reported regularly in African countries.



2022-2023

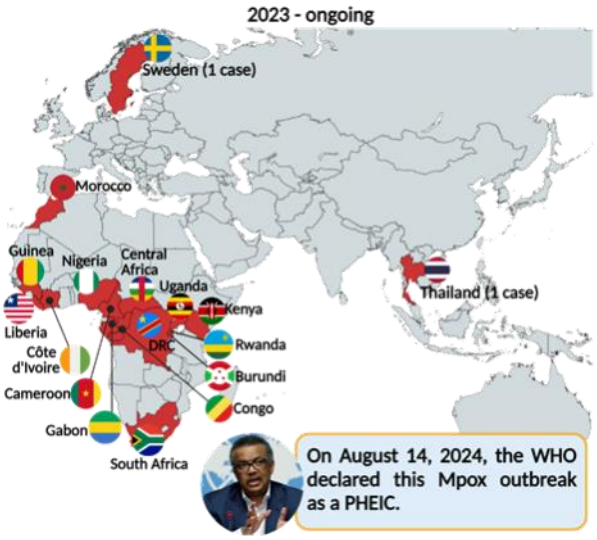
- The first Mpox cluster was identified in the UK, with the initial case detected in London on May 6, 2022, in a patient who had recently traveled from Nigeria.
- Mpox cases also began appearing in Europe and US countries, predominantly among men who have sex with men (MSM) after festivals.
- Subsequently, many countries reported Mpox cases, affecting diverse populations.
- This marked the first time Mpox cases surged rapidly in non-endemic countries worldwide, with how the virus's spread to some regions still not fully understood.

On July 23, 2022, the WHO declared the Mpox outbreak a Public Health Emergency of International Concern (PHEIC) - ended in May 2023. In November 2022, the WHO renamed Monkeypox to Mpox to avoid misperception, racist, and discriminatory connotations.

References: DOI: 10.1056/NEJMra2208860, DOI: 10.1038/s41577-022-00775-4, DOI: 10.3389/fcimb.2024.1360586, https://doi.org/10.3390/v14102155, https://doi.org/10.1016/j.imj.2024.100105, https://doi.org/10.3390/v15040995, https://doi.org/10.3390/microorganisms11112713, *continue...*

2023 - ongoing

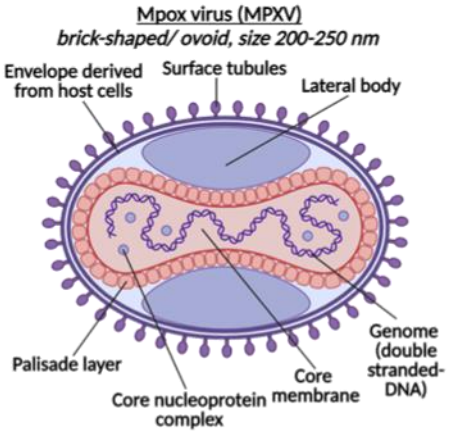
- It began in the fall of 2023 in Kamituga, DRC, that previously had been Mpox-free. The most affected group were sex workers.
- There was also a drastic surge in Mpox cases, affecting many children.
- Currently, over 24,000 confirmed or suspected Mpox cases, including more than 600 deaths, were reported across Africa.
- This outbreak is complex → scientists hypothesize multiple outbreaks are occurring simultaneously: Clade Ia (older variant) and Clade Ib (novel variant) in the DRC and neighboring countries, and Clade II in South Africa, primarily in people living with HIV.
- Outside of Africa, the novel Mpox strain (Clade Ib) cases have been reported in Sweden and Thailand, both linked to recent travel from African countries.



M for "Meet" the virus

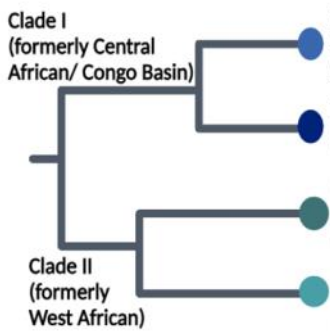
A colorized transmission electron micrograph of Mpox particles, in red, found within an infected cell in blue (US-NIAID file).

MPXV illustration. Credit: Stephanie Rossow via CDC Public Health Image Library.



- **Family Poxviridae**, genus **Orthopoxvirus**.
- Same group with variola (smallpox), cowpox, and vaccinia virus.

- The MPXV genome is about 197,000 kb.
- The mutation rate is lower than RNA viruses → 2 nucleotide substitutions/ genome/ year.
- However, the virus from the 2022 pandemic showed a rapid evolution → resulting from continued interaction with the human immune system since 2016.
- Most new mutations were characterized by activity of an antiviral enzyme in the human immune system called **APOBEC3** → sustained human-to-human transmission.



Ia -> classic form, 1970-present. Primarily animal-to-human (limited human-to-human transmission). High proportion in children <15 years. More clinically severe. CFR up to 11%.

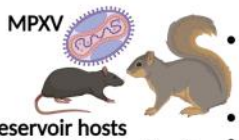
Ib → novel, 2023-present. Differ from Ia; Ib linked to sexual contact (sex worker >>) - CFR <4%? - still under investigation. CFR up to 11%.

IIa → classic form, 1970-present. Responsible for 2003 US outbreak. Primarily animal-to-human (limited human-to-human transmission). Milder than clade I. CFR <2%.

IIb → (actually found in 1971?) 2017-present. Responsible for 2022 pandemic (lineage B.1). Primarily human-to-human transmission, high proportion in young adults (MSM >>). CFR <2%.

M for "Modes" of transmission and "Manifestations"

Zoonosis (animal-to-human)



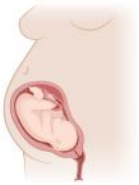
Reservoir hosts
** still under investigation*

- Close contact with infected animals or their body fluids.
- Scratch or bite.
- Handling or consuming the meat.
- Contaminated food or objects.

Intermediate or incidental hosts

Zoonosis (animal-to-human)

Human-to-human

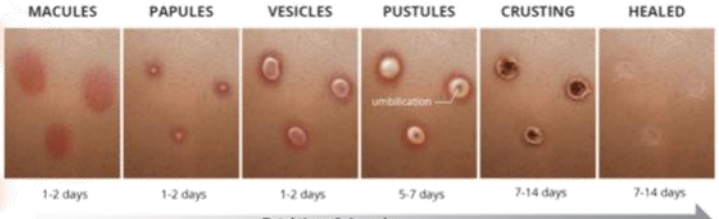


Please, use condom!

Virus can survive outside the body for several hours.

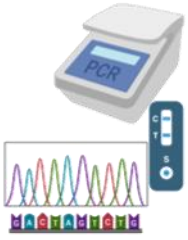
- Direct contact with an infected skin lesions or mucosa.
- Direct contact with an materials contaminates with the virus (bed, clothes, utensils, etc.)
- Sexual transmission → vaginal/ anal intercourse, oral-genital contact, mouth-to-mouth kissing, direct contact with groin and genital lesions.
- Transmission via semen has been documented (MPVX DNA in the semen of infected individuals (+)) → under investigation.
- Pregnant mother to child transmission.
- Droplets (face-to-face long conversation).
- Aerosolized respiratory secretions → NO (lacking data).

- Incubation period of 5-21 days.
- It is also possible to be asymptomatic or clinically silent.



- Fever (38.5'C - 40.5'C), chills, sore throat, headache, and myalgia.
- Swelling at the maxillary, cervical, or inguinal lymph nodes (lymphadenopathy) → not found in variola and varicella.
- Rashes appear following the onset of fever, beginning on the face, tongue, and oral cavity (pain lesions), before spreading across the body (centrifugally).
- Self-limiting in immunocompetent individuals.
- Research is ongoing to determine how long immunity from Mpox lasts. While other *Orthopoxviruses* offer lifelong immunity, some Mpox reinfections have been reported.

Severe complications: respiratory and gastrointestinal issues, ocular infections leading to vision loss, secondary dermal bacterial infections, encephalitis, sepsis, and pregnancy (mother and/or fetus) complications.



- Lesion swabs, scabs, and aspirated lesion fluid → viral detection.
- Other samples from the throat or genitals.
- Serum antibodies → need paired sera and may cross-react.

M for "Medicine" and "Measures"

Currently, there is no specific antiviral or treatment for Mpox.

Mild or uncomplicated Mpox

- Symptomatic treatment (antipyretic, analgesics, antihistamine).
- Adequate hydration and nutrition.
- Supplementing Vit. A for deficient patients.
- Antimicrobial cream for skin if secondary bacterial infection is suspected.
- Mental health support.

High-risk patients and severe Mpox

- High-risk patients: children, pregnant women, the immunocompromised, history of eczema, and elderly → recommend to be hospitalized for monitoring.
- Antiviral agents (e.c., tecovirimat/ TPOXX (initially for smallpox), cidofovir (initially for CMV), brincidofovir (initially for smallpox).
- Passive immunotherapy (VIG/ vaccinia immunoglobulin → bind to poxvirus virion and prevent the virus infecting new cells.
- Specific treatment according to the clinician.

- Human-to-human spread can be controlled by individual and public health measures including early case-finding, diagnosis and care, isolation and contact-tracing.
- There is no specific vaccine for MPXV, but the smallpox vaccines give 85% cross-immunity due to shared antigenic features.
- Licensed vaccines for Mpox:
  - 2nd generation, live vaccinia virus (VACV) → ACAM2000 for ≥18y.o, but no longer licensed by European Union due to safety issues).
  - 3rd generation, attenuated vaccines → JYNNEOS (≥18y.o), MVA-BN, and LC16 (also approved for children).
- Prophylaxis is recommended for health workers, laboratory personnel, and people at high-risk of getting Mpox (household contact, sex workers, multiple sex partners, MSM).

Why has the Mpox virus resurged and spread?

- Maybe it's because our immunity to **Orthopoxviruses** has weakened since smallpox eradication in 1980.
- Maybe the virus has successfully mutated and evolved to spread better between humans.
- Maybe we are belittling the "One Health" strategy for attaining optimal health for people, animals, and the environment.
- Maybe we've been ignoring some red flags like people messing with wildlife, folks traveling without proper precautions, or some risky sexual behaviors.
- Maybe we've been neglecting vulnerable groups like children and women dealing with poor nutrition and poverty in countries with conflicts.
- Maybe there are too large gaps in access to diagnosis, surveillance, care, or vaccines, especially in the countries that need them most.
- Maybe we're just not educating ourselves enough about this virus, and we're still stigmatizing the disease.

What is the future of Mpox?

- Maybe it will become milder, rare, and eventually vanish.
- Maybe it will turn into a nightmare more than COVID-19.
- Maybe we just don't know.
- Maybe all we have to do is strengthen individual precautions and do more research!

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* https://www.nytimes.com/2024/05/16/health/cdc-mpox-congo.html.
* Created with Biorender.com.

"An infectious anywhere is potentially an infection everywhere."
Dr. Anne Rimoin, Professor of Epidemiology.

INA-RESPOND Newsletter

THE PARTNERSHIP OF CLINICAL RESEARCH IN GUINEA (PREGUI)

By: Jackie Perodin

FROM OUR PARTNER

In 2015, the Ministry of Health (MOH) of the Republic of Guinea and the National Institute of Allergy and Infectious Diseases (NIAID) signed a Memorandum of Understanding (MOU) for Cooperation in Biomedical Research. Under the MOU, involved parties conducted collaborative clinical research on the Ebola virus and other infectious diseases, including the randomized clinical trials PREVAIL II and the Partnership for Research on Ebola Vaccination (PREVAC). Through these efforts emerged the Partnership of Clinical Research in Guinea (PREGUI), created to support collaborative research between NIAID's Division of Clinical Research (DCR) and the Guinean MOH, whose mission is to implement and conduct national and international high-quality research focused on public health priorities in Guinea and develop sustainable research capacity in-country. Conakry, Guinea's capital, and Maferinyah, a rural town in the Forecariah prefecture, approximately 46 miles from Conakry, were chosen as the central locations for PREGUI operations. Most logistical, administrative, and general operations occur in Conakry, while clinical operations and study-related activities occur in Maferinyah. To support research implementation and conduct, core infrastructure and capacities were built at the existing Maferinyah National Training and Research Center in Rural Health, including a clinical research unit, pharmacy, participant flow area, laboratory, training and conference rooms, and biorepository, as well as facilities (water, waste, electricity, storage) management, information management capabilities. In collaboration with PREGUI partners, CMRPD pro-

Picture 1. CMRPD Team PREGUI

vides clinical research infrastructure and operational and facilities management support, from conceptualization through the implementation, conduct, and closeout of research activities.

CMRPD staff members play an important role in directly supporting PREGUI. A clinical project manager and a program manager are responsible for overseeing the entire program and ensuring that all project activities run smoothly. Their responsibilities include not only day-to-day oversight, but also the management of various subcontracts required for the successful implementation of research projects. In addition to these managerial roles, the team includes a dedicated research scientist who is responsible for providing scientific guidance and laboratory training to local personnel, ensuring that high-quality research standards are maintained throughout the project. A senior logistics analyst and a senior program coordinator will help to strengthen PREGUI's operational capabilities. These two professionals specialize in procurement and logistics, ensuring that all necessary supplies, equipment, and materials are available when needed while also managing the logistics of their delivery and management. These five staff members form a cohesive team, ensuring the successful execution of PREGUI's research activities.

Political unrest poses unforeseeable challenges to clinical research activities in country. A coup d'etat in September 2021, civil protests/demonstrations, distrust in public authorities, shortage of resources (e.g., the explosion of a fuel depot in December 2023), and electrical and connectivity issues affect clinical operations of ongoing research. This requires the project team to readjust often and find alternatives to mitigate situations for continuity of work, as feasible. The nature of the project requires CMRPD staff to provide continuous guidance, hands-on and remote training, and support to ensure the availability of critical resources for smooth operations on the ground.

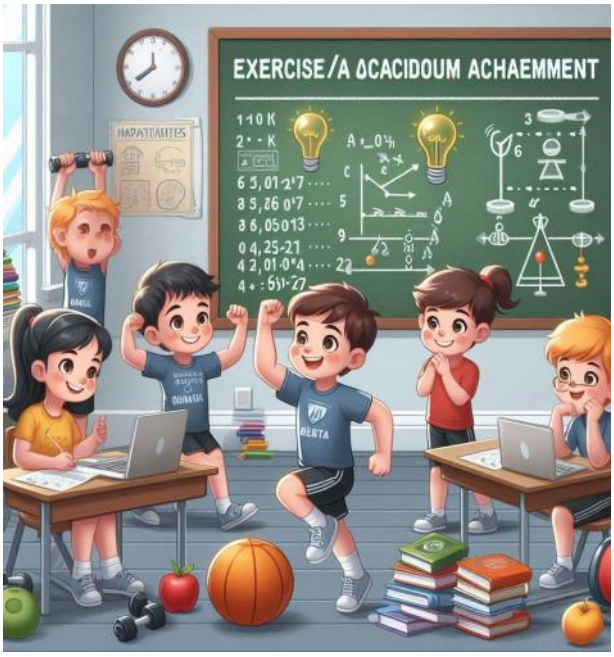
Despite numerous challenges, PREGUI has demonstrated remarkable resilience and has successfully participated in a wide range of important studies supported by NIAID and other international partners. These studies have spanned various infectious diseases of public health significance, such as an HIV study known as D2EFT, which focuses on treatment options for those who have failed first-line antiretroviral therapy. Additionally, PREGUI has been deeply involved in malaria research, contributing to critical studies like the Malaria Burden study, DeTACT, and the EDCTP-Malaria technology and data Transmission project. Most recently, PREGUI has played a key role in the ongoing NIAID DCR- supported InVITE COVID-19 and measles studies.

The 2017-2022 PREGUI strategic plan outlined the network's many collaborating partners, stakeholders, goals, and approach to achieve their mission. Assessments and discussions are currently underway with the network's leadership to determine the best approaches to support PREGUI's growth in its next phase.

INA-RESPOND Newsletter

THE HIDDEN LINK BETWEEN EXERCISE AND ACADEMIC ACHIEVEMENT IN CHILDREN

By: Marco Ariono



Physical inactivity is a global concern, with fewer than 20% of school-aged children meeting the recommended physical activity guidelines. Research consistently shows that physical activity supports both physical and mental well-being. According to Vangnero-Solis et al., engaging in physical activity during childhood positively impacts body mass index (BMI), physical development, movement skills, self-esteem, and social behavior.

The Importance of Active Play in Childhood

Active play during early childhood is not only beneficial for physical health but also fosters emotional and social development. Through play, children strengthen bonds with caregivers and peers, enhancing communication skills—especially for those who struggle to express their needs. Outdoor play, in particular, is associated with increased physical activity. It also helps children form friendships, learn to share, resolve conflicts, and develop self-advocacy and leadership skills.

Physical Activity Guidelines for Children

In 2020, the World Health Organization (WHO) updated its physical activity guidelines, recommending that children and adolescents aged 5–17 engage in at least 60 minutes of moderate to vigorous activity daily. Regular physical activity during adolescence promotes healthy skeletal and cardiovascular development, improves fitness, enhances physical performance, and supports healthy body weight. It also increases circulation, improves oxygen supply to the brain, strengthens bones and muscles, and builds resilience to stress.

The Impact of Physical Activity on School Performance

Physical activity also significantly impacts academic performance. Research by Solberg et al. demonstrated that students who participated in two school-based physical activity programs—providing an additional 120 minutes of physical activity per week over nine months—showed significant improvements in numeracy and reading skills compared to a control group. Similarly, Mavilidi et al. found that active breaks improved students' behavioral control, while Daly-Smith et al. confirmed that lessons incorporating physical activity enhanced classroom behavior.

Watson et al.'s systematic review explored how classroom-based physical activity affects academic outcomes. The review found that incorporating physical activity into the classroom generally improved student behavior, particularly on-task behavior and overall classroom management. However, the effect on cognitive function was less clear, with mixed results across studies. Interventions that included cognitive engagement often led to improvements in cognitive outcomes, but this was not consistent. Watson et al. suggested that variations in study design and the nature of physical activities may account for these differing results.

The Role of Physical Education (PE) in Schools

Physical education (PE) plays a vital role in students' holistic development by linking physical health with academic success. Unfortunately, many schools have reduced PE time in favor of core academic subjects, potentially overlooking the significant benefits physical activity offers. PE classes provide a structured environment where students engage in physical exercise, learn new skills, and develop lifelong healthy habits. These classes contribute to improved physical fitness, better social interactions, and the development of essential values such as teamwork and persistence. Regular participation in PE fosters a positive attitude toward physical activity, encouraging students to remain active beyond school hours.

To maximize the benefits of physical education, schools should incorporate physical activity throughout the day—through brief movement breaks between classes, encouraging active play during recess, and offering after-school sports programs. These initiatives ensure that physical activity remains an integral part of the educational experience, supporting both academic and personal growth.

Recommendations for Parents and Educators

Parents and educators play a crucial role in fostering physical activity in children's lives. Here are some practical recommendations to ensure children get the exercise they need:

- Encourage Active Play at Home: Promote outdoor activities and family outings like hiking or biking. Limiting screen time and encouraging simple actions, such as walking the dog or playing in the backyard, can significantly increase children's daily physical activity.
- Advocate for Physical Activity in Schools: Collaboration between educators and parents is key to promoting physical education in schools. Advocate for extended PE classes and emphasize the importance of active play during recess to create school environments where children thrive, physically and academically.
- Promote Sports and Extracurricular Activities: Sports teams and after-school clubs offer excellent opportunities for children to stay active while developing new skills and making friends. Schools and communities should ensure that these activities are accessible to all children, regardless of athletic ability or socioeconomic background.
- Incorporate Movement Into Learning: Enhance learning by integrating movement into the classroom. Simple techniques like standing during discussions, using physical objects for math lessons, or incorporating short "brain breaks" can help students stay focused and engaged.
- Make Physical Activity Fun: Children are more likely to stay active when they enjoy what they are doing. Introduce a variety of games, sports, and activities that cater to different interests and skill levels, making physical activity a fun and enjoyable part of their daily routine.

Research underscores the importance of parental involvement in promoting physical activity. For example, the "Dads and Daughters Exercising and Empowered" (DADEE) intervention, an 8-week program, significantly increased physical activity in both fathers and daughters, improved motor competence in girls, and reduced screen time.

By following these recommendations, parents and educators can help children develop a lifelong appreciation for physical activity, supporting their overall health and well-being.

Conclusion

Physical activity is essential for children's physical health, mental well-being, and academic success. By encouraging regular exercise and integrating movement into daily routines, parents and educators can help children establish healthy habits that support their overall development and learning.

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INA-RESPOND Newsletter

POLICY BRIEF: PUTTING IT IN THE RIGHT HANDS TO MOVE FORWARD

By: Aly Diana

As scientists, we dedicate our careers to conducting rigorous research, with the aim of improving public health, education, and societal well-being. We carefully design studies, collect data, and present our findings, hoping they will lead to real-world improvements. However, we often find ourselves questioning: Does our research truly influence policy? Are we merely publishing papers, or are we translating our work into policies that shape a better future?

One of the biggest obstacles in translating research into policy is the **misalignment between research and policy timelines**. Scientific studies can take years to complete, but policymakers often operate on much shorter schedules, driven by urgent concerns or political pressures. By the time our findings are ready, the window of opportunity for influencing policy may have already closed. To overcome this, researchers need to be proactive in tracking policy cycles and identifying upcoming debates where their findings could be relevant. Engaging with policymakers throughout the research process, rather than waiting until the study is complete, can help ensure that findings are timely and actionable.

Improving Communication Between Researchers and Policymakers

Another major hurdle is communication. The language used in scientific papers—technical, detailed, and full of statistical analysis—does not easily translate into the fast-paced world of policy. Policymakers require clear, concise, and actionable insights. While policy briefs are a recognized tool for bridging this gap, success depends not just on summarizing research but on framing the issue in a way that resonates with decision-makers. It's essential to highlight the tangible impacts of re-

search findings and provide practical recommendations. In a world where policymakers juggle numerous issues, even groundbreaking research risks being overlooked if it doesn't present a compelling narrative aligned with current policy priorities.

Policymakers often face competing priorities, such as economic shifts, public health crises, or political turbulence. In this crowded landscape, even significant research can struggle to gain attention. Research must be directly tied to **timely and relevant policy questions** to stand a chance of influencing decisions. One effective strategy is to engage in collaborative research efforts with policymakers or institutions that have a direct influence on policy. These partnerships help align research with ongoing policy needs, making it more likely that findings will be applied. Additionally, established relationships with think tanks, advocacy groups, and NGOs can help promote research findings, ensuring they are supported by stakeholders capable of championing the work.

Even when researchers overcome these challenges, they often face "**research-to-policy fatigue.**" The slow pace of policy change can be discouraging. While the research process itself may be rewarding, the long journey to policy impact can cause some to lose motivation. Policy change is often incremental, and success may not always come in the form of sweeping reforms. Instead, it may manifest in smaller victories, such as contributing evidence that influences part of a larger policy conversation or shaping the language of a policy proposal. Maintaining a long-term perspective and recognizing that incremental progress is still progress can help sustain momentum and motivation.

Persistence is key in translating research into policy. Policy changes rarely happen overnight, and researchers must continue to engage with policymakers, refine their communication strategies, and form partnerships that amplify their work. By consistently working at the intersection of science and policy, researchers can ensure that their findings don't just remain within academic journals but lead to meaningful changes that improve lives.

Conclusion

To drive real-world improvements, researchers must recognize the importance of timing, communication, and collaboration in the policy process. By engaging with policymakers early, refining how we present our findings, and building partnerships, we can bridge the gap between research and policy. With persistence and strategic engagement, our research can become a catalyst for the positive changes we seek to create.

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