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INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASES

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OPERATIONS & ACTIVITIES

Optimizing Quality and Compliance in Clinical Trials
Monitoring Activities, Investigational Product, and Specimen Management

By: **INA-RESPOND CRA and CRSS**

Introduction

Clinical trials play a key role in shaping evidence-based medicine, guiding regulatory approvals, clinical decisions, and public health policies. The success of any clinical trial depends not only on a robust protocol but also on the meticulous execution of operational aspects, including monitoring activities, investigational product (IP) management, and specimen handling. These components ensure adherence to ethical standards, regulatory frameworks, and scientific rigor—ultimately guaranteeing the validity and reliability of the trial's findings.

However, in practice, many research sites face challenges such as inconsistent documentation, inadequate IP storage conditions, and delayed specimen shipment—each of which can compromise study integrity if not properly addressed through effective monitoring and site management.

This article draws on internal training materials delivered at the RSPI Sulianti Saroso (RSPI-SS) in Jakarta, Indonesia, and offers a comprehensive discussion on practical and regulatory considerations related to clinical trial monitoring, investigational product management and biological specimen handling. It serves as a guide for Clinical Research Associates (CRAs), site personnel, and sponsors seeking to ensure compliance with Indonesian regulatory requirements (Indonesian Food and Drug Administration (FDA)/Badan Pengawasan Obat dan Makanan (BPOM)), International Council for Harmonization (ICH) E6, and Good Documentation Practices (GDP).

Regulatory and Ethical Framework

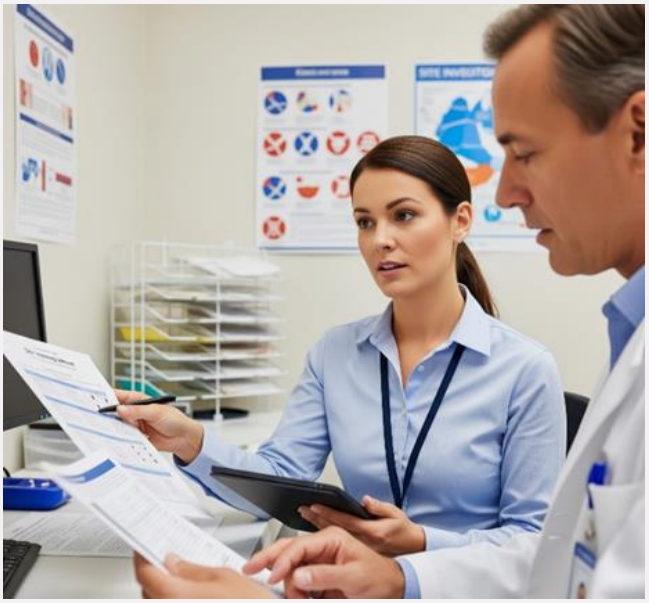
The foundation of all clinical trial operations is rooted in GCP, which ensures that trials are conducted ethically and that the data collected are credible and reliable. In Indonesia, these principles are reinforced through Cara Uji Klinik yang Baik (CUKB), which integrates global standards such as ICH E6(R2), while aligning with national requirements from BPOM.

Key GCP principles highlighted include:

- Protection of trial participants' rights, safety and confidentiality.
- Reliability and accuracy of data collection and reporting.
- Compliance with approved protocols, amendments and applicable regulations
- Proper and timely documentation of all trial-related activities

Accordingly, every individual involved in the clinical trial—ranging from site personnel to CRAs—must be appropriately qualified, trained, and delegated. These qualifications must be well-documented through updated Curriculum Vitae (CV), valid GCP certificates, and current training logs.

Monitoring Activities (Methodology & Practices)



Objectives & Scope of Monitoring

The primary objective of monitoring is to ensure the rights, safety and well-being of trial participants, as well as the reliability of trial results as the trial progress. Monitoring is one of the key quality control activities in clinical research.

Monitoring covers a wide range of activities designed to uphold the quality and integrity of a clinical trial. These include maintaining effective communication with investigator sites, assessing staff qualifications and site capabilities, providing training, and reviewing trial documentation. Review methods may involve source data review, source data verification, data analytics, as well as on-site and remote monitoring visits. Some monitoring tasks—such as centralized monitoring—may be carried out by individuals in specialized roles (e.g., data scientists or biostatisticians). However, monitors must remain independent of the trial's conduct at the site they oversee. Being independent means that the monitor should not be directly involved in the conduct of the study and must have no vested interests that could compromise their objectivity. The selected monitoring approach should reflect the specific trial activities and settings, including decentralized elements, and must be clearly defined in the monitoring plan. All personnel involved in monitoring must comply with relevant data protection, confidentiality policies, and data security standards as required by regulations and institutional policies.

Monitoring may involve on-site, remote, and centralized methods, depending on the overall monitoring strategy and the trial's design. The sponsor is responsible for determining the appropriate type and extent of monitoring based on the specific risks identified. This decision should take into account various factors, including the trial's objectives, purpose, design complexity, blinding, number of participants, the investigational product, and current understanding of its safety profile and endpoints. Each type must be outlined in a Monitoring Plan, tailored to study complexity, blinding, number of participants, investigational product risk profile, and endpoints.

There are two types of monitoring activities: investigator site monitoring, which is usually performed by a CRA appointed by the sponsor, and centralized monitoring, which may be conducted by different methods and persons with different roles (e.g., data scientist). The ICH E6(R3) guideline clearly states the definition for each type of monitoring activity.

Investigator site monitoring involves overseeing trial-related activities at the investigator's site, including related areas such as the pharmacy or local laboratories when applicable. This may be performed either on-site or remotely, depending on the nature and purpose of the trial activities. The frequency and intensity of monitoring should be risk-based and adjusted as more insights are gained during the trial. Remote monitoring may also include secure, read-only access to source documents and essential trial records.

Centralized monitoring, on the other hand, involves timely data evaluations by qualified individuals appointed by the sponsor—such as medical monitors, data scientists, or biostatisticians. It enhances the ability to detect systemic or site-

specific issues, such as protocol deviations or questionable data, and can either complement or reduce the need for on-site monitoring. Additionally, centralized monitoring helps in identifying which sites or processes may require focused attention through targeted monitoring.

Monitoring Visits and Documentation

A standard clinical trial typically includes the following types of monitoring visits:

- Site Initiation Visit (SIV): conducted to prepare the site for trial activation.
- Site Monitoring Visit (SMV): conducted periodically to assess protocol compliance, participant safety and data accuracy.
- Site Close-Out Visit (SCV): conducted to ensure study closure is complete and documented.

All monitoring activities must be thoroughly documented in the SIV, SMV and SCV report. The CRA is responsible for ensuring that all action items are resolved prior to the next monitoring visit. All findings must be shared with both the sponsor and the site. This report should be reviewed and approved by line manager and sponsor. Once approve, CRA distributes this document to the investigator and site personnel for their action and references. These reports should be appropriately filed in the Trial Master File (TMF) and/or Site Regulatory Binder (SRB).

Investigational Product Management

Managing Investigational Products (IPs) effectively at clinical trial sites is vital to ensuring protocol compliance, participant safety, and data integrity. IPs may include pharmaceuticals, medical devices, biological products, and even dietary supplements, all of which are participant to strict regulatory control.

According to BPOM regulations and CUKB guidelines, IPs must meet the appropriate safety, quality, and manufacturing standards before use. Trial sites are required to maintain complete accountability for every IP unit received, dispensed, returned, or destroyed. Each activity must be appropriately documented, including details such as batch numbers, expiry dates, and participant identifiers.

Principal Investigators (PIs) may delegate IP-related responsibilities to qualified pharmacists or other trained personnel, but the ultimate accountability remains with the PI. Delegation must be clearly listed in the Authorized Signature and Delegation Log (ASDL), and all personnel involved in IP handling must have current training, GCP certification, and CVs on file.

Required documentation includes delivery records, inventory logs, dispensing logs, temperature monitoring records, and return/destruction records. These documents must be stored in the SRB and be readily available during monitoring visits and regulatory inspections. Sponsors may also require reconciliation of IP inventory at specific study milestones or during SCV to ensure no discrepancies remain in supply records. Discrepancies, if found, must be investigated and resolved with documentation retained for audit purposes.

At each participant visit, dispensing and return of IP (if applicable) must be reconciled against the participant's visit schedule and documented in

both source documents and Case Report Forms (CRFs). Any discrepancy—such as missed or excess dosing—must be reported and explained.

IP storage conditions—whether ambient, refrigerated, or frozen—must adhere strictly to the specifications outlined in the Investigator's Brochure (IB) and the trial protocol. The use of automated temperature monitoring systems with real-time alert functions is encouraged to promptly detect temperature excursions. Manual logs should be used as backup and reviewed periodically by assigned personnel. Any temperature excursion must be reported immediately to the sponsor, with corrective actions documented using appropriate excursion forms. Only sponsor-approved decisions should determine whether affected IPs can be used.

During randomization and unblinding procedures, it is crucial to follow protocol-defined steps to maintain the integrity of the study's blinding. Any premature or unintended unblinding must be documented, justified, and reported promptly to both the sponsor and ethics committee.

Specimen Management Workflow

Handling biological specimens—such as blood, urine, or other biological samples—during clinical trials requires meticulous attention to ensure data quality and biosafety. Specimen management begins at collection and continues through processing, storage, shipment, and analysis.

Collection must be preceded by participant identification confirmation, using the Informed Consent Form (ICF) and source documents. The laboratory technician at the site should prepare the appropriate collection tubes/containers as specified in the study protocol. Labels must be waterproof, durable, and properly coded with participant's identification number and visit number.

Specimen processing includes centrifugation, aliquoting, and barcoding, with data recorded in Specimen Logs. Cryovials should be pre-labeled

and arranged in storage boxes according to predefined mapping templates. Specimens are stored under appropriate conditions—as mentioned in the Laboratory Manual or Specimen Management Standard Operating Procedure (SOP) or Manual of Procedure (MOP) requirements.

Sites are required to monitor freezer temperature daily and log data using Freezer Temperature Log. If deviations occur, forms like the Freezer Condition Report must be completed and submitted within 10 working days. This ensures traceability and stability of stored samples throughout the study period.

For shipment to the reference laboratory, specimens should be packaged with or without dry ice depending on the temperature requirements and must include temperature recorders in accordance with International Air Transport Association (IATA) guidelines. Documents such as shipment lists, cryobox maps, and specimen shipping statement letter for each shipment. Staff must be trained in biosafety and international shipping procedures.

Specimens are analyzed based on the study's lab manual and protocol using validated methods and calibrated instruments. Whether it involves hematology, biochemistry, or other assays, the testing must follow SOPs and quality control standards to ensure accurate results.

Coordination between site staff, sponsors, and reference laboratories is essential to avoid delays and maintain specimen integrity. From the moment a sample is drawn to its final analysis, every step in the specimen management workflow plays a vital role in safeguarding data quality and participant safety. Standardization, documentation, and regulatory compliance are the keys to successful biospecimen handling in clinical research. All steps must adhere to Good Clinical Laboratory Practice (GCLP) and national biosafety regulations.

Specimen Management Lessons Learned and Best Practices

Running clinical trials is no simple task, and consistent attention to detail can significantly influence study outcomes. Key lessons from internal training sessions include the following:

Clear documentation is essential: Incomplete or inconsistent records can result in data rejection, regulatory findings, or protocol deviations.

Training must be continuous: Staff turnover and protocol updates necessitate regular refresher courses.

Communication between site and sponsor is critical: Prompt escalation of issues ensures faster resolution and regulatory compliance.

Monitoring visits should be viewed as collaborative: Rather than punitive, monitoring visits help improve site performance and identify gaps.

SOP adherence must be routinely audited: Standard procedures only work when consistently applied.

Implementing checklists for daily, weekly, and visit -based activities has shown to improve site compliance. Cross-checking IP accountability with Case Report Forms and source documents, ensuring timely uploads of data, and maintaining version control of documents are all necessary steps in a quality-driven research environment.

Conclusion and Recommendations

The success and trustworthiness of clinical trial results rely heavily on how well monitoring activities, IP, and specimen management are carried out. Adherence to regulatory requirements, robust documentation, and proactive communication form the pillars of a successful clinical research infrastructure.

It is imperative that CRAs, investigators, and sponsors work collaboratively to maintain high standards of GCP compliance. Continuous training, accurate, timely record-keeping, and a strong culture of accountability should be embedded into every stage of the trial process. By investing in proper monitoring strategies, IP management systems, and specimen handling systems, we can ensure that trial data are both credible and ethically obtained—ultimately contributing to the advancement of safe and effective medical interventions.

FAREWELL

Science Is For Everyone

By: **Adhella Menur**

Hello, for regular or new readers of the INA-RESPOND Newsletter, I am Adhel, a member of the Science Team who has loved routinely contributing to this Newsletter for the past several years. Today, I would like to share my journey with INA-RESPOND, which has been my second home for the past seven years.

I still remember March 2017, when I was a general practitioner working at a general hospital in Kandangan, a remote area in South Kalimantan. While looking for a new job in my hometown, I was contacted by dr. Wang Erna, my brilliant senior from *Universitas Diponegoro*, who was then a research assistant (RA) for the INA-RESPOND AFIRE study at Kariadi Hospital (Site 560) in Semarang, Central Java, under Prof. dr. Muhammad Hussein Gasem, Sp.PD-KPTI, Ph.D. With little knowledge of the world of clinical research, I took the opportunity to be an RA for TRIPOD, INA-RESPOND's tuberculosis (TB) study under dr. Banteng Hanang Wibisono, Sp.PD-KP and dr. Desvita Sari, Sp.MK. It was a blast. I never imagined research could be so much fun, even though it was also complex and serious.

I learned how to approach potential participants, conduct informed consent, and enroll them ethically. It required discipline and diligence to follow the protocol and complete the mountain of documentation. I discovered professions I had never heard of before, like Clinical Research Site Specialist and Clinical Research Associate, and saw how every role, from principal investigators and nurses to laboratory technicians and admin staff, worked together toward one goal: producing good science for a better future. The long-term observational study built deep bonds between me and the participants. I was deeply touched by the way they and their families faced disease and poverty with resilience, while still generously contributing their data and specimens for research.

After two years in Semarang, I moved to the INA-RESPOND Reference Laboratory to support the Pneumonia in Pediatric Study. This role gave me valuable experience in enrolling and working with child participants and their parents or legal guardians. I also assisted the head of the Reference Lab, dr. Dewi Lokida, Sp.PK (K), in laboratory operations, serving as a bridge to the Science Team. The experience opened my eyes to the vital importance of proper specimen handling, from storage to testing, and deepened my admiration for laboratory technologists who work diligently behind the bench to produce results that form the backbone of scientific publications.

When the studies ended, I was honored to be offered a position in the Science Team under dr. Herman Kosasih, Ph.D, and dr. Nurhayati, M. Epid., focusing on publications and scientific activities. I was just a medical doctor without a Master's or PhD degree, and my English was still limited, but they believed in me and gave me the chance to learn and contribute. I have no regrets. I truly love working in science, transforming study results into stories that honor participants' contributions, and sharing those results with those who need them most, especially health policymakers. Beyond that, I had the joy of working with a

smart, solid, yet fun Science Team (dr. Herman, dr. Nurhayati, dr. Yan Mardian, dr. Aly Diana, and dr. Adi Pranata) and a dedicated Data Team (Melinda, Danu, Ariqa, and Chandra), whose support and camaraderie made the work even more meaningful.

The work is never boring. We review data, discuss the key messages, analyze, read countless references, design tables and figures, craft manuscripts word by word, submit them, face rejections, come back stronger, acknowledge limitations, and start the cycle again. From AFIRE (fever study), TRIPOD (TB study), PEER PePPeS (pneumonia in pediatric study), SchisCCA (schistosomiasis study), ORCHID-COVID-19 (COVID-19 study), InVITE (COVID-19 vaccines study), to INA-PROACTIVE (HIV study), I have been blessed to contribute to the discussions, reports, and publications. I have learned so much from the investigators, accomplished clinicians with busy schedules, who remain deeply committed to publishing research that can shape health policy. I have also had the privilege of learning directly from top Scientists at the US NIAID/NIH.

I was also given the opportunity to work with the international TB consortium, the Regional Prospective Observational Research for Tuberculosis (RePORT), supporting dr. Nurhayati and Hanum, after the previous coordinator resigned. I did my best to highlight TRIPOD study results and to ensure INA-RESPOND's active involvement in RePORT International projects, including data harmonization, TB biomarker research across consortium studies, grant proposal writing, and collaborating with junior investigators to submit abstracts for the annual RePORT meeting. I am deeply grateful for the chance to meet inspiring TB researchers from around the world and to witness how strong scientific evidence can be translated into real-world actions that improve global health.

This Newsletter has been my fun space. I have enjoyed working with Dedy Hidayat to produce the Science Corner, collaborating with RAs from study sites across INA-RESPOND. Every month, we learned something new or revisited old knowledge, and wrote about it in a way that was scientific yet accessible to everyone. Even if the readers could be counted on one hand, I sincerely hope each one gained something valuable from it.

Over the past two years, like many institutions, INA-RESPOND has faced internal and external challenges. I am grateful that despite these challenges, the partnership has remained strong and is now entering an exciting new phase following significant changes in the Ministry of Health. After mastering observational studies and starting with a few clinical trials, the partnership is ready to excel in more complex studies. I am proud to have witnessed this transition as my journey with the institution comes to an end. I remain excited about INA-RESPOND's great potential and wish the partnership every success as they continue this important journey.

I am deeply grateful to this institution and to everyone who has built and supported it from the scratch, particularly Dr. H. Clifford Lane, M.D., and the late dr. Endang R. Sedyaningsih, M.P.H., Dr.P.H. During one of Dr. Lane's visits, he stopped by my cubicle and noticed my favorite motivational quote from Nelson Mandela displayed on the wall: "*It always seems impossible until it's done.*" He told me he liked it too. Although he may not remember that moment, it has always held a special place in my heart.

I cherish the ways this experience with collaborative clinical research has shaped my professional growth and enriched my life. I am certain I will always carry science with me, even outside formal research. I will use it in everyday life, even in small decisions like choosing my morning coffee. The best thing about science is that you do not need to be a genius, wealthy, or in a position of power. As long as you remain curious, honest, open-minded, and dream of a better world, you can do science.

Because science is, and always will be, for everyone.

SCIENCE CORNER

Bitten But Not Beaten: Malaria Keeps Its Grip on Indonesia

By: **Syndi Siahaan, Nurul Hidayah, Fadlika Harinda, Tiara Kumala Putri**

What's this about?

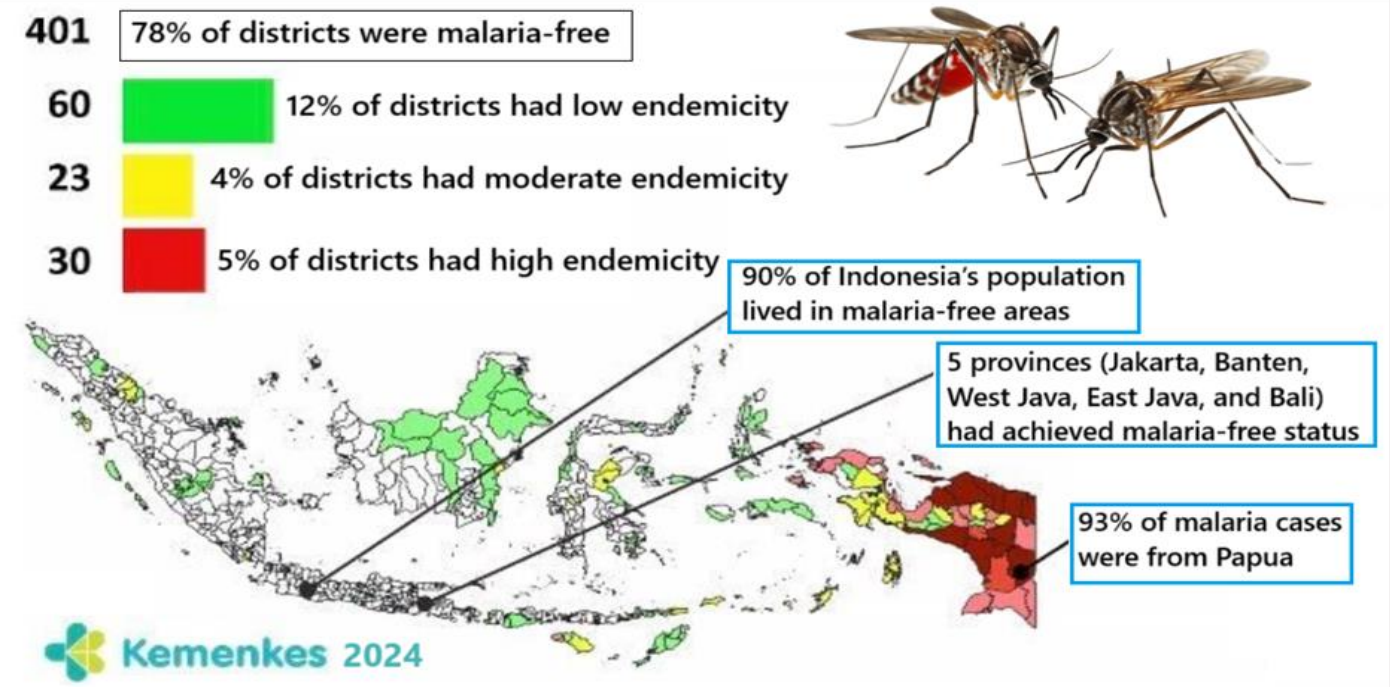
This month, we commemorate World Mosquito Day (August 20), a reminder of the ongoing battle against mosquito-borne diseases such as malaria, dengue, Zika, yellow fever, and chikungunya. The day marks the 1897 discovery by Sir Ronald Ross that female Anopheles mosquitoes transmit malaria, paving the way for prevention and control measures. In this edition, we spotlight Malaria, a disease that has had its grip on Indonesia since at least the 1950s. The Indonesian Ministry of Health has fought malaria for several decades through several programs. Currently, malaria eradication programs have been included in the health system, enabling extensive screening and prevention strategies. Despite long-standing and varied programs for controlling malaria, the estimated incidence remained high, with the World Health Organization (WHO) estimating 800,000 cases in 2021, and the Ministry of Health (MoH) reporting an overall malaria mortality rate of 0.04% during 2015-2020.

Malaria and how it affects Indonesia

Malaria is a mosquito-borne disease caused by *Plasmodium spp*. parasites affecting people of all ages. Its clinical manifestation varies, from asymptomatic to severe malaria, which can result in fatality. Patients often report fever with chills, headache, weakness, vomiting, diarrhea, etc. Patients with uncomplicated malaria can be treated in the clinics, while severe cases are hospitalized.

In the last two decades, malaria incidence has been slightly decreasing. Among the WHO South-East Asia Region, Indonesia reported the second-highest malaria incidence after India. High endemicity was reported, especially in Papua, East Nusa Tenggara, and West Papua (88.79%, 3.57%, and 2.95%, respectively).

A recent BMJ Global Health publication by Setiawan et al. analyzed National Health Insurance (*Jaminan Kesehatan Nasional/JKN*) claims data from 2015–2020, providing new insights into the



burden and economic costs of malaria in Indonesia. Among 12,970 recorded malaria episodes in 8,833 patients, 60.5% occurred in just three provinces: Papua (42.9%), East Nusa Tenggara (9.2%), and West Papua (8.4%). *Plasmodium falciparum* (ICD-10 B50) accounted for 46.4% of episodes, P. vivax (ICD-10 B51) for 33.2%, and 19% were recorded as 'unspecified malaria' (ICD-10 B54), typically reflecting clinical diagnosis without parasitological confirmation, often due to limited diagnostics or technical challenges in remote areas. Almost half of all cases first presented at hospitals: outpatient consultations cost an average of US$16.2, while inpatient care averaged US$228.7 per episode. P. falciparum cases were more likely to be classified as severe (7.6%) than P. vivax cases (5.2%), with in-hospital mortality rates of 2.1% and 1.2%, respectively. These figures highlight not only the ongoing health burden but also the significant economic impact of malaria in Indonesia, particularly in high-transmission provinces.

The 'culprit' behind the disease

More than 24 species of Anopheles mosquitoes are known as malaria vectors. Anopheles multiply rapidly in warm and humid places, such as rice fields, swamps, and shallow streams. Several factors influence their habitat, including standing water, warm temperatures, and proximity to human dwellings. Adult mosquitoes fly less than 2 km from their larval habitat to feed and return to lay their eggs in the water, as they cannot survive in dry conditions. Female mosquitoes need blood to produce eggs; therefore, they bite people, especially at night. Some mosquitoes feed outdoors while others prefer indoors. They will then rest in dark and sheltered areas for several days to digest blood and develop eggs.

Cutting malaria off at the buzz

To reduce malaria incidence, several efforts for vector control have been implemented by the Indonesian government through the malaria elimination program. Insecticide treatment through Indoor Residual Spraying (IRS) and Insecticide Treated Net (ITN) is used. For the IRS, the interior walls and other surfaces in the house are sprayed with a long-lasting insecticide, which shortens mosquitoes' lifespan and prevents malaria transmission. To protect a community, more than 80% of houses need to be sprayed.

ITN controls mosquitoes through preventing contact between mosquitoes and humans, thus reducing malaria incidence. Although untreated bed nets may also be used, the treated ones are more efficient due to their toxicity for mosquitoes but pose a low risk in humans. The increase in insecticide resistance may pose a problem; therefore, it is recommended to use proper insecticides and different classes of insecticides.

Figure 1. Insecticide-Treated Nets (ITN). Credit: WHO/Herdiana/2019

Environmental management, including habitat modification, manipulation, and source reduction, is suitable for controlling larvae and mosquitoes that feed outdoors. The focus of these efforts is to remove or permanently destroy mosquito habitats and breeding sites. Efforts include clearing vegetation, filling holes that can cause stagnant water, draining swamps, ditching marshy areas, and implementing water management strategies. Chemi-

cal insecticides can also be used for larviciding, the application of insecticides in the larval habitats, if habitat elimination is impossible.

Personal protection measures are also crucial in reducing contact between mosquitoes and humans. These measures include installing window screens, wearing light-colored long-sleeve shirts and pants, and using topical repellents. Repellents may be appropriate in areas where mosquitoes bite outdoors or early in the evening when ITNs are not used.

The fight so far: Today's reality

The Indonesian Ministry of Health implemented several strategies to control malaria, including large-scale ITN distribution and the use of IRS in endemic regions. These were supplemented by environmental management and the strategic application of larvicides.

Key innovations in surveillance and case management have strengthened Indonesia's malaria control efforts in recent years. The Malaria Surveillance Information System (SISMAL), a nationwide electronic surveillance platform, and Rapid Case Reporting (LaCaK) Malaria, a mobile-based tool, enable near real-time case tracking. Electronic self-assessment tools now monitor intervention effectiveness, allowing for rapid response. With the WHO support, hundreds of local health workers have been trained in case reporting, microscopy, and vector mapping, skills critical in high-risk areas. Recognizing that malaria does not stop at national borders, Indonesia and Timor-Leste have forged a cross-border elimination strategy, establishing mechanisms to share case data and vector surveillance information in real time. This collaboration helps detect and respond swiftly to outbreaks in border regions, closing critical gaps in regional malaria control.

Indonesia's National Malaria Elimination Roadmap sets a clear vision and timeline for malaria-free certification nationwide by 2045, with a major milestone of achieving malaria elimination in most districts by 2030. However, these efforts might face crucial challenges. One of the biggest obstacles is Indonesia's vast and diverse geography. With thousands of islands and remote, difficult-to-reach communities, ensuring consistent access to healthcare services and preventive measures is a logistical challenge. Additionally, mobile populations such as migrant workers, fishermen, and nomadic groups complicate efforts to maintain continuous diagnosis, treatment, and follow-up, increasing the risk of undetected transmission. Lastly, sustainable funding remains a critical issue. Continued financial support is essential not only to maintain the gains made so far but also to prevent malaria resurgence after elimination certification is achieved. Addressing these challenges will require innovative solutions, ongoing government commitment, and strong collaboration with international partners.

Conclusion

Efforts to lower malaria incidence have been implemented, including the use of insecticides and environmental changes, yet case numbers remain high — especially in endemic regions. This highlights the urgent need for sustained government commitment, reliable logistics, and community engagement in prevention and early treatment-seeking. In parallel, research continues to advance more effective treatments and the development of malaria vaccines, offering hope for long-term elimination. On this World Mosquito Day, let's break down the barriers to achieve Indonesia's malaria-free future—bitten, but not beaten!

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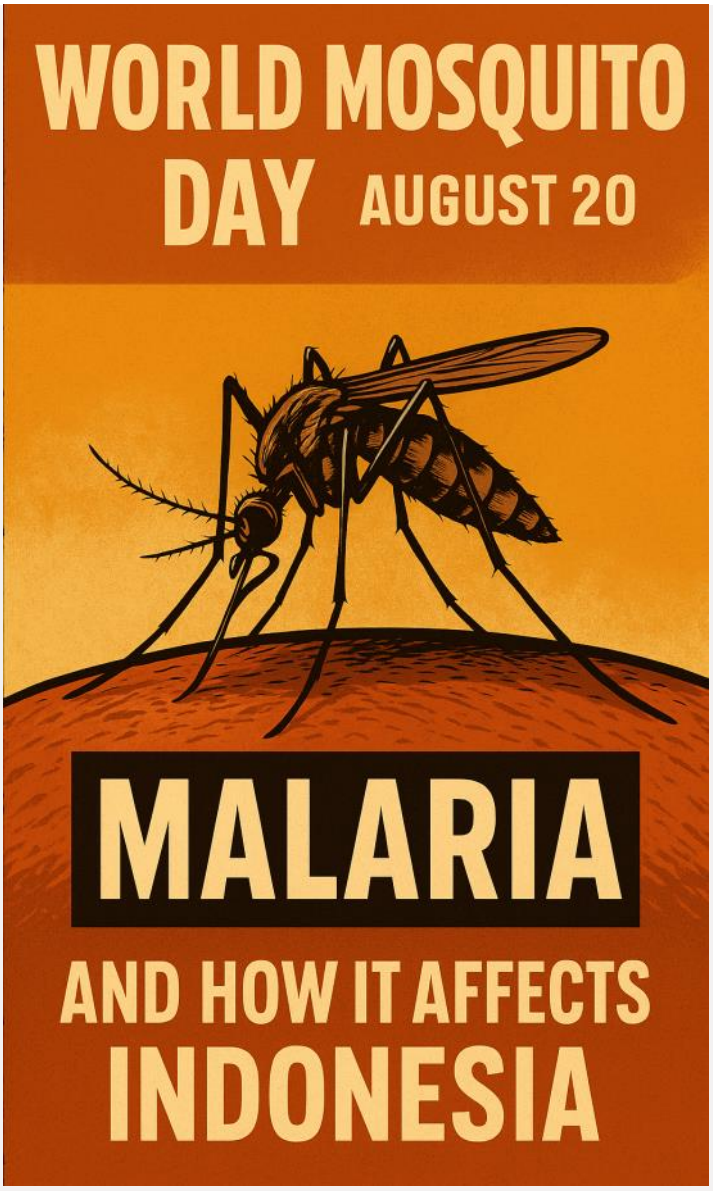

The Role of Sports Medicine Specialists: Now and Next – Current Roles and Future Developments

By: **Edrick Purnomo Putra**

The sports medicine field has been developing recently. A lot of issues are coming up, yet the current roles are still not well-known by the public. This article would like to discuss what a sports medicine specialist doctor does in modern day and also what is in store in the future for emerging advancements.

In general, a sports medicine specialist is a medical doctor who specializes in the prevention, diagnosis, treatment, and rehabilitation of injuries and conditions related to sports and physical activity. On the other hand, sports medicine specialists also use exercise and physical activity for chronic disease management and health promotion. Sports medicine specialists are not only taking care of athletes, but also the general population. The slogan “Exercise is Medicine” was initiated by the American College of Sports Medicine (ACSM) to encourage healthcare providers to include physical activity in treatment plans and also refer patients to evidence-based resources.

In clinical settings, sports medicine specialists diagnose and manage injuries, chronic conditions, and medical conditions related to sports and exercise using a non-surgical approach. Personalized rehabilitation programs are designed to prepare the athlete or client so that they can return to play or return to sport. However, the role of sports medicine specialists has expanded beyond just treating injuries. Nowadays, injury prevention and performance optimization are encouraged as part of long-term management for athletes and patients. Studies have shown that injury pre-

vention programs such as plyometrics, strength and balance training, and neuromuscular training have been proven effective in reducing injuries and require implementation in training and on the field. Sports biomechanics analysis and movement screening tools help to identify the biomechanical factors that make the athlete prone to injury.

Sports medicine specialists are sometimes also involved in becoming the medical doctor for a sports team or club. In this case, sports medicine specialists are responsible for the health of the athletes, such as taking care of injured athletes, maintaining the physical and mental well-being of athletes, consulting with the coach about the training program, and also talking with other professionals related to the athlete's needs. Sports medicine doctors are also qualified to become medical directors and field doctors in sporting events. The medical director is responsible for planning, coordinating, and supervising all medical and emergency services before, during, and after a sporting event. A medical director is also responsible for the safety of athletes, spectators, and staff. Meanwhile, field doctors play a part as the medical team on the field and are responsible for the implementation and practice on the field, race, and match.

Sports medicine specialists can prescribe exercise for anyone who needs exercise as a part of their lifestyle. Therefore, sports medicine specialists not only take care of athletes but also patients or clients with lifestyle-related diseases or those who just want to start exercising. Physical activity and exercise are an inseparable part of a healthy lifestyle to prevent noncommunicable diseases. To safely engage in exercise, sports medicine doctors will do pre-participation examinations to ensure safety and prescribe a personalized exercise plan. Exercise prescription is personalized based on the client's goal, health status, level of physical fitness, and medical condition. It is usually described as FITT, which stands for frequency, intensity, time, and type. A comprehensive assessment and multidisciplinary approach should be done in managing sports medicine cases. Not only physical and psychological health, but also nutrition and recovery must be monitored to achieve holistic health.

Specifically in sports and ethics, sports medicine specialists are also involved in doping control. Doping control is essential in competitive sports in order to protect athletes' health, ensure fairness of the competition, and uphold professional integrity. Meanwhile, in the public health area, sports medicine specialists are responsible for educating people on the safety of engaging in physical activity, while also encouraging people to achieve the physical activity recommendation. Special attention needs to be given to specific communities such as children and young athletes as well as the elderly.

Clinical integration in hospital settings needs to be improved, especially for inpatient care. Sports medicine specialists are not only responsible for sports injuries in the hospital, whether it is preoperative or postoperative rehabilitation, but also for training and activity recommendations as early as possible in the hospital. As part of holistic patient management, an exercise prescription should be given to every patient leaving the hospital. A sports medicine specialist should be considered a clinical consultant for various cases in the hospital as part of comprehensive management. Therefore, in the future, the presence of a sports medicine consultancy in every hospital should be highly considered.

Technology is also an inseparable part of modern society and will keep on developing in the future. The current diagnostic tools and therapy modalities that we have right now may change and improve in the future. Telemedicine will also play a big part in the future of the medical field, including sports medicine. Other aspects of technology, such as applications, wearable devices, immersive technology (VR and AR), and AI-related tools are developing rapidly in the sports medicine field. While these technologies will definitely help, ethical issues need to be discussed. The use of digital databases, especially for athletes, has become increasingly important for sports medicine specialists to identify patterns and trends in athletes' data, thus preventing injuries and optimizing training programs.

In the future, precision and personalized medicine will become increasingly prominent. Genetic, molecular, biomechanical, and environmental data can be used to customize personalized care planning for each indi-

vidual. The use of regenerative therapies will also increase in the future. These treatments aim to reduce recovery times and enhance healing by repairing or replacing damaged tissues.

There are new fields that need to be discussed in the upcoming years, such as the role of sports medicine specialists in extreme sports and e-sports. The role of sports medicine specialists in sports tourism is also growing as global interest in active traveling, adventure sports, and international sporting events increases. It is essential to ensure health, safety, and performance, both for recreational and professional participants involved in sport-related travel. In corporate settings, sports medicine specialists can also take part in promoting physical activity and improving overall employee health through evidence-based strategies which lead to better productivity, lower absenteeism, and reduced healthcare costs.

Walking into the future, more people will realize the benefits of physical activity as part of a holistic lifestyle. Prevention through physical activity and exercise will become more popular. Emerging trends and upcoming technologies are redefining the bright future of sports medicine. Sports medicine specialists also play a big part in the public health aspect. Hence, the role of sports medicine specialists will become more apparent and the need for sports medicine specialists will increase.

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