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OPERATIONS & ACTIVITIES

Ensuring Clinical Trial Readiness through a Comprehensive Site Initiation Visit and Site Management During Ongoing Clinical Trial

By: INA-RESPOND CRA and CRSS

Site readiness is a cornerstone of successful clinical trial execution. The journey from site activation to ongoing trial management requires careful planning, clear communication, and continuous oversight. One of the most critical steps in this process is the Site Initiation Visit (SIV), which serves as the official launch of site activities and ensures alignment between the sponsor/ Contract Research Organization (CRO) and the site team. But the work doesn't stop there-ongoing site management is essential to maintain protocol adherence, ensure subject safety, and uphold data quality throughout the study. These topic was presented during operational management training for the Clinical Research Unit team at Rumah Sakit Pusat Infeksi Prof. Dr. Sulianti Saroso (RSPI).

SITE INITIATION VISIT

SIV represents a crucial milestone in the successful commencement of a clinical trial from study planning and site execution. Conducted by sponsor or CRO, an SIV ensures that the site is fully prepared to begin participant enrollment. It usually follows a Site Preparation Visit (SPV), although both may be combined.

A SIV is scheduled once the Principal Investigator (PI) and clinical trial site team have fulfilled all regulatory and protocol requirements. The SIV should be attended by clinical trial site team members, and sponsor representatives such as Clinical Research Associates (CRAs) and/or Protocol Specialists and/or other relevant personnel. This may include the Clinical Site Specialist (CRSS), Data Manager (DM) and Laboratory Technician (LT) from Reference Laboratory, particularly when SIV is conducted along with a SPV.



Source: Google Picture https://images.app.goo.gl/GEFJq3YkUtgUCqUR8

The primary objective of an SIV is to align the clinical trial site team with study protocol, regulatory expectations, and Good Clinical Practice (GCP) standards. The visit confirms that all necessary infrastructure, staffing, and documents are in place, and that the clinical trial site team clearly understands their roles and responsibilities.

Key Objectives of an SIV

- Ensuring Site and Clinical Trial Site Team Readiness. The SIV confirms that the staffing, infrastructure, equipment, and systems are in place to conduct the trial effectively.
- Reinforcing Protocol Understanding. Key clinical trial site team members are trained on study rational, objectives, key procedures, timelines, and delegated responsibilities.

- 3. Reviewing GCP and Regulatory Requirements. This ensures the all-site staff are well-informed about ethical standards, informed consent procedures, documentation standards, and participant protection guideline.
- 4. **Discussing Investigational Product (IP) Management.** If the study involves an IP, the SIV provides clear guidance on IP logistics, including receipt, storage, accountability, dispensing, return, and destruction.
- 5. Providing Training on Study Procedures. Depending on the site's experience and familiarity with similar studies, the SIV may include role plays or mock scenarios or Question & Answer (Q&A) sessions to enhance understanding of specific study procedures.
- 6. Planning for Recruitment and Enrolment. This includes setting realistic recruitment targets, identifying eligible patient pools, discussing potential barriers, and planning outreach activities where relevant.
- 7. Reviewing Essential Documents. The SIV includes a review of essential study documents, such as ethics committee approvals, protocol versions, site contracts, training logs, delegation logs and Site Regulatory Binder (SRB). These documents must be available, accurate, complete, and organized.
- 8. Final Confirmation for Identifying and Addressing Potential Barriers. Before the clinical trial begins, the SIV offers a chance to discuss and troubleshoot any possible issues that might hinder site performance—such as limited staffing, unclear procedures, or logistical concerns. Early identification allows for timely mitigation strategies. If there are any outstanding action items, a clear follow-up plan is agreed upon to resolve them.

Conditions for SIV Waiver

Under specific circumstances, an SIV may be waived. A waiver is only acceptable if an SPV has

already been conducted properly, and all critical elements—such as site readiness, infrastructure assessment, staff qualifications, and documentation—have been adequately verified during the SPV. The decision to waive the SIV must also ensure that the site is fully trained, compliant with the study protocol, and capable of initiating study activities without additional risk to data quality or participant safety. This can occur upon a formal request from the sponsor or if the site has:

- Previously participated in studies with the same sponsor; or
- Received essential study-specific training during an Investigator Meeting.

Such waivers must be properly documented and archived in accordance with regulatory and institutional requirements. To formalize this process, an SIV Waiver Form must be completed to formally record the rationale and approval for the waiver.

SIV Preparation Requirements

Preparation for an SIV requires extensive documentation and logistical arrangements, including but not limited to:

- ⇒ Independent Review Board (IRB)/Independent Ethics Committee (IEC) approvals for all study documents.
- ⇒ Clinical trial approvals and/or import permits from the Indonesian Food and Drug Authority/ Badan Pengawas Obat dan Makanan (BPOM).
- ⇒ Updated Curriculum Vitae (CVs) and valid GCP certificates for all site staff.
- \Rightarrow Hospital or laboratory accreditation documents.
- ⇒ Signed contracts and institutional registrations (e.g., Clinical Trial Agreement (CTA), International Organization of Regulatory Guideline (IORG), Federalwide Assurance (FWA)).
- \Rightarrow Confirmation of IP delivery and readiness if applicable.

 \Rightarrow Finalized SRB (essential document) and relevant agenda templates.

Onsite vs Remote SIV: Criteria and Considerations

The SIV may be conducted either onsite or remotely, based on sponsor and/or CRO decisions. While traditional SIVs are conducted onsite, remote SIVs are now a practical alternative. A remote SIV may be considered if:

- 1. The site has previous experience with other studies conducted by the same sponsor.
- 2. The clinical trial site team is adequately trained and experienced.
- 3. All documentation and facilities are prepared.

This approach can save time and resources while maintaining the integrity, compliance, and participant safety that are central to every clinical trial. Regardless of the format, the session typically involves:

- 1. Introduction and Opening Remarks
- 2. Protocol and Study Design Review
- 3. GCP and Regulatory Compliance
- 4. IP Management (if applicable)
- 5. Facilities and Resource Review
- 6. Monitoring Plan
- 7. Essential Document Review
- 8. Q&A session and Final Clarifications

Post-SIV Activities and Site Activation

Post-visit, the CRA prepares a detailed SIV Report and Site Action Item Tracking Log, which are distributed to the PI, sponsor, and CRO.

Any pending item identified during the SIV should be resolved and completed. Once addressed, the CRSS updates the Site Preparation Visit Checklist. When all requirements are fulfilled, the checklist is signed by the PI, sponsor, and CRO. The CRSS will then issue a Site Activation Email, officially confirming that the site is activated and may begin screening and enrollment. Completion of all action items is mandatory before site activation.

A well-executed SIV is a critical milestone that sets the tone for a successful trial. With proper preparation and follow-through, it ensures that the site operates in full alignment with study objectives, regulatory expectations, and participant safety standards.

SITE MANAGEMENT

Effective Site Management During Ongoing Clinical Trials

In every clinical trial, day-to-day operations at the site level are the engine that keeps the study moving forward. Within the INA-RESPOND network, site management is a collaborative effort between clinical trial site teams and the Clinical Research Site Specialist (CRSS), ensuring that everything from participant visits to documentation is handled efficiently and in full compliance with study protocols.

As trials progress, site teams are deeply involved in core activities like **screening**, **enrollment**, **and follow-up visits**. Behind the scenes, CRSS provides essential operational support. This includes organizing training, compiling weekly progress reports, conducting regular and on-demand calls, supporting monitoring visits, managing IRB/IEC/regulatory submissions, and keeping the EDMS organized and audit-ready.

Strengthening Communication

Regular **operational calls** bring together site staff, core study teams, and the Secretariat to discuss updates, challenges, and any changes to study documents. Meanwhile, **weekly Screening Progress Reports** compiled from site-submitted logs track recruitment and keep the momentum going across all sites. Urgent issues? CRSS and site Research Assistants (RAs) connect through **ondemand teleconferences** for quick resolutions, all recorded and stored for future reference.

Ongoing Training and Team Transitions

Maintaining a trained and compliant site team is key. CRSS coordinates ongoing training, including updates for protocol amendments. Missed a session? The PI/Co-PI or RA ensures the information is shared and documented. For new team members, the process includes submitting required credentials (CV, GCP certificate, license), granting EDMS access after training, and revoking access for outgoing staff to maintain system integrity.

Logistics, Shipments & Supplies

Specimen shipment coordination starts at the site, with RAs submitting shipment details to the Secretariat. From there, the Reference Lab and Finance & Procurement team handle pick-ups and documentation. Similarly, **study supply** reshipments are processed within 10 working days using a standardized request form, ensuring no disruption to site operations.

Regulatory & Documentation Oversight

Sites are responsible for reporting SAEs, Unexpected Problems, and protocol deviations to IRB/IEC. CRSS supports these efforts and also ensures timely submission of related reports and amendments to BPOM, with all records maintained in the SRB and EDMS. The CRSS also ensures proper file naming and accurate placement within the EDMS to keep all documentation organized, compliant, and inspection ready.

In summary, **effective site management** is a multi-layered process, driven by teamwork, training, co-ordination, and attention to detail. By maintaining clear communication and compliance-focused operations, site teams and CRSS help ensure the success of every study conducted within the INA-RESPOND network.



Source: Image made with Canva

Notes: GCP training gives a good start, but the real work begins at the SIV and after. The SIV helps the clinical trial site team learn the study rules and their jobs before they begin. Even with training and SIV, problems like incorrect patient consent, tasks done by the wrong person, or missing notes can happen at the first monitoring visit. That's why it's important to give clear instructions, keep checking the work, and offer support to make sure the study is done correctly and follows the rules.

SCIENCE CORNER

Bridging The Gaps in Hepatitis B Vaccination in Indonesia: From Childhood Coverage to Adult Willingness

By: Cintya Naya Danastri, Ivana Yulian, Putri Permata Sari

What's this about?

World Hepatitis Day, observed every year on July 28, is one of the World Health Organization's (WHO) nine officially designated global public health days. It serves as a global call to action to raise awareness about the burden of viral hepatitis and to foster collective efforts toward its elimination by 2030. The theme for 2025, "Hepatitis: Let's Break It Down", highlights the urgent need to dismantle the financial, social, and systemic barriers that hinder prevention and care. It emphasizes simplifying, scaling up, and integrating hepatitis services, such as vaccination, safe injection practices, harm reduction, testing, and treatment, into national health systems. Among these, testing and treatment coverage remain critically low. Vaccination plays a crucial role in prevention, helping to reduce the burden on testing and treatment services.

There are five main strains of the hepatitis virus – A, B, C, D, and E. Together, hepatitis B and C are the most common infections and result in 1.3 million deaths and 2.2 million new infections per year. Hepatitis B is a viral infection that causes inflam-

mation of the liver and can lead to chronic disease, cirrhosis, or liver cancer if left untreated. Most people chronically infected with the Hepatitis B Virus (HBV) are unaware of their infection; thus, the disease often goes unnoticed and undiagnosed until the virus has caused severe liver damage. HBV is most commonly transmitted from mother to child at birth, but it can also spread through contact with infected blood or bodily fluids (e.g., saliva, semen, vaginal fluids).

How was the study conducted?

The first study used a large, nationally representative dataset from the 2017 Indonesia Demographic and Health Survey (IDHS). It employed a cross-sectional analysis of secondary data, focusing on mothers with children aged 1–3 years who had complete information on hepatitis B vaccination status. Mothers who were unaware of their child's immunization history were excluded. The study examined the associations between potential factors and completion of the three-dose hepatitis B vaccine series using multivariable logistic regression analysis.

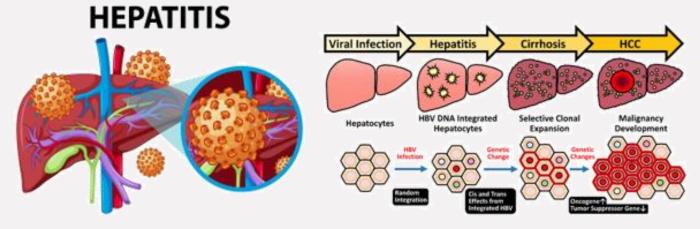


Figure 1. Pathogenesis of hepatitis. Insertional mutagenesis, through the integration of the HBV genome, predisposes to potential genetic changes that facilitate selective clonal expansion in hepatocellular carcinoma development (Wang, S.-H., et al., 2001).

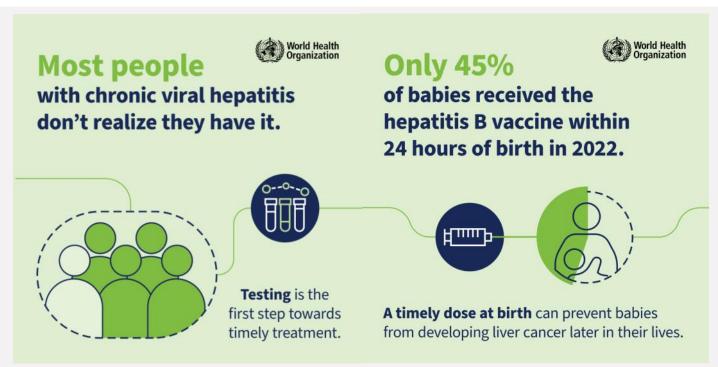


Figure 2. Timely vaccination is protection for life. Let's raise awareness and close the gaps — for every liver, every life. (WHO Media Library)

The second study also employed a cross-sectional design, conducted from February to March 2020, across 16 community health centers in Aceh and Yogyakarta provinces, which were selected for their contrasting hepatitis B vaccination coverage (highest in Yogyakarta and lowest in Aceh: 83.7% vs. 19.5% for complete vaccination, based on the 2018 national survey). Participants were outpatients or healthcare workers aged ≥15 years, physically healthy, willing to participate, and had not received hepatitis B vaccination as adults. Individuals with a history of HBV infection or prior vaccination were excluded. The survey collected data on sociodemographic characteristics, knowledge, attitudes, and willingness to receive the hepatitis B vaccine. Bivariate and multivariate analyses were used to identify factors influencing vaccine willingness.

What did the study find?

The first study analyzed data from 7,860 Indonesian mothers of children aged 12–59 months, revealing that about 10% of children were either never vaccinated or had received fewer than three doses of the hepatitis B vaccine. On average, children were 1.69 years old, with most living on Java (29.5%) and Sumatra (26.3%). Most parents had

completed secondary education; 80% of fathers were employed, while more than 50% of mothers were housewives. Nearly half of the families belonged to the low-income group, and around 60% lacked health insurance. Most mothers reported using media regularly in the last year of the survey. Several parental and household factors were associated with higher odds of complete hepatitis B vaccination. Children of older mothers (≥30 years) had nearly twice the odds of complete vaccination than those of mothers aged 15-19 years. Secondary or higher parental education was linked to 2fold higher odds of completion. Additional positive factors included regular maternal media exposure (AOR = 1.80), higher household income and health insurance coverage (AORs ≈ 1.5-1.6), and having two or fewer children (AOR = 1.90). Maternal employment (AOR = 1.20) was unexpectedly associated with complete vaccination despite known scheduling barriers, warranting further studies.

The second study surveyed 757 adults (373 from Aceh, 384 from Yogyakarta) at community health centers. About half of the participants in both provinces had previously heard about adult HBV vaccination, mainly through health providers and media (television and social media). However, partici-

pants in Yogyakarta had better knowledge of hepatitis B and its vaccine, greater risk perception, and higher willingness to be vaccinated (88% vs. 81% in Aceh). The most consistent predictor of willingness in both provinces was high risk perception, with higher odds in Yogyakarta (AOR = 5.11) than in Aceh (AOR = 2.58). In Yogyakarta, other positive predictors included female sex (AOR = 3.92), insurance coverage for vaccination (AOR = 4.80), and better HBV knowledge (AOR = 4.77). In Aceh, working in a high-risk healthcare setting was the only significant factor (AOR = 4.07). Religious concerns, especially doubts about the vaccine's halal status, may partly explain lower willingness in Aceh, even among those with comparable knowledge. However, due to the small number of non-Muslim participants, the study cannot draw firm conclusions.

Why does this matter?

HBV remains a major global and national health threat. It contributes significantly to liver-related complications, including chronic hepatitis, cirrhosis, and hepatocellular carcinoma (HCC)—the sixth most common cancer and the fourth leading cause of cancer-related death. Although hepatitis B vaccination provides long-lasting protection for at least 20 years and has been included in the national childhood immunization program since 1997, coverage remains suboptimal. According to the 2018 National Health Survey, while 83.1% of infants received the timely birth dose, coverage for subsequent doses dropped to just above 60%. Although adult vaccination is recommended for highrisk groups, Indonesia has yet to implement a nationwide policy. A new regulation is being developed, starting with the voluntary immunization of healthcare workers.

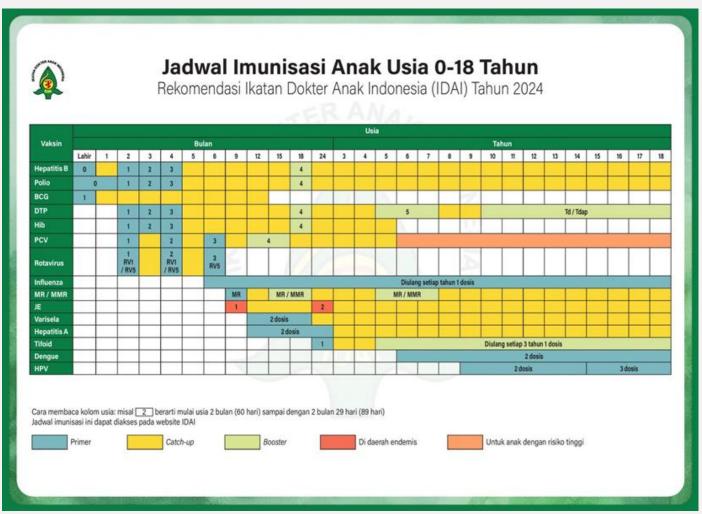


Figure 3. The 2024 Indonesian Pediatric Society recommendations for childhood vaccines. (https://www.idai.or.id/news-event/agenda-nasional/others/6798)



Figure 4. The 2025 Indonesian Society of Internal Medicine recommendations for adult vaccines.

(https://satgasimunisasipapdi.com/jadwal-imunisasi-dewasa/)

The two studies highlighted key barriers to HBV elimination through vaccination. The first revealed persistent socioeconomic disparities in childhood vaccination, even when vaccines are offered free of charge. Equitable healthcare access, reliable health information, and strategies to reduce economic and logistical barriers, especially in underserved communities, are critical to improving coverage. The second study found that perceived risk of HBV infection is the strongest driver of adult vaccination willingness in both Yogyakarta and Aceh. Regional and cultural contexts also shape acceptance. To increase adult hepatitis B vaccine uptake, efforts must include risk communication campaigns, expanded insurance coverage, and culturally tailored, locally relevant approaches. Strengthening both childhood and adult vaccination strategies is essential for Indonesia to meet its national and global hepatitis elimination goals.

Any limitations?

Both studies had notable limitations. The first study relied on secondary data, which had the potential for residual confounding due to the limited descriptions of key variables. For example, although some mothers were unemployed, the dataset did not capture whether they had sufficient free time to take their children for vaccination, creating the possibility of missed opportunities. Additionally, the study was unable to determine whether children were primarily cared for by their mothers or by other caregivers, particularly in households where mothers worked. This gap may have masked differences in vaccination uptake related to caregiving dynamics.

The second study faced potential selection bias, as most of the visitors in the included health centers were females, which may have limited the generalizability of the study's results. Another limitation was that some studies had shown economic factors to be a significant factor in vaccination status (Chung et al., 2012; Park et al., 2012, 2013), but this was not included in this study due to the high amount of missing data. Additionally, with 95.9% of participants identifying as Muslims, the study could not fully explore religious influences on vaccine willingness. Lastly, social desirability bias may have influenced participants to provide favorable responses during interviews.

What's next?

To support HBV elimination efforts, expanding public education on hepatitis is essential. Education should target various age groups and settings, including schools, workplaces, and community centers, with a focus on modes of transmission and prevention. Reiterating safe sex practices and personal hygiene guidelines can help reduce transmission risks. Primary healthcare facilities, being the most accessible to the public, have a vital role in both screening and early detection. While screening targets asymptomatic individuals at risk, early detection focuses on those presenting symptoms or with a family history of liver disease or autoimmune conditions. Strengthening both strategies can prevent disease progression and reduce long-term complications.

An important takeaway from the second study is the need for culturally sensitive, locally tailored strategies to improve hepatitis B vaccination uptake. Future research should investigate effective approaches to cultural and religious engagement that support vaccine acceptance. Expanding adult hepatitis B vaccine readiness assessments to other provinces would also provide a more representative picture of Indonesia's diverse population and support nationwide planning efforts. Let's break down the barriers—protect every liver, every life!

Article source:

Machmud P.B., Gayatri D, Astutik E. Complete dose of hepatitis B vaccination among children in Indonesia and factors associated: A community-based study. Kesmas. 2024 Aug;19(3):178-186.

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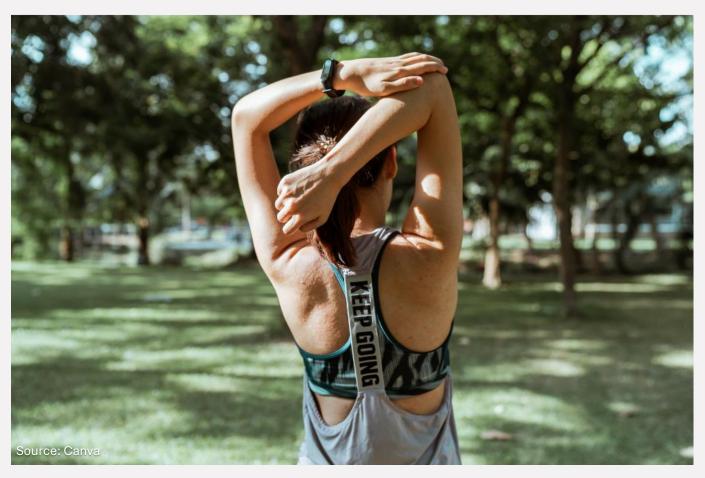
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SPORTS & LIFESTYLE

The Recovery Pyramid: A Scientific Guide to Smarter Recovery

By: Maria Lestari



Training places physical stress on the body, but it is not the only source of stress athletes must manage. Daily life—such as work, school, relationships, and the constant hustle—can add to the overall stress load. When this heightened stress state persists, it can trigger a chain reaction of negative effects on health.

Recreational athletes, unlike professionals, often juggle demanding careers, family responsibilities, and training. Recovery is frequently overlooked in favor of a "more is better" mentality, but chronic under-recovery can lead to non-functional over-reaching or even Overtraining Syndrome (OTS).

The Recovery Pyramid, much like Maslow's Hierarchy of Needs, emphasizes fulfilling the most essential recovery strategies first before considering higher-tier interventions. This model is evidence-based and allows for practical decision-making in real-world settings.

Make Sleep a Priority

Sleep is when the body repairs and builds muscle tissue. It also plays a key role in balancing hormones, supporting immune function, and improving mood. For active individuals, creating a sleep-friendly environment—cool, dark, and free of screens—can go a long way in promoting quality rest.

Incorporate Dynamic Stretching

Studies show that dynamic stretching—moving through a full range of motion before training—can boost performance by stimulating the neuromuscular system and improving blood flow to muscles.

Dynamic stretching also lowers the risk of injury by preparing muscles for the movements they will face during a workout, which in turn supports better recovery.

Inactivity right after a tough session should be avoided. A light walk can help promote muscle activity that flushes out waste products from the tissues.

While cold plunges (ice baths) have not been definitively proven to enhance performance, they may help lower post-exercise lactic acid levels.

Schedule Regular Rest Days

Planned rest days are essential for allowing the body to recover and repair after workouts or competitions. Many athletes benefit from periodization, a training approach that cycles between intense activity and recovery phases—for example, training for three weeks followed by a recovery week. This strategy also supports immune health, which is crucial for staying healthy, especially during competition seasons.

Rest and recovery are all about giving the body time to repair, rebuild, and strengthen itself between workouts. Intense physical activity causes small tears in muscle fibers. As the body rests and recovers, these microtears heal, leading to increased strength and muscle growth. It is crucial to understand that this improvement happens after the workout—during rest, not during the training itself.

Progress in fitness and optimal physical performance can only be achieved when the body is given adequate time to recover and repair. Rest must be incorporated by stepping away from regular training routines, allowing the recovery process to take place effectively.

Short- and Long-Term Recovery

Short-term recovery, also known as active recovery, is carried out in the hours following intense physical activity. Research shows that engaging in low-intensity exercise during the cool-down phase is associated with improved performance.

This type of recovery involves actions taken immediately after a workout to support physical and mental restoration. Blood circulation is increased through active recovery, allowing waste products from stressed tissues to be removed more efficiently, while fresh blood delivers nutrients that aid in the repair of muscles, tendons, and ligaments.

Light physical activity that gently elevates the heart rate is typically performed, while repetitive motions from the main workout are avoided. Alternative movement patterns and enjoyable activities are recommended. Examples include walking, swimming, light cycling, and using machines such as the elliptical or rowing machine.



Picture 1. The Recovery Pyramid. Source: NSCA's Essentials of Sport Science



Picture 2. Using foam rolling as s recovery method. Source: Canva

Since muscles are already warmed, stretching and massage are more effective, helping to improve flexibility and reduce the risk of injury. Recovery methods such as foam rolling or yoga are often incorporated. Additionally, proper nutrition is emphasized, with adequate intake of calories and a balanced supply of protein and carbohydrates required to replenish energy stores.

Long-term recovery refers to planned rest and recovery phases integrated into a broader training schedule over a season. It can also involve scheduled breaks lasting several days or weeks as part of an athlete's annual training plan. The duration of a recovery period depends on factors such as age, sport, and training regimen.

The American Council on Exercise (ACE) suggests that athletes engaging in high-intensity exercise should schedule a rest day every seven to ten days. However, this is not a hard and fast rule—some athletes may need more frequent rest days, such as two per week.

In a seasonal training program, a method known as periodization is often adopted, where recovery days and even recovery weeks are pre-scheduled throughout the year. Workout routines are modified during this process by varying exercise types, incorporating cross-training, and adjusting the intensity, duration, and distance of training sessions.

The importance of long-term rest and recovery is emphasized for injury prevention. Acute injuries are often seen in individuals who are fatigued or not well-conditioned, particularly those participating in sports such as basketball or soccer.

Overuse injuries—including chronic soft tissue damage, tendon injuries, and bone stress injuries—are also commonly prevented through proper recovery planning. Additionally, the risk of Overtraining Syndrome (OTS)—a condition where the body is unable to keep up with training demands—is reduced when rest and recovery are properly timed.

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INA-RESPOND Newsletter

The Indonesia Research Partnership on Infectious Disease newsletter is an internal bulletin of INA-RESPOND research network intended to disseminate information related to the network's studies, activities, and interests to all members of the network as well as its sponsors and related parties.

The INA-RESPOND newsletter welcomes all network members and stakeholders to contribute by submitting articles related to the network's studies and interests. Send your articles or subscribe to our latest newsletter by sending an email to

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