INA-RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

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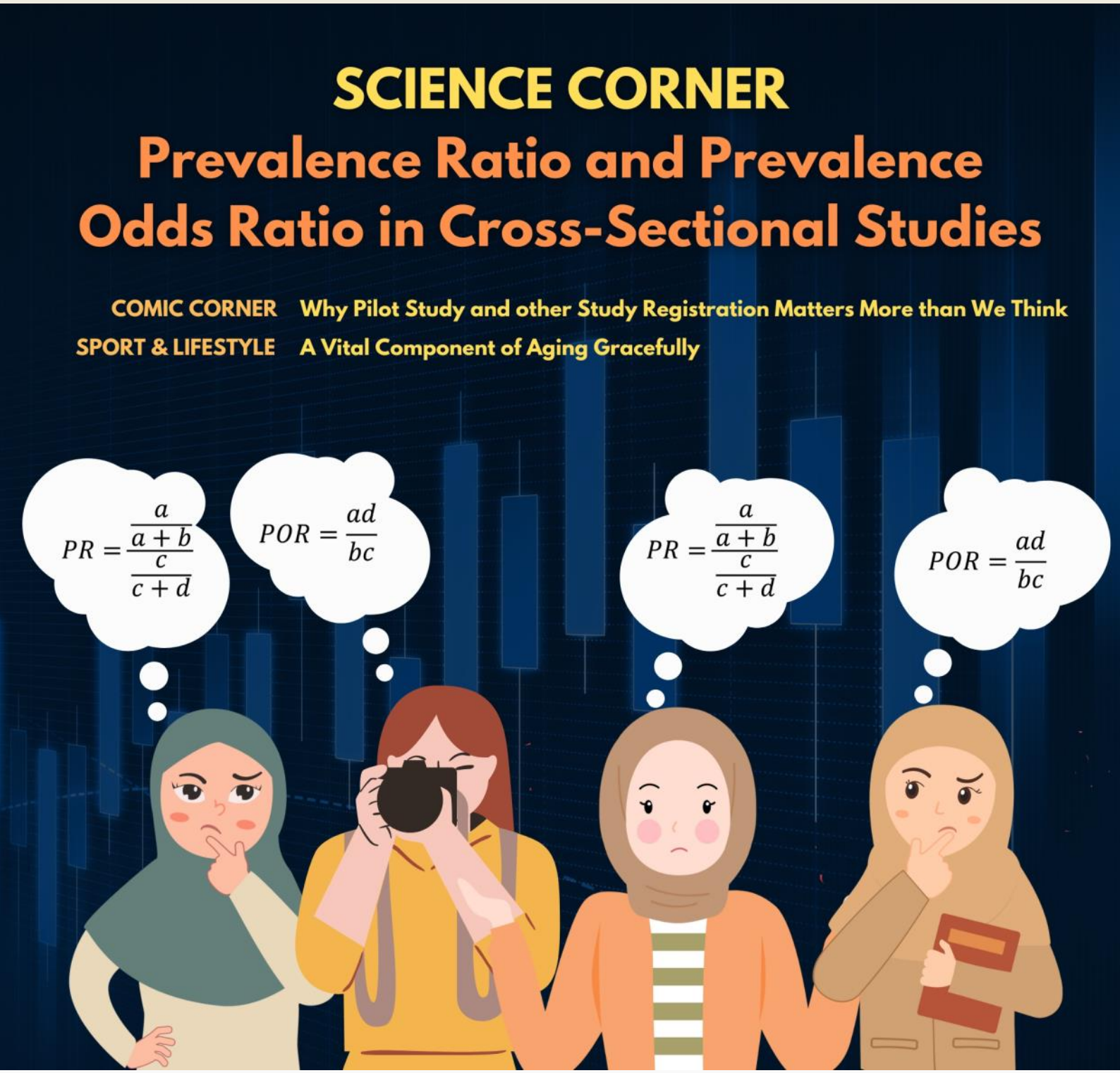
May 2024



HEALTH POLICY AGENCY

MINISTRY OF HEALTH REPUBLIC OF INDONESIA

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FEATURES

INA-RESPOND Newsletter

InVITE & PROACTIVE Study Updates

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

InVITE

The InVITE study in Indonesia has reached the end of the study period. All participants have completed study visits, with the last visit of the last participant on January 24, 2024.

All site specimens have been sent to the INA-RESPOND Reference Laboratory. Currently, all specimens, including those from the Central Laboratory, are being verified by the Reference Laboratory team and the InVITE Global Data Management team in preparation for specimen shipment. Both teams are collaborating to check the completeness and accuracy of specimen information between the Specimen Database and the CRF Specimen Log. The Secretariat is also reviewing the completeness of documents for the Reference Laboratory Binder. In parallel, the Secretariat is preparing the logistics and shipment documents.

The Clinical Research Associate (CRA) is conducting a QA Study Specimen Inventory to ensure the integrity of specimens stored at the INA-RESPOND Reference Lab from the ongoing study, in accordance with SOP and protocol. The CRA has determined that 950 vials will undergo physical specimen verification. This verification is planned to take place at the INA-RESPOND Reference Laboratory from June 3-7, 2024.

Source Document Verification (SDV) for critical variables such as the date and type of vaccine received and SARS-CoV-2 infection information has been completed by the INA-RESPOND Secretariat team for Site 02 and Site 03. For Site 01, the SDV process is ongoing for uploaded source documents. It is hoped that this SDV will be completed before the global data cleaning specific to Indonesia, which is scheduled to begin in June 2024.

The InVITE Global study design includes plans for multiple sub-studies, resulting in multiple manuscripts. Three manuscripts have been published, and other manuscript plans are periodically discussed by the InVITE Publication Committee. The first manuscript, entitled "Study protocol: Design of an observational multi-country cohort study to assess immunogenicity of multiple vaccine platforms (InVITE)," detailed the study design and will be used as a reference for the following manuscripts, particularly the methods section. The second manuscript, entitled "Challenges of conducting an international observational study to assess immunogenicity of multiple COVID-19 vaccines," addressed the challenges and suggestions for conducting a multicountry observational vaccine study and was published in PLOS Global Public Health on June 20, 2023. The manuscript's idea emerged when the InVITE team from each country encountered significant challenges while conducting the study during an international health emergency. Therefore, the manuscript focused on the challenges and hurdles successfully mitigated by the team's proactive thinking and collaborative approach.

The team categorized challenges into study logistics, national vaccine policies, pandemic-induced and supply-chain constraints, and cultural beliefs. Challenges related to the study's logistics included the initiation and execution of the study, such as the varied country-specific regulatory policies for vaccine delivery and distribution timelines, informed consent requirements, SOPs, and other essential needs. Flexibility was essential to accommodate and incorporate those challenges. By allowing each country to develop and submit its own site-specific appendix along with the main protocol for country regulatory review, InVITE provided flexibility to accommodate country-specific regulatory policies. The next challenge involved national vaccine policies, where the type of vaccine and the protocols for initial and booster doses varied by country, affecting recruitment and follow-up processes. The study relied on the anticipated timing of the complete vaccine schedules, which depended on factors outside the study team's control, such as vaccine availability, distribution schedules, and adherence to follow-up vaccine visits. Case Report Forms (CRFs) were updated as needed, and site-specific forms were created. Phone calls and home visits were conducted to remind par-

ticipants of follow-up visits. Tailored solutions were implemented by partnering with government health authorities. For example, the Indonesia team provided participants with the results of SARS-CoV-2 serology tests performed locally as an incentive to participate in the study and boost participant excitement for attending follow-up or symptomatic visits. To avoid missed visits, the window periods for each visit were broad (1–2 months). To maximize specimen and data collection, an SOP was developed to allow for out-of-window visits, emphasizing the importance of collecting visit samples outside the original 1–2-month window while remaining within protocol requirements.

The next challenge was regarding site pandemic-induced and supply chain constraints, with many study supplies not available in-country having to be shipped from the U.S. without a guarantee of timely delivery due to limited supply, flight shortages, customs requirements, and import costs. Laboratory teams across the sites had to manage laboratory supply shortages due to the global disruption of supply chains. On the other hand, a team conducted monthly inventory checks and maintained frequent communication with those impacting inventory shipping. The last challenge was about cultural beliefs, which could significantly impact study implementation. For example, rumors and misconceptions about COVID-19 vaccines made participants reluctant to get vaccinated. Perceptions of decreased virus threat led to poor attendance at scheduled study visits and symptomatic visits. Solutions to this challenge relied on the team's collaboration with community health workers to educate participants and dispel vaccine-related fears, rumors, and doubts. This included making regular follow-up calls to participants. Regular communication between the study team and participants likely contributed to the very high compliance with follow-up visits.

The InVITE experience with study planning, regulatory submission, training, and study initiation and implementation during an ongoing pandemic has contributed to each country member's research capacity and preparedness. Despite the obstacles faced by the InVITE team, collaborative efforts enabled the study team to address challenges that arose during the study. This study exemplifies how established programs in resource-limited settings can be leveraged to contribute to biomedical research during a pandemic response. Lessons learned from this study can be applied to other studies mounted to respond rapidly during a global health crisis and will contribute to the capacity for more robust pandemic preparedness in the future when there is a crucial need for urgent response and data collection.

Figure. The InVITE Indonesia implementation in Site 3-1 (Tangerang) and 3-2 (Maumere) during the early enrolment period (August 2021).

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Currently, INA-PROACTIVE investigators, along with the Secretariat and partners, are preparing the primary and additional manuscripts. Meanwhile, in collaboration with INA-RESPOND Warm Based Research Assistants (RAs), the Secretariat is performing a scoping review on HIV research in Indonesia, encompassing all fields since the first HIV case was reported in Indonesia in 1987. The first topic of this scoping review project is research on children living with HIV in Indonesia, aiming to identify gaps in the current research. The team hopes to provide scientific summaries for this age group and promote HIV control in Indonesia. This scoping review will also support the preparation of a PROACTIVE manuscript on pediatric subjects.

Besides that, the INA-RESPOND Secretariat and RAs are also active in journal club activities. The fourth journal club meeting was held on January 23, 2024, with an article entitled "**Incidence of Post-suppression Virologic Rebound in Perinatally HIV-Infected Asian Adolescents on Stable Combination Antiretroviral Therapy.**" The article was presented by Dr. Erni from the Semarang site and Dr. Putri from the Jakarta site. Below is the summary of this article:

Advances in combination antiretroviral therapy (cART) have made it possible for HIV infection to be a chronic and manageable lifelong illness. In countries where cART is available and accessible, people living with HIV (PLWH) can achieve improved life expectancy and a better quality of life. Most perinatally HIV-infected adolescents currently in care began cART early in childhood. They often face challenges with adhering to their lifelong medications and risk discontinuing treatment during this crucial period of emotional and neurocognitive development. Thus, it is challenging to maintain continuous HIV treatment and virologic suppression for this unique and vulnerable population. Virologic rebound (VR) after suppression on cART has been reported in perinatally HIV-infected youth and adults. A study comparing the risk of VR between non-perinatally HIV-infected adolescents and adults found that adolescents had a significantly higher incidence than adults. Previously reported predictors of VR in HIV-infected individuals included younger age, female sex, being heavily treatment-experienced, receiving complicated regimens, poor immunologic and virologic status, and having persistent low-level viremia. However, these studies have rarely included adolescents in Asia. **The discussed manuscript summary below assessed the incidence and predictors of VR in perinatally HIV-infected Asian adolescents on stable cART with previously undetectable virus levels.**

This manuscript was a sub-analysis of The TREAT Asia Pediatric HIV Observational Database (TApHOD), a multicenter, longitudinal observational cohort of children and adolescents living with HIV in the Asia Pacific region established in 2008. The study cohort was enrolled during childhood and followed through Asian adolescence (aged between 10 and 19 years). Non-nucleoside reverse transcriptase inhibitor (NNRTI)-based cART is usually prescribed as the first-line regimen, whereas boosted protease inhibitor (PI)-based second-line regimens are recommended for these individuals failing their first-line treatment. In September 2014, TApHOD included data from 5609 children and adolescents who had ever received care from one of 16 pediatric clinical programs in Cambodia (n = 1), India (n = 1), Indonesia (n = 2), Malaysia (n = 4), Thailand (n = 5), or Vietnam (n = 3). These sites are predominantly public or university-based pediatric HIV referral clinics.

For this sub-analysis, perinatally HIV-infected Asian adolescents aged between 10 and 19 years enrolled in TApHOD through September 2014 were included if they

had been on cART and had a documented period of virologic suppression (defined as two consecutive plasma viral load (VL) measurements <400 copies/ml at least six months apart) before or during adolescence. Adolescents exposed to mono- or dual-therapy prior to cART initiation were excluded. Demographic characteristics, anthropometric measurements, and HIV-related parameters were abstracted from the database. Post-suppression VR was defined as a single plasma VL >1000 copies/ml while on cART after a previous documented history of undetectable virus levels. Authors selected the cut-off level of 1000 copies/ml to avoid misclassification with low-level viremia and viral blips. Loss to follow-up was defined as not presenting to care for at least 12 months without documentation of transfer to another clinic or death. Mortality was defined as all-cause deaths notified from any source.

Of 1379 eligible adolescents, 47% were males. At baseline, 22% were receiving PI-containing regimens; median CD4 cell count (IQR) was 685 (448-937) cells/mm3; 2% had pre-adolescent virological failure (VF) before subsequent suppression. During adolescence, 180 individuals (13%) experienced post-suppression VR at a rate of 3.4 (95% CI: 2.9-3.9) per 100 person-years, which was consistent over time. The incidence rate of post-suppression VR was lower than those documented in other adolescent cohorts, which was likely related in part to variations in the study populations in terms of age, mode of infection, and cART regimen sequence. The median time to VR during adolescence (IQR) was 3.3 (2.1-4.8) years. Wasting (weight-for-age z-score <-2.5), being raised by grandparents, receiving second-line PI-based regimens, starting cART after 2005, and having pre-adolescent VF were independent predictors of adolescent VR. At VR, median age, CD4 cell count, and VL (IQR) were 14.8 (13.2-16.4) years, 507 (325-723) cells/mm3, and 4.1 (3.5-4.7) log10 copies/ml, respectively. Overall, during adolescence, the loss to follow-up and mortality rates among this study population were low. **These results emphasize that although adolescents may have a childhood history of viral suppression, they remain at risk of developing VR later in life**.

Wasting remains an important clinical problem, particularly among children and adolescents living in Asian and African countries. Although there were no studies demonstrating the adverse consequences of wasting on VR, it is well-documented that low weight-for-age has been significantly correlated with clinical and immunologic failure in children and adolescents. Unfortunately, in the analysis, authors did not include incident opportunistic infections (OIs). Opportunistic and other coinfections could have been factors in transient or long-term changes in plasma VL due to acute illness and adherence problems. Authors also found that adolescents raised by grandparents demonstrated a higher VR rate compared with those cared for by biological parents. Although several studies have shown that grandparents play a key role in providing care and support for HIV-infected orphans and children, challenges with their health issues related to advancing age and social stress may limit their ability to optimally care for their grandchildren as they age into adolescence. Additionally, half of this adolescent cohort (50%) were double orphans, putting them at risk of mental health conditions related to the social and family instability associated with orphanhood. These factors have the potential to impact medication adherence and the risk of VR in these individuals.

Finding that second-line PI-containing cART and pre-adolescent VF were significant predictors of VR in this study reflects the importance of medication adherence to successful virologic outcomes. In this region, PI-based cART is generally used as second-line treatment after failure of first-line NNRTI-based regimens, so patients receiving these regimens were more likely to have poorer earlier adherence to treatment compared with those who remained on traditionally first-line therapy. Therefore, the management of adherence issues and VR during childhood has long-term consequences, highlighting the importance of support for standardized pediatric clinical guidance. In conclusion, the incidence rate of post-suppression VR during adolescence was moderate and consistent in this cohort of perinatally HIV-infected adolescents in Asia. **More frequent VL monitoring of adolescents, particularly for those at higher risk of treatment failure and VR, may be useful to promptly detect poor virologic outcomes and support long-term treatment success during this vulnerable period of life**.

INA-RESPOND Newsletter

PREVALENCE RATIO AND PREVALENCE ODDS RATIO IN CROSS-SECTIONAL STUDIES

By: Syndi Siahaan, Nurul Hidayah, Hafsah Amalia, Adhella Menur

A cross-sectional study is an observational study in which all data from each subject is collected at a single point in time. It is considered more affordable and feasible than longitudinal studies, as it does not require following patients over time. Traditionally, a cross-sectional study has been used to determine the prevalence of a disease or condition, defined as the proportion of a population with a specific characteristic at a given time. This is why a cross-sectional study is also referred to as a "prevalence study." However, it can also analyze the association between two or more variables, providing an analytical approach. This makes a cross-sectional study a valuable option for exploring associations, especially in preliminary investigations or when resources are limited. Of note, the interpretation of the analysis requires caution regarding the potential association of disease duration with exposure status (survival bias).

The cross-sectional analysis results are often presented as Prevalence Ratio (PR), which measures and compares disease prevalence between two groups. The Odds Ratio (OR), a result commonly presented in case-control studies, can also be applied in cross-sectional studies, where it is referred to as the Prevalence Odds Ratio (POR). There has been a debate about whether the OR should be exclusively used for case-control studies, with some authors reporting that when disease prevalence is high, the POR tends to overestimate the PR. This article will summarize how PR and POR are applied in cross-sectional studies.

What to Choose: Cross-Sectional or Case-Control Studies

Cross-sectional and case-control studies are commonly used in analytical observational study designs. As mentioned before, in a cross-sectional study, data on exposure and outcomes (disease or condition) are collected simultaneously from each subject at one point in time (Figure 1). The analysis compares outcomes prevalence between exposed and unexposed individuals or the exposure levels between those with and without the disease or condition. Although cross-sectional studies are often more practical to conduct, they have several limitations. They are not suitable for conditions with low prevalence, as such studies require a large sample size. Additionally, the findings depend on the disease's dura-

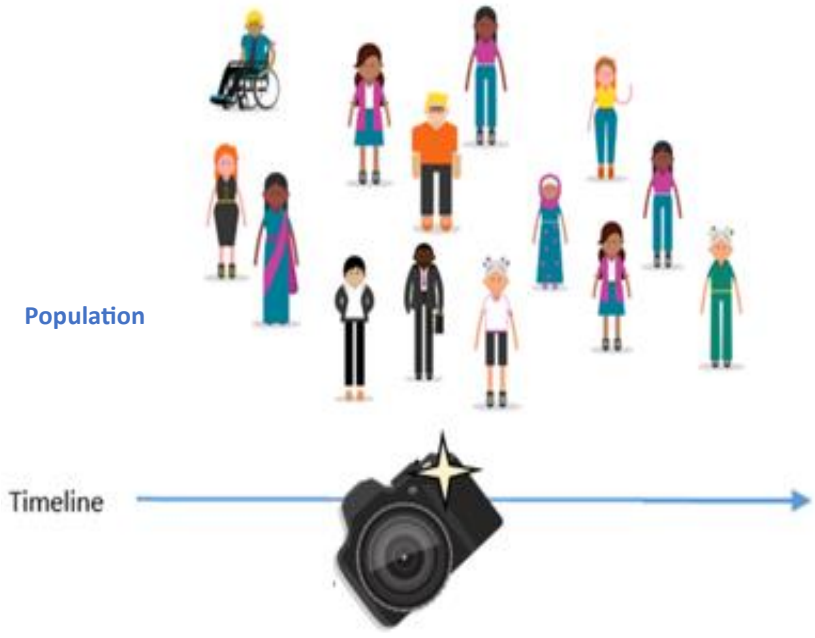

Figure 1. Cross-sectional studies design - take a "snapshot" of the proportion of individuals in the population that are, for example, diseased and non-diseased at one point in time.

Table 1. Choosing a cross-sectional or case-control study according to research questions.

Research question		**Suggested study design**
Frequency	How common is the outcome (e.g., disease, condition)?	Cross-sectional
Diagnosis	Does the new test perform as well as the 'gold standard'?	
Prognosis	How can you predict the likelihood of a particular outcome for your patient?	Case-control
Risks	Is any exposure more common in those with the disease than those without?	

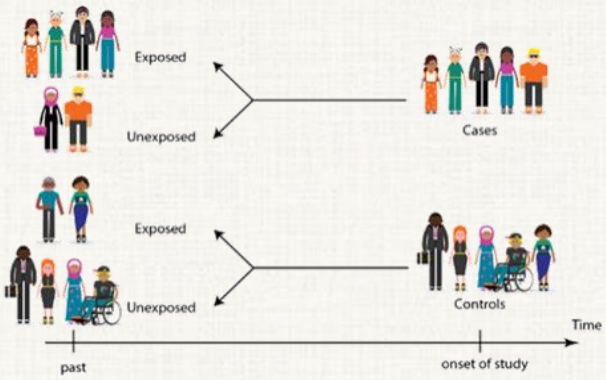

Figure 2. Case-control studies design.

tion since data is collected only once. While cross-sectional studies can identify associations, they cannot determine causal relationships because it is unclear whether the disease or the exposure occurred first.

When studying the development of a condition or disease with low prevalence, a case-control study is more commonly used. This design compares a case group (individuals with the disease) to a control group (individuals without the disease) (Figure 2). Data on past exposures for both groups are collected retrospectively through medical records or laboratory results.

Choosing between cross-sectional and case-control studies depends on the research questions; therefore, developing a specific research question is essential. Table 1 lists several research question types with the appropriate study design.

Measuring Association in Cross-Sectional Studies: Prevalence Ratio and Prevalence Odds Ratio

Measures of association are utilized to compare the association between a specific exposure and the outcomes. Note that evidence of an association does not imply that the relationship is causal; the association may also be artifactual or non-causal. To measure the association, analysis of epidemiological studies is performed using a 2x2 table, as shown in Table 2.

		Disease		**Row total**
		Yes	**No**	
Exposure	**Yes**	a	b	a + b
	No	c	d	c + d
Column total		a + c	b + d	

Table 2. The elements of a 2x2 table for analyzing epidemiological studies.

Notes: a is defined as individuals exposed and have the disease, b is individuals exposed but do not have the disease, c is individuals not exposed but have the disease, d is individuals not exposed and do not have the disease, a + b is total of exposed individuals, c + d is total of unexposed individuals, a + c is total of individuals with the disease, and b + d is total of individuals without the disease.

Prevalence ratio (PR) is analogous to the risk ratio (RR) of cohort studies. PR is interpreted as "exposed individuals have a disease or condition XX times greater than unexposed individuals." Based on the Table 2, PR can be calculated as follows:

(1) Outcome = "Yes"

$$PR = \frac{\frac{a}{a+b}}{\frac{c}{c+d}}$$

$$PR = \left(\frac{(n)exposed\ cases}{(n)total\ of\ exposed\ cases}\right) / \left(\frac{(n)unexposed\ cases}{(n)total\ of\ unexposed\ cases}\right)$$

(2) Outcome = "No"

$$PR = \frac{\frac{b}{a+b}}{\frac{d}{c+d}}$$

$$PR = \left(\frac{(n)exposed\ non-cases}{(n)total\ of\ exposed\ cases}\right) / \left(\frac{(n)unexposed\ non-cases}{(n)total\ of\ unexposed\ cases}\right)$$

From this formula, we can see that the two equations are not reciprocal to each other. The denominators for both equations are fixed populations. This differs from the Prevalence Odds Ratio (POR), where the equations are reciprocal using different outcomes. POR represents the odds that an outcome will occur given a particular exposure compared to the odds of the outcome occurring without that exposure. The formula is as follows:

(1) Outcome = "Yes"

$$POR = \frac{a/c}{b/d} = \frac{ad}{bc}$$

$$POR = \frac{(n)exposed\ cases\ \times\ (n)unexposed\ non-cases}{(n)exposed\ non-cases\ \times (n)unexposed\ cases}$$

(2) Outcome = "No"

$$POR = \frac{b/d}{a/c} = \frac{bc}{ad}$$

$$POR = \frac{(n)exposed\ non-cases\ \times (n)unexposed\ cases}{(n)exposed\ cases\ \times\ (n)unexposed\ non-cases}$$

A POR value equal to 1 means the exposure is not associated with the disease. A POR greater than 1.0 indicates a positive association, and a POR less than 1.0 indicates a negative, or protective, association. Authors sometimes misinterpret POR with statements like "exposed individuals have XX times higher probability or risk of disease or condition." Such statements are incorrect because the odds are not a ratio of probabilities or risks, and cross-sectional designs cannot evaluate risk. The correct language is "exposed individuals have XX times greater odds of disease or condition."

The literature is rich with articles discussing the advantages and disadvantages of PR versus POR and debating the 'appropriate' measure of association. Cvetkovic-Vega et al. introduced the concept that the measure of association in a cross-sectional study can be either PR or POR, depending on the initial observation of the outcome prevalence. It is considered that when the outcome prevalence is greater than or equal to 10%, PR should be used as the appropriate measure of association in cross-sectional studies. Using POR in these cases would overestimate the PR value. When the prevalence of the outcome is below 10%, POR and PR are closer to each other; hence POR may be used. However, some researchers argue that PR is more recommended for cross-sectional studies with analytical purposes.

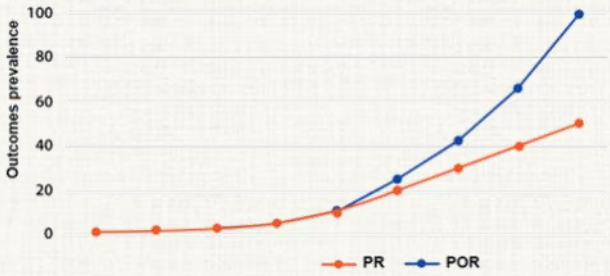

Figure 3. Comparison between PR and POR based on the prevalence of the outcome [adapted from the comparison between RR and OR by Soto A, Cvetkovic-Vega A., 2020, DOI: 10.25176/RFMH.v20i1.2555]. POR tend to overestimate the strength of association when outcomes prevalence ≥10%.

The potential cause-effect relationship between the variables may provide consideration for selecting between PR and POR. When there is a reasonable assumption about which variable is the exposure and which is the outcome, it is convenient to compare the prevalence of the effect between exposed and non-exposed individuals and calculate the PR. When the causal relationship between the variables is unclear, POR has the advantage of maintaining the same numerical value regardless of its position in the contingency (2x2) table. For acute disease studies, PR is the preferred measure of association. For chronic disease studies or studies of long-lasting risk factors, POR is the preferred measure of association.

Case Example

In this case example, we cite research by Tamhane et al. (2016) on the association of race-sex with hypertension control status. Descriptive characteristics are shown in Table 3.

Table 3. Descriptive characteristics according to hypertension control status by Tamhane et al. (2016).

Variable	Hypertension control		Overall
	Yes (n, %) n = 380	No (n, %) n = 319	n = 699
White-female	24 (70.6)	10 (29.4)	34
White-male	159 (58.9)	111 (41.1)	270
Black-female	80 (53.3)	70 (46.7)	150
Black-male	117 (47.8)	128 (52.2)	245

Table 4 below shows the results of PR and POR from the study. Using POR results in an overestimation of the strength of the association. For instance, in the White-female group, when 'Hypertension control = Yes' was modeled ('No' as the reference group), POR was 2.63, while PR was 1.48.

In this case, since the prevalence of the outcome (hypertension control) is ≥10% (54.4%, 380/699), reporting PR was deemed more appropriate than POR due to the considerable overestimation of the association's strength by POR.

Conclusion

To conclude, choosing the appropriate study design depends on the research question. In cross-sectional studies, measuring association can be done using either PR or POR based on the initial observation of the prevalence and characteristics of the outcomes (disease or condition). Employing proper statistical methods in the analysis is crucial to avoid inappropriate estimates and interpretations. While using PR is generally recommended, reporting POR in cross-sectional studies is acceptable as long as authors interpret POR correctly as the ratio between odds or for conditions or diseases with low prevalence.

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	PR (95% CI)		POR (95% CI)	
	Hypertension control = "Yes" modeled	Hypertension control = "No" modeled	Hypertension control = "Yes" modeled	Hypertension control = "No" modeled
Black-male	Ref	Ref	Ref	Ref
White-female	1.48 (1.15 – 1.90)	0.56 (0.33 – 0.96)	2.63 (1.20 – 5.72)	0.38 (0.18 – 0.83)
White-male	1.23 (1.05 – 1.45)	0.79 (0.65 – 0.95)	1.57 (1.11 – 2.22)	0.64 (0.45 – 0.90)
Black-female	1.12 (0.92 – 1.36)	0.89 (0.72 – 1.10)	1.25 (0.83 – 1.88)	0.80 (0.53 – 1.20)

Table 4. Prevalence Ratio (PR) and Prevalence Odds Ratio (POR) to measure the association between race-sex and hypertension control.

INA-RESPOND Newsletter

A VITAL COMPONENT OF AGING GRACEFULLY

By: Caleb Leonardo Halim

The passage of time is an undeniable force, bringing with it a myriad of changes that shape our bodies and minds. As we traverse the landscape of aging, the importance of maintaining physical strength and vitality becomes increasingly apparent. In this essay, we will explore the significance of strength training as we grow older and the pivotal role that sports medicine physicians play in assisting individuals in optimizing their health and fitness in the aging process.

Understanding the Aging Process

Aging is a natural and inevitable process characterized by a multitude of physiological changes that impact our bodies in various ways. Among these changes, one of the most significant is the progressive loss of muscle mass and strength, known as sarcopenia. As individuals age, the rate at which muscles are built and maintained decreases, leading to a gradual decline in physical function and performance. Additionally, bone density tends to diminish over time, increasing the risk of fractures and osteoporosis, further exacerbating the challenges associated with aging.

The Role of Strength Training in Aging

Strength training emerges as a potent antidote to the effects of aging, offering a myriad of benefits that extend far beyond the confines of physical fitness. Unlike traditional aerobic exercise, which primarily targets the cardiovascular system, strength training focuses on building and maintaining muscle mass and bone density through resistance-based activities. By engaging in regular strength training exercises, individuals can effectively counteract the age-related decline in muscle and bone health, preserving strength, mobility, and overall function well into their later years.

The benefits of strength training are manifold and encompass both physical and mental well-being. From improving muscle tone and posture to enhancing balance and coordination, strength training enhances functional capacity, enabling individuals to perform activities of daily living with greater ease and efficiency. Moreover, research has shown that strength training can help reduce the risk of falls and fractures, thereby promoting safety and independence in older adults.

Furthermore, strength training plays a crucial role in mitigating the risk of chronic diseases commonly associated with aging, such as heart disease, diabetes, and hypertension. By promoting cardiovascular health, regulating blood sugar levels, and improving metabolic function, strength training serves as a cornerstone of preventive medicine, empowering individuals to take control of their health and well-being as they age.

Additionally, strength training has been shown to have a positive impact on mental health and cognitive function. Regular exercise has been linked to improvements in mood, sleep quality, and cognitive performance in older adults, reducing the risk of depression, anxiety, and cognitive decline. By stimulating the release of endorphins and other neurotransmitters, strength training can enhance mood, alleviate stress, and promote overall well-being, contributing to a higher quality of life in later years.

The Role of Sports Medicine Physicians

In navigating the complexities of aging and physical fitness, sports medicine physicians play a pivotal role in assisting individuals in optimizing their health and well-being. Sports medicine physicians are highly trained medical professionals with expertise in the diagnosis, treatment, and prevention of sports-related injuries and conditions. However, their scope of practice extends beyond the realm of athletics to encompass all aspects of musculoskeletal health and performance, making them valuable allies in the pursuit of optimal health and fitness, regardless of age or athletic ability.

Sports medicine physicians possess specialized knowledge and skills that enable them to assess and address the unique needs and challenges faced by older adults. From conducting comprehensive musculoskeletal evaluations to developing personalized exercise prescriptions, sports medicine physicians can tailor treatment plans to meet the individual needs and goals of their patients. Whether it's managing chronic conditions such as arthritis or osteoporosis or optimizing athletic performance in older athletes, sports medicine physicians provide expert guidance and support every step of the way.

One of the primary roles of sports medicine physicians in assisting older adults is the prescription and supervision of strength training programs. By conducting thorough assessments of muscle strength, joint mobility, and functional capacity, sports medicine physicians can identify areas of weakness or imbalance that may predispose individuals to injury or limit their ability to perform daily activities. Based on these assessments, sports medicine physicians can prescribe targeted strength training exercises designed to address specific areas of concern and improve overall physical function.

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Moreover, sports medicine physicians play a crucial role in ensuring the safety and effectiveness of strength training programs for older adults. With their expertise in biomechanics, exercise physiology, and injury prevention, sports medicine physicians can provide valuable guidance on proper exercise technique, progression, and modification to minimize the risk of injury and maximize the benefits of strength training. Additionally, sports medicine physicians can monitor progress, adjust treatment plans as needed, and provide ongoing support and encouragement to help individuals stay motivated and engaged in their fitness journey.

In addition to prescribing strength training programs, sports medicine physicians can also offer comprehensive care for a wide range of musculoskeletal conditions commonly encountered in older adults. From arthritis and tendonitis to ligament sprains and fractures, sports medicine physicians are skilled in the diagnosis and treatment of orthopedic injuries and conditions, employing a variety of conservative and interventional techniques to promote healing and restore function. Whether it's through physical therapy, bracing, injections, or minimally invasive procedures, sports medicine physicians can provide personalized care to help individuals manage pain, regain mobility, and return to the activities they love.

Furthermore, sports medicine physicians can provide valuable guidance on nutrition, hydration, and supplementation to support optimal health and performance in older adults. By addressing factors such as protein intake, hydration status, and micronutrient deficiencies, sports medicine physicians can help optimize the effectiveness of strength training programs and enhance overall physical function and well-being. Additionally, sports medicine physicians can offer advice on lifestyle modifications, such as smoking cessation and stress management, to further support the health and longevity of their patients.

Conclusion

In conclusion, as we navigate the journey of aging, the importance of strength training becomes increasingly evident. By preserving muscle mass, enhancing bone density, and promoting overall physical function, strength training offers a multitude of benefits that can help older adults maintain their independence, vitality, and quality of life. However, achieving these benefits requires guidance and support from knowledgeable and experienced healthcare professionals, such as sports medicine physicians. With their expertise in musculoskeletal health and performance, sports medicine physicians play a crucial role in assisting older adults in optimizing their health and fitness, empowering them to live life to the fullest, regardless of age or athletic ability. Through personalized assessment, prescription, and supervision of strength training programs, sports medicine physicians can help individuals harness the power of exercise to age gracefully and maintain optimal health and well-being for years to come.

The collaboration between older adults and sports medicine physicians creates a tailored approach to health that addresses individual needs and goals, ensuring effective and safe interventions. This holistic care includes mental well-being, nutritional advice, and lifestyle modifications, promoting a balanced and healthy lifestyle essential for overall happiness and fulfillment.

As the population ages, the need for specialized care and targeted exercise programs will grow. Emphasizing the importance of strength training and sports medicine can lead to a healthier, more active, and independent older population. This approach offers a pathway to maintain and even improve physical function, enhance mental well-being, and enjoy a higher quality of life, guiding us towards a future where aging is embraced with strength, vitality, and confidence.

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INA-RESPOND Newsletter

COMIC CORNER

WHY PILOT STUDY AND OTHER STUDY REGISTRATION MATTERS MORE THAN WE THINK

By: Aly Diana

Not long ago, a journal asked me to submit a clinical registration number for a pilot study I had conducted. I had registered my main randomized controlled trial (RCT), but not the pilot study. It turns out the CONSORT statement includes a checklist for pilot and feasibility studies (the CONSORT checklist of information to include when reporting a pilot or feasibility trial), which was new to me. While the International Committee of Medical Journal Editors (ICMJE) rules and regulations on the registration of pilot studies are not entirely clear, I would encourage everyone to register their studies. In this case, more is definitely better. Registering RCTs, pilot studies, systematic reviews, and more, to be on the safe side. Since there's nothing wrong with it, it's probably a good practice.

Reasons for Registering Studies

Clinical trials are indispensable for advancing medical knowledge and improving patient care. Registering these trials, particularly with platforms like ClinicalTrials.gov (also known as the National Clinical Trial, NTC registry), is a critical process that ensures transparency, accountability, and accessibility of clinical research data. Clinical trial registration promotes transparency by providing a public record of all initiated studies, regardless of whether they yield positive or negative results. This practice is essential for preventing selective reporting, where only favorable outcomes are published, thereby reducing publication bias and offering a more accurate picture of the research landscape.

Moreover, registration fosters scientific rigor. By requiring detailed documentation of study protocols, researchers must specify objectives, methodologies, and statistical analyses in advance. This requirement minimizes the risk of data manipulation and enhances

the reproducibility of results, contributing to the overall quality and reliability of scientific research. One of the most significant benefits of registering a study is the necessity of thinking through the statistical analysis plan before conducting the study. This planning stage helps in truly designing the study well. Although the registry itself may approve the registration without a clear or detailed statistical plan, some funders or journals have stringent regulations requiring this.

In addition, registration improves access to information, ensuring that data about ongoing and completed trials are available to researchers, clinicians, and the public. This fosters collaboration, prevents duplication of efforts, and accelerates the translation of research findings into clinical practice or community service. Furthermore, registered trials are viewed as more credible and trustworthy. Journals, funding agencies, and regulatory bodies often require registration as a prerequisite for publication or support, reinforcing the importance of this practice. Comprehensive trial registries also provide a valuable resource for systematic reviews and meta-analyses. These studies rely on complete datasets to draw robust conclusions about treatment efficacy and safety, ultimately guiding clinical decision-making. Additionally, ethical guidelines such as the Declaration of Helsinki emphasize the necessity of trial registration to protect participants and maintain public trust. By ensuring that trials are conducted ethically and responsibly with proper oversight and adherence to established protocols, registration upholds the ethical standards of clinical research.

Conclusion

In conclusion, the registration of clinical trials and other studies is a fundamental practice that enhances the transparency, ethical conduct, and scientific rigor of medical research. By adhering to registration requirements and CONSORT guidelines, researchers contribute to a more reliable and trustworthy scientific enterprise, ultimately benefiting patients and advancing healthcare knowledge.

Note:

The World Health Organization mentioned: "For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

While reading, I found an article on common uses and misuse of pilot studies (cited here); maybe you can read or maybe we can discuss it another day.

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