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SERVICES FOR SCIENCE AND EDUCATION

Comparative Impact of Hospital-Based versus Non-Hospital-Based Staff Employment Models: A Focus on Clinical Trial Execution Performance

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ABSTRACT

Recruitment and assigning staff for the clinical study is a crucial exercise that significantly affects cost, budget, timeline, quality, and overall outcomes. Therefore, we aimed to determine the overall performance of recruited qualified hospital-hired and non-hospital hired staff in implementing clinical trial execution performance. Data were extracted from the clinical trial management system database of a teaching hospital in Taiwan. We compared the trial execution performance between hospital-hired and non-hospital-hired staff. Hospital-hired staff included clinicians, nurses, and coordinators, whereas non-hospital-hired staff were affiliated with site management organizations (SMOs) that provide professional clinical research coordinator (CRC) services. In this study, we

specifically investigated rate of recruitment, screening failure, and subject's early withdrawal between the two staffing models (hospital-Hired and non-Hospital-Hired staffing). We also found determined the association between staffing model and clinical trial distribution (Phase I-IV). Through logistic regression analysis, we identified the association between rate of recruitment, time to first subject (in days), screen failure, early withdrawal, and clinical phase distribution, with employment type. The post standardized coefficients which indicates the direction and strength of association between each predictor and outcome were also determined. Conclusively, our study revealed no significant differences for recruitment, time to first subject (in days), screen failure, early withdrawal, or clinical phase distribution between hospital-hired and non-hospital hiring models.

INTRODUCTION

A clinical trial is one of the most effective approaches to determine the safety and efficacy of diagnostic of treatments (1). Notably, clinical trials are a long, complex, and costly process, and are affected by factors such as site performance, investigator involvement, and patient experience(2). Considering the discernment of healthcare providers could also be an effective way to determine clinical efficacy and regulatory approval in a generic drug compared to a branded one (1, 3). The Recruitment of qualified hospital-hired and non-hospital hired staff plays a critical role in the overall performance of clinical trial execution performance. High-performing sites are often distinguished by well-trained clinical staff, effective coordination teams, and strong community engagement, all of which directly influence patient recruitment, protocol adherence, and data quality(4). Studies have shown that staff expertise and infrastructure quality are major determinants of successful enrolment and retention(4). Recent technological advances, such as telemedicine and AI-based tools, have expanded opportunities to engage non-hospital personnel and remote support teams, further improving trial accessibility and efficiency (5). By optimizing staff selection and training across both hospital and decentralized settings, clinical trials can achieve greater speed, accuracy, and participant satisfaction. Recruitment and assigning staff for the clinical study is the most crucial exercise and affects cost, budget, time, quality, and outcome of the study (6). The staff of the clinical trial is crucial for healthcare facilities. recruitment of participants, communication between stakeholders, data collection, and analysis, etc. Considerable resources, time, and experience are required for the recruitment of staff for a clinical study (6). The staff for the clinical trial could be from a hospital or a non-hospital organization, such as a specialized organization/ or experienced personnel involved in clinical trial studies. The recruitment of non-hospital staff could accelerate and assist in managing clinical trials effectively. Thus, it is crucial to evaluate the impact of hospital and non-hospital staff on the clinical performance of the study.

As clinical trials continue to advance, the structure of research staff employment may play a crucial role in influencing operational efficiency, outcome attainment, and overall project management. To understand the impact of hospital-hired and non-hospital-hired staff on clinical execution performance. Our study evaluates the effectiveness of hospital-hired and non-hospital-hired staff in performing clinical trials at different phases of the study. This study investigates how different employment models; namely, hospital-based versus non-hospital-based affect the performance of clinical trial project execution. Through quantitative analysis, the study assesses key differences between the two models by examining metrics such as recruitment rates, the timespan from site initiation visit (SIV) to first patient enrolment, trial

quality indicated by resource utilization. It also identifies potential contributing factors, aiming to offer valuable insights for institutions to guide employment strategies and enhance the efficiency of clinical trial implementation.

METHODS

The data were extracted from our Clinical trial management system database of a teaching hospital in Taiwan. We compared the trial execution performance of hospital-Hired and non-Hospital-Hired staff. Hospital-hired staff include clinicians, nurses etc. whereas the non-Hospital-Hired staff may belong to Site Management Organizations (SMOs), providing professional clinical research coordinator (CRC) services. It may also include directly employed by pharmaceutical companies or contract research organizations (CROs) or freelance/outsourced CRC. In this study, we specifically investigated recruitment rate, screening failure rate, and subject early withdrawal between the two staffing models. We also found determined the association between staffing model and clinical trial phase distribution. The clinical research coordinator belonged to bachelor's degree or higher, without nursing background such as Medicine, Pharmacy, Public Health or Life Sciences. The limitation of these staff included no permission to conduct intervention procedures like injection. Clinical research nurses had bachelor's degree or higher, with a nursing license.

Analysis of Recruitment Rate

In the clinical trials, an efficacious participant recruitment is a critical challenge. An Inadequate recruitment may incur delays, increase costs, and compromise scientific integrity. Therefore, we analyzed recruitment rate of hospital-Hired and non-Hospital-Hired staffing models.

Analysis of Screening Failure Fate

The screening failure may be encountered due to lack of efficacy, safety issues, or funding trial, in addition to other factors like failure of maintaining good manufacturing protocols, or FDA guidance, or problems with patient recruitment, enrollment, and retention.

Subject Early Withdrawal

A participant's right to withdraw from the all-research procedures is widely accepted. But it can cause failure to detect safety signals, inaccurate efficacy estimation, or lack of acceptance of trial results, which amend the study's benefit-risk ratio. Therefore, we compared the subject's early withdrawal rate between hospital-hired and non-hospital-hired staff.

Employment Model and Clinical Trial Phase Distribution

Based on the hospital and non-hospital hired staff model, the analysis of clinical trial phase distribution (Phase 1-IV) was done.

Post Standardized Coefficients

We determined the post standardized coefficients which indicates the direction and strength of association between each predictor and outcome. The positive coefficient (>0) imply that when the predictor increases, the probability of the outcome increases. On the other hand, the negative coefficient (< 0) indicate that when the predictor increases, the probability of the outcome decreases. Each line represents the effect of predictors on a different outcome.

Logistic Regression Analysis

We examined the relationships between recruitment, screen failure, and early withdrawal rates, with employment type, clinical phase, and time to first subject (in days) as predictor variables.

Statistical Analysis

The statistical analysis was done by SPSS. We employed descriptive and logistic regression using odds ratio (OR). P value less than 0.05 was considered statistically significant.

RESULTS

Comparative Association of Recruitment Rate Between Hospital-Hired and Non-Hospital-Hired Staffing Models

A total of 138 clinical trials were found in our database; of those, 64 were hospital-hired, while the remaining 74 were non-hospital-hired clinical trials. The recruitment rate among non-hospital hired was slightly higher than hospital-hired staff; however, no significant difference was noted between them (p = 0.863) (Figure 1A).

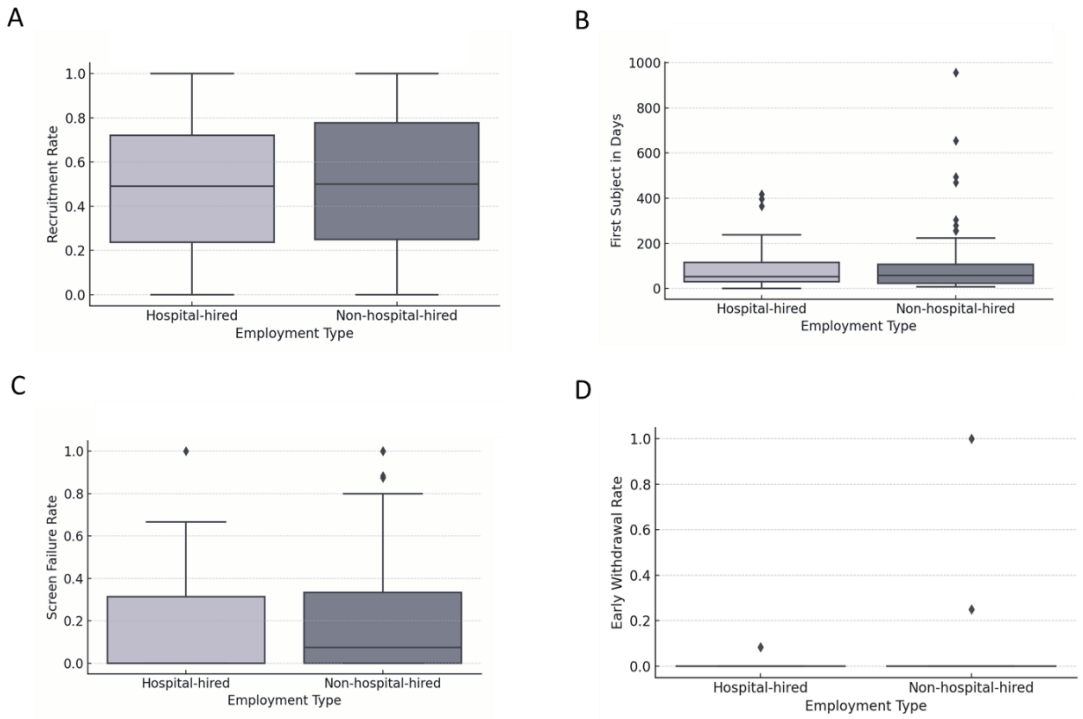

Figure 1: Determination of (A) Recruitment rate (B) Time to first subject joining, (C) Screening failure rate (D) Subject early withdrawal between the two staffing models (Hospital-hired and non-hospital hired).

First Subject in Days by Employment Types

Our study tracked the first subject in days between hospital and non-hospital hired staff model. The result (Figure 1B) indicates no significant difference in time to first subject in between the comparative groups (p = 0.376).

Screen Failure Rate by Employment Type

The screen failure rate represents a loss of time and resources employed to allocate subjects for the clinical study. We assessed (Figure 1C) the impact of hospital-hired and non-hospital-hired staff type on the screen failure rate and found no significant difference ($p = 0.318$) between them.

Early Withdrawal Rate by Employment Types

Patient withdrawals adversely impact study objectives, sample size, data analysis, risk of bias between study groups, and increase the study duration(7). In our study, we found that the early withdrawal rate (Figure 1D) was not significantly different ($p = 0.267$) between hospital and non-hospital hired groups.

Number of Trials, Clinical Phase Distribution, and Employment Type

We further assessed the association between several clinical trials, their phase distribution, with both employment models (Hospital and non-hospital hired) (Figure 2). A total of 174 clinical trials were found to be conducted in our database, out of which only 138 were included in the study based on the inclusion criteria. Out of which 64 were associated with a hospital-hired clinical study, while the remaining 74 were linked with non-hospital-hired clinical trials. Our analysis finds no association ($p=0.0657$) between employment type (Hospital-hired vs. non-hospital-hired) and clinical trial phase.

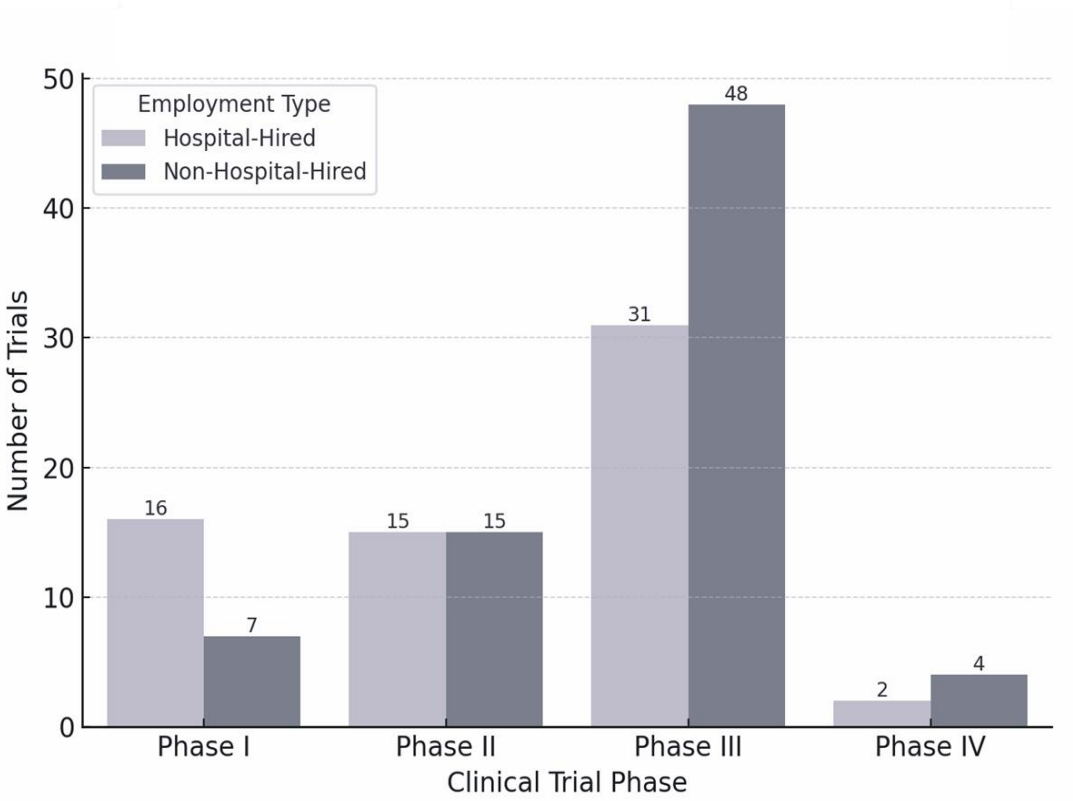

Figure: 2 Distribution of clinical phases (I-IV) and number of trials based on the employment types.

Staffing Models-Based Prediction of The Relationship Between Variables: The Logistic Regression

Logistic regression [(Odds ratio (OR)] was used to examine the relationships between recruitment, screen failure, and early withdrawal rates, with employment type, clinical phase, and time to first subject (in days) as predictor variables.

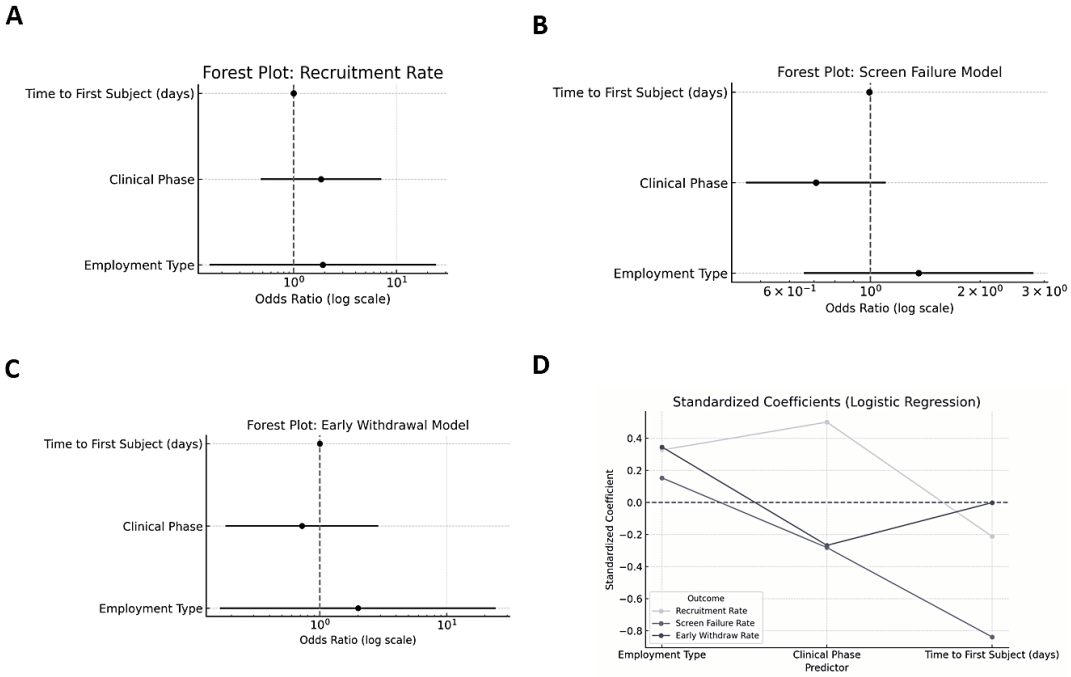

Figure 3: Logistic regression-based forest plot for predicting the relationship between the variables, including (A) Recruitment Rate (B) Screening failure rate, (C) Subject's early withdrawal, (D) Standardized coefficients between the two staffing models (Hospital-hired and non-hospital hired).

The forest plot (Figure 3A) showed that the clinical phase considerably impacts the recruitment rate, and the recruitment in phase IV was successful. Similarly, the time to first subject in was significantly associated with screen failure ($p < 0.05$, odds ratio<1) (Figure 3B), which suggests that a longer time to first subject is associated with a reduced risk of screen failure. Further, an early withdrawal was not significantly associated with employment type, clinical phase, and time to first subject (Figure 3C). The standardized coefficient for the logistic regression model represented in the Figure 3D reveals that the variable-t*ime to first subject (days)* consistently showed the largest negative standardized coefficients in both the recruitment rate and screen failure rate models, suggesting that delays in enrolling the first participant are strongly linked to reduced recruitment success and increased risk of screening failures. In contrast, employment type and clinical phase demonstrated smaller, statistically nonsignificant effects on these outcomes.

DISCUSSION

Clinical trials are intricate and resource-intensive, with failures often resulting from issues related to efficacy, safety, funding, regulatory compliance, or patient engagement (8). These challenges frequently linked to study sites, investigators, and patient factors can lead to significant losses, especially in later trial stages where investments are highest. Potentially effective drugs may fail to demonstrate efficacy for various reasons, such as poor study design, the selection of unsuitable statistical endpoints, or an underpowered clinical trial, often due to

low enrolment or high patient dropout rates (8). Notably, the low recruitment of subjects and patients' withdrawal is one of the major causes of underreporting of drug efficacy or termination of the study (9).

Patient participation, adherence, and retention also decrease due to factors such as hospital admissions, extra procedures, frequent follow-up visits, long travel distances, and extended waiting times, loss of motivation, and enthusiasm (9). Further, clinical trial staff play a crucial role in subject retention and recruitment. The study staff is involved in motivation for enrolment, communication, protocol explanation, interaction with patients, providing emotional support, motivation, and compensation to study subjects for extra visits and inconvenience. These activities of the staff are very crucial for compliance, retention, and lower withdrawal rate. In our study, we compared the effect of employment type (hospital-hired and non-hospital-hired) on recruitment rate, first subject in days, screen failure rate, and early withdrawal rate to determine the impact of staff on subjects. In addition, the logistic regression was used further to elaborate on the relationship between employment types and variables like recruitment rate, time to first subject joining, screening failure rate, and subject early withdrawal rate.

To our knowledge, our study is the first of its kind that compares the performance of hired staff /employment type. We reported no significant difference between hospital-hired and non-hired hospital staff performance. The recruitment rate is primarily affected by the demographic and operational factors of the study (10). Further, communication with patients, incentives, and staff training play a crucial role in retention and recruitment (11). Clinical trial recruitment is also influenced by multiple overlapping factors, making it difficult to assess the impact of individual strategies (12, 13). Clinical staff, including those not directly involved in recruitment, play a crucial yet often underrecognized role in supporting enrolment (12, 14). Additionally, gatekeeping by healthcare professionals and misperceptions about trial risks by staff and patients can significantly hinder recruitment efforts (12, 15). Similarly, time to subject of first joining was not affected by whether the hospital hired staff or non-hospital staff. Delayed subject joining could adversely affect the study, resulting in the loss of time, quality, and finance, or worst-case scenario, the dropping of the study.

Similarly, the withdrawal rate and screening failure rate of subjects in our studies was similar both in hospital and non-hospital hired staff. Notably, low withdrawal is associated with factors such as private insurance and caregivers with some college education, quality of life, availability of caregivers, and emotional states during the study (16). A recent study reveals that factors such as a specific ethnic group, participation in a randomized placebo-controlled trial, lack of enthusiasm of healthcare professionals, serious adverse events of study, and being aged 75 or older plays an important role in patient withdrawal (7, 17). As non-hospital staff for the clinical study i.e. SMOs, CRC, and CROs etc. directly employed by the pharmaceutical companies were qualified and experienced in clinical trials so the risk of withdrawal, low recruitment, and delays in study joining is lower as these personnel were qualified enough to handle subjects for the study resulting in similar outcomes related to the recruitment rate, time of subject joining, withdrawal rate, and screening failure rate.

We further explored the distribution of conducted clinical trials studies in a phase-wise manner in studies conducted by hospital-hired or non-hospital-hired staff. The results demonstrated that studies were similarly distributed in various phases for hospital-hired and non-hospital-

hired staff. This demonstrates that phase-wise comparison between hospital-hired staff and non-hospital-hired staff is not statistically meaningful, as no significant difference was observed. The logistic regression analysed the factors influencing recruitment efficiency and screen failure. Notably, the clinical phase affects recruitment rates specifically in clinical phase IV trials, which confirms considerably higher subject recruitment. Our finding confirms the previous finding that explaining that the experience gained in recruitment and retention is passed to the later phase of the studies, leading to more effective protocols and confidence to improve subject enrolment (2). Further, the short time to first subject joining increases the screen failure rate, which is confirmation of a previous finding by Getz et al. (18). The rapid enrolment of subjects could overlook stringent guidelines for enrolment criteria, resulting in higher screen failures. In addition, our study also reveals that after enrolment, withdrawal of study participants is not affected by the recruitment rate, employment type, and clinical phase. Our finding indicates that if the criteria for enrolment are followed by the staff, then withdrawal will be low. Moreover, the standardized coefficient of our study shows the importance of the time of first subject joining in conducting clinical trials effectively. It is necessary to adopt effective protocol to ensure the subject enrolment is not rushed, as it might negatively affect the study quality.

CONCLUSION

Our study revealed that the hospital-hired and non-hospital-hired staff may be equally effective in conducting the clinical trials without adversely impacting the recruitment rate, screen failure rate, time to first subject joining, and withdrawal rate. In addition, our finding also confirms the significance of the enrolment of subjects promptly and its impact to ensure quality and to reduce the risk of study failure. However, since it is the first study of its type, more studies are required to confirm our findings.

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