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Conference Abstracts

Optimizing Recruitment and Retention for a Multicenter Vaccine Clinical Trial at a Study Site in Puebla, Mexico: A Qualitative Analysis

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BACKGROUND

Adequate participant recruitment and retention are essential to achieve statistical power in clinical trials, yet up to 50% of trials do not meet recruitment targets.[1] In this study, we sought to optimize recruitment and retention at the Puebla, Mexico site of ULACNet-201, a multicentric, Phase III interventional trial of the nine-valent HPV vaccine.

METHODS

We employed a qualitative approach to identify characteristics relevant to recruitment and retention within the clinical workflow and patient population of CAPASITS, an outpatient HIV clinic in Puebla, Mexico. Clinical staff were selected for direct observation and interviews by purposive and snowball sampling. Observational priorities and interview questions were developed based on the Consolidated Framework for Implementation Research outer setting and inner setting domains.[2] Aggregated data were analyzed using content analysis.[3]

RESULTS

Fourteen participants were selected, approximately half of patient-facing staff. Content analysis revealed eleven subthemes within four primary domains: 1.) Patient-provider familiarity; 2.) Patient motivation; 3.) Patient demographic and socioeconomic factors; 4). Fear of stigma. Key findings included that psychology and pharmacy staff play an outsize role in monitoring adherence and providing social support to patients at CAPASITS, while patient motivation to engage in longitudinal interventions varies. We also found that variable health literacy, transportation time, privacy concerns, and complex insurance policies have the potential to limit the willingness and ability of certain patients to engage in research, and thus pose risks to recruitment and retention.

CONCLUSIONS

Our findings suggest that emphasizing study confidentiality measures, engaging psychologists and pharmacists in recruitment and retention efforts, and implementing additional screening related to motivational and socioeconomic factors may improve recruitment and retention. More broadly, out results illustrate how differing provider roles and social context may impact international clinical trial implementation and how a qualitative approach can be utilized to identify risks and protective factors.

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