Abstract

Nursing Care Intensity in Clinical Research: A Retrospective Time Analysis of Nursing Activities for Patients Enrolled in Clinical Trials

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Introduction. Clinical trials add protocol-driven activities to routine oncology care, increasing nursing workload in ways not captured by conventional staffing models. This study quantified the additional nursing time associated with non-standard-of-care procedures for patients receiving parenteral investigational treatments.

Methods. This retrospective time analysis included patients enrolled in clinical trials at a single oncology centre between 2018 and March 2026. Eligible patients received intravenous or subcutaneous investigational products. Protocol schedules of activities were reviewed to identify non-standard-of-care pharmacokinetic (PK) sampling, vital-sign monitoring, and electrocardiograms (ECGs). Institutional benchmark times were applied: 15 minutes per PK sample, 10 minutes per vital-sign assessment, and 15 minutes per ECG.

Results. Seventy-six patients from 20 trials were evaluated; phase II and phase III accounted for 7% and 93%, respectively, while 76% received treatment in an experimental arm. Treatment categories were combination therapy (53%), immunotherapy (34%), and antibody–drug conjugates (12%); the median number of treatment cycles was 14 (range, 1–128). PK sampling was required in 50% of patients and multiple post-dose sampling in 8%, with a median estimated nursing time of 182 minutes (range, 45–645). Baseline and post-dose ECGs were required in 15% and 3%, respectively; median ECG time was 85 minutes (range, 15–390). Vital-sign monitoring was required in 20%, with a median of 153 minutes (range, 30–670). Overall, non-standard-of-care procedures required a mean of 267 minutes per patient (range, 75–985).

Discussion. Protocol-driven nursing workload is substantial and variable but may be overlooked by staffing models focused on clinical complexity. Incorporating research-related activities into workload measurement could support realistic resource allocation and maintain data quality.

Keywords: Nursing, Clinical Research, Clinical Trials

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