Abstract: PROSPECT-Times

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Background
Understanding requirements for multicenter trials from a Research Coordinators' (RCs) perspective is crucial for both participating sites and methods centers, to plan personnel and reflect resource needs.

Objectives
In a prospective, observational multicenter time-in-motion study, our objective was to document and describe the RC time and activities for the PROSPECT Pilot Randomized Trial.

Methods
PROSPECT RCs followed their first 10 randomized PROSPECT patients, concurrently documenting their trial-related activities in 14 domains using a self-administered daily time management log. We hypothesized that RCs would spent the greatest amount of time on Study Day 1, due to enrolment procedures such as screening, consenting, and communicating with the family/patient, ICU team, and pharmacy. Also, over the course of the enrolment period, we hypothesized that RCs would spend the majority of their time on Case Report Form (CRF) completion and query responses.

Results
In this time-in-motion study, 63 patients were enrolled in PROSPECT-TIMES from 7 centers (of 14 participating in the PROSPECT trial). Overall, 9.2 hours/patient were spent by RCs (range 3.2-28.5 hours). Study Day 1 activities took significantly longer than subsequent days in the trial (2.1 (±1.1) hours versus 0.76 (±0.2) hours, respectively [$p<0.01$]). The average study day occupied 0.9 (±0.8) hours. Primary activities included CRF completion (55%), ICU team communication (10%), obtaining consent (6%), responding to queries (6%), and bedside charting (5%). RCs tended to spend fewer hours on each enrolled patient as the trial unfolded.

Conclusions
Research coordinators engaged in several types of activities while participating in the PROSPECT Pilot Trial. These findings represent the broad scope of RC work, reflect the time commitment for early protocol implementation, and estimate personnel costs for the pilot phase of a multicenter trial, which will be used to inform the workload and budget for the future main PROSPECT Trial.

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References
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