

Abstract: Screening Weeks: A Pilot Trial Management Metric

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Background: Estimated completion of randomized clinical trials (RCTs) in the ICU typically depends on active screening for eligible patients over most weeks in a calendar year. Predictions of patient recruitment in RCTs are often inaccurate due to overestimated accrual rates.

Objective: Our objective was to document the proportion of weeks during which patients were screened for eligibility during a pilot RCT testing probiotics (*Lactobacillus rhamnosus GG*) versus placebo on infectious outcomes during critical illness (PROSPECT Pilot Trial, clinicaltrials.gov NCT01782755).

Methods: Research Coordinators were asked to prospectively self-report the weeks following ethics approval during which patients were actively screened and when they were not, for any reason. We projected the number of additional patients who might have been enrolled during non-screening weeks based on mean recruitment during active screening weeks.

Results: Across 14 participating centers, there was staggered start-up for the PROSPECT Pilot trial, extending to the Vanguard phase. 285 patients were enrolled over 715 potential screening weeks, of which 108 weeks (15.1%), did not involve screening for eligible patients. Reasons included holidays, conferences, and other research activities including site visits, close-out visits and a Health Canada audit. Had it been possible to screen patients during those weeks, based on pro-rated accrual during other weeks, an estimated 49 additional patients may have been recruited. Thus, 334 patients rather than 285 would potentially have been enrolled in the Vanguard phase of this trial.

Conclusions: Documentation of non-screening weeks helps to better plan and transparently document patient recruitment in critical care RCTs. Such an approach may assist with more accurate timeline estimates when grant writing, and may inform the logistic and financial operations for clinical trials research.

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