



Optimizing clinical trial supply requirements: simulation of computer-controlled supply chain management

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ABSTRACT

Background Computer-controlled systems are commonly used in clinical trials to control dispensing and manage site inventories of trial supplies. Typically such systems are used with an interactive telephone or web system that provide an interface with the study site. Realizing the maximum savings in medication associated with this approach has, in the past, been problematic as it has been difficult to fully estimate medication requirements due to the complexities of these algorithms and the inherent variation in the clinical trial recruitment process. **Methods** We describe the traditional and automated methods of supplying sites. We detail a simulation approach that models the automated system. We design a number of simulation experiments using this model to investigate the supply strategy properties that influence medication coverage and other strategy performance metrics.

Results The computer-controlled medication system gave superior performance to the traditional method. In one example, a 75% overage of wasted medication in the traditional system was associated with higher supply failure than an automated system strategy with an overage of 47%. In a further example, we demonstrate that the impact of using a country stratified as opposed to site stratified scheme affects the number of deliveries and probability of supply failures more than the amount of drug wasted with respective increases of 20, 2300 and 4%. Medication savings with automated systems are particularly significant in repeat dispensing designs. We show that the number of packs required can fall by as much as 50% if one uses a predictive medication algorithm.

Conclusions We conclude that a computer-controlled supply chain enables medication savings to be realized and that it is possible to quantify the distribution of these savings using a simulation model. The simulation model can be used to optimize the prestudy medication supply strategy and for midstudy monitoring using real-time data contained in the study database.

Clinical Trials 2004; 1: 399-412. www.SCTjournal.com

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