Special Feature

Mathematical Modeling to Reduce Waste of Compounded Sterile Products in Hospital Pharmacies

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Abstract

In recent years, many US hospitals embarked on “lean” projects to reduce waste. One advantage of the lean operational improvement methodology is that it relies on process observation by those engaged in the work and requires relatively little data. However, the thoughtful analysis of the data captured by operational systems allows the modeling of many potential process options. Such models permit the evaluation of likely waste reductions and financial savings before actual process changes are made. Thus the most promising options can be identified prospectively, change efforts targeted accordingly, and realistic targets set. This article provides one example of such a data-driven process redesign project focusing on waste reduction in an in-hospital pharmacy. A mathematical model of the medication prepared and delivered by the pharmacy is used to estimate the savings from several potential redesign options (rescheduling the start of production, scheduling multiple batches, or reordering production within a batch) as well as the impact of information system enhancements. The key finding is that mathematical modeling can indeed be a useful tool. In one hospital setting, it estimated that waste could be realistically reduced by around 50% by using several process changes and that the greatest benefit would be gained by rescheduling the start of production (for a single batch) away from the period when most order cancellations are made.

Key Words—CSP batch preparation, mathematical inventory models, Monte Carlo simulation, waste reduction

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There have been several calls for the application of best practices from other industries in the design and management of health care processes.^{1–7} This article describes our experience of collaboration between operations management professionals and pharmacy managers working in the in-house pharmacy of an 830-bed university-based hospital in upstate New York. At the time of the study, the hospital was implementing “lean” initiatives in many departments with the goals of reducing costs and/or improving patient experience. In the hospital pharmacy, a physical 5-day audit of wasted compounded sterile products (CSP) found that, on average, 100 doses of prepared medication were wasted

daily. Given the cost of raw materials, the estimated annual waste amounted to over one-third of a million dollars. Pharmacy management selected CSP waste reduction as one of its process improvement projects.

Because preparing and dispensing CSP doses one at a time is inefficient, they are typically produced in batches. The primary cause of the CSP waste is the cancellation (or change) of orders for CSPs that have already been prepared or are in the process of being prepared as part of a batch.⁸ The doses that are dispensed but not administered are seldom recycled; the logistics of collecting them is complex, and many of the CSPs have short expiration dates.

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In deciding on the number of daily CSP batches, managers must trade off the reduction in medication waste against the increase in employee hours needed for preparation and delivery of additional batches. There is no single optimal solution for every hospital of a certain size with a given mix of cases. In selecting batch schedules, pharmacy managers have either made their decisions intuitively or used labor-intensive methodologies such as trying different implementations and cataloging CSP waste by physically collecting it⁹ or by tracking it through an information technology (IT) system.¹⁰

Some pharmacy professionals reported using *computer simulation* for analysis and design of pharmacy operations,¹¹⁻²¹ but there have been few reports of the use of *analytical modeling* for operational decision making. This is despite the fact that analytical models are often easier to develop,²² and well-known analytical models (eg, the economic order quantity inventory management model) have long been used for the analysis and redesign of processes in manufacturing and service industries generally and in health care²³⁻²⁵ in particular. The experience described here demonstrates how analytical modeling combined with the use of existing pharmacy data helps to prospectively (and cost efficiently) evaluate a variety of operational configurations for in-hospital CSP preparation.

We provide an overview of the CSP preparation process at our hospital. Then we introduce a mathematical model of this process and use the model to show how the pharmacy could leverage the data captured by its information systems to plan operational changes that reduce waste. Using the model, we estimate the savings from (a) rescheduling a single daily batch to minimize the impact of cancellations, (b) scheduling multiple batches, (c) changing the workflow information system to a system with a virtual queue, and (d) using the workflow information system to schedule preparations of orders within a batch. The modeling approach is explained in detail in the hope that hospital pharmacy managers will find it to be a useful aid in making their operational decisions.

CSP WORKFLOW AND INVESTIGATION OF PROCESS CHANGES

CSP batch preparation is a multistep process. A batch consists of doses that are administered over a certain period of time, for example, from 16:00 of one day until 15:59 of the following day. In our pharmacy, at the start of a batch preparation process, the pharmacy information system (PIS) prints out labels

for all order doses to be administered over the batch administration period. The labels are distributed to pharmacy technicians who prepare CSPs to fulfill the orders. After being checked by a pharmacist, the prepared batch of CSPs is delivered to the nursing units.

When an order is cancelled, doses that have been delivered to the nursing units, but not yet administered to the patients, are usually wasted. If the cancellation arrives during batch preparation, a “cancellation” label is printed in the pharmacy. The printing of such label is intended to serve as a signal not to produce the order. However, in practice, it is difficult to stop production of a cancelled order — an employee would have to search through hundreds of production labels that have already been distributed to technicians. So doses cancelled during batch preparation process are routinely produced and subsequently wasted.

Misdirected doses are another source of CSP waste in a hospital. This occurs, for example, when a patient is moved to a different unit but the medication prepared for the patient is not forwarded to the new unit, or when the pharmacy sends the medication to the wrong unit and then another dose has to be prepared and sent to the correct unit. However, in our hospital, the largest reason for CSP waste is order cancellations. Examining 3 months of data, we found that only 12% of orders are actually completed; the rest are cancelled prior to the initially specified end date. As can be seen from **Figure 1**, 80% of orders are cancelled within 7 days of initiation.

When the CSP waste reduction project was initiated in our hospital, CSPs were prepared in a single daily batch. The labels were printed at 06:00 for doses to be administered between 16:00 of the current day and 15:59 of the next day. Batch preparation was completed by 14:00, and doses were delivered to the nursing units between 14:00 and 16:00. Pharmacy managers considered changing the process to produce 2 batches daily: one for doses administered between 16:00 and 07:59 of the following day, and the other for doses administered between 08:00 and 15:59. The first batch would be prepared by the day shift, using the original work schedule; the second batch would be prepared by the overnight shift, with labels printed at 22:00 and doses delivered to the units between 06:00 and 08:00.

During the same period, pharmacy managers considered purchasing a new electronic workflow system to enhance the audit trail and improve safety. One of the features of this new IT system is a virtual label queue, that is, the physical label is not printed

Figure 1. Distribution of number of days from order initiation to completion or cancellation.

until a technician is ready to prepare the required doses of a particular medication. This feature would prevent production of doses for an order that has already been cancelled by a provider. In evaluating the benefits and costs of schedule changes and of the new IT system, pharmacy managers wanted to estimate prospectively the achievable reduction in CSP waste.

RESULTS OF MODELING ANALYSIS

Using mathematical modeling (explained in the following sections), the operations management professionals on the team were able to prospectively estimate waste reduction from the addition of the second batch and from the implementation of the new IT system with virtual queue functionality. Furthermore, they proposed other interventions that the pharmacy management team had not previously considered: staying with a single daily batch, but changing its start time; and using the new IT system to schedule order production considering the cost of ingredients and the probability of order cancellation. Key quantitative results of the prospective waste reduction

analysis are captured in **Figure 2**, with all reductions in waste shown relative to the then-current level.

Rescheduling operations with the proposed 2 batches would reduce waste 28%. Notably, that is only an 8% (8 doses daily) improvement relative to an alternative single daily batch schedule, in which batch preparation would start at 20:00. This is an important realization, because the addition of a second batch comes with an increase in employee time needed to deliver the extra batch. Assuming that CSP batches are delivered daily to 30 hospital units and delivery to each unit takes 5 minutes of pharmacy employee time, a second daily batch needs 2.5 extra employee hours daily. If an average dose takes 2 minutes to prepare, the net effect of 2 batches is an increase of 1.5 employee hours every day.

As shown in **Figure 2**, the waste reduction benefit of an IT system with virtual queue functionality depends on batch schedules. Given the original single-batch schedule, the ability to remove cancelled orders from the preparation queue would decrease waste by 18%. If the start of batch preparation is moved to 20:00, then the benefit is less (12%). Sorting the

Figure 2. Waste reduction impact of different interventions. The reduction is shown relative to the original waste level.

order preparation by expense and likelihood of cancellation could provide additional cost savings in raw materials of around 1% to 5% — despite reducing the number of wasted doses by only 1% to 2%.

Based on this analysis and on other considerations, pharmacy managers decided to change the production process to 2 daily batches and to continue investigating alternative IT vendors. After the introduction of the 2-batch process, pharmacy employees conducted a 5-day physical waste audit. They found that 33% fewer doses were wasted relative to the previous waste-collection audit. This finding compared favorably with the model's prediction of long-term waste reduction of 28%. Our team considered this a reasonable validation of the analytical model. As pointed out by Dean et al,²² to determine the appropriate level of model validation, managers need to balance the cost of errors in the model's forecast against the cost of carrying out the validation. To slightly paraphrase Schlesinger and co-authors, who discussed validation of computer simulation models, model validation is a substantiation that a model possesses a satisfactory range of accuracy consistent with its intended application.²⁶

The next section explains the development of a mathematical model for CSP inventory and demonstrates how it can be used to estimate waste reduction.

ANALYTICAL MODEL FOR CALCULATING WASTE

The key to understanding the mathematical model is the realization that one can compare waste under different conditions by comparing expected (average) daily waste per cancelled order. For a particular cancelled order, the amount of waste depends on the number of doses that have been prepared (or have been committed to production) but not administered when the cancellation arrives. If one knows that an order will be cancelled during a particular 24-hour period but does not know exactly when the cancellation will arrive, it is possible to calculate the expected waste for this order by computing the weighted sum

$$\sum_t I(t) \cdot Pr \{ \text{cancellation arrives at time } t \}$$

where $I(t)$ is the level of unused order inventory at time t , and Pr denotes probability. In computing the value numerically, different discretization schemes

can be applied to time t ; the smaller the time interval, the greater the precision. For example, the time could be discretized hourly and expected waste calculated as

$$\sum_{h=1}^{24} I(h) \cdot \Pr\{h - .5 \leq \text{cancellation arrival time} \leq h + .5\}$$

with inventory at the start of hour h weighted by the probability that the cancellation arrives within half-an-hour of h . Hourly cancellation probabilities can be estimated from historical pharmacy data by calculating (over an extended time period) what percentage of orders were cancelled within each 1-hour period. **Figure 3** shows probability estimates based on 3 months of data from our hospital.

The next step is to extend the analysis to calculate average waste per average cancelled order. For that, one must know the inventory level at time h , averaged over all cancelled orders. This average inventory level, $\bar{I}(h)$, could be estimated using a weighted sum:

$$\bar{I}(h) = \sum_z z \cdot \left\{ \begin{array}{l} \% \text{ of orders that at time } h \\ \text{have inventory level } z \end{array} \right\}.$$

However, although it is clear how cancellation time probabilities can be estimated from existing data, the calculation of the distribution of order inventory levels for each hour h is a formidable challenge. The analytical inventory model described next was developed to address the unavailability of such data in our PIS.

For any actual order, inventory levels over time jump in discrete steps as doses are prepared or administered. However, when considering the average over all orders, it is possible to think of average inventory as a continuous quantity, measured in hours of supply. Thus, as medications are administered, the average order inventory in the nursing units declines at a constant rate – 1 hour of supply for each hour of time that passes. During the batch preparation time, the average inventory level also changes continuously and constantly, increasing from zero at the start, and grows linearly until the entire needed amount is prepared (**Figure 4**).

In addition to inventory in the nursing units and inventory in batch preparation, there are 2 other regions in **Figure 4**. Inventory being delivered models average level of inventory of orders being delivered from the pharmacy to the nursing units. Virtual

Figure 3. Distribution of time of order cancellations.

Figure 4. Model of average order inventory level during the life cycle of a batch.

Figure 5. Application of the continuous inventory level model to a 24-hour batch.

inventory is the difference between dose preparation that has already been committed to and what has actually been prepared. This models the difficulty

with processing cancellations during batch preparation. The inability to stop the production of a dose that has been cancelled but has yet to be prepared

Figure 6. 24-hour inventory for a single daily batch prepared starting at 06:00.

effectively means that, from the moment production starts, the pharmacy commits to making the entire amount that was requested at the time the batch started.

Figure 5 illustrates an application of the model by analyzing a single 24-hour batch. On the y-axis, the maximum level of inventory is 24 hours of supply. Whereas the medication is administered over 24 hours, inventory levels are considered over 34 hours (x-axis) to include the preparation and delivery time. A graph of cancellation probabilities is superimposed on inventory levels. Because the model assumes the same daily distribution of cancellations, the probabilities of cancellations for hours 06:00 through 16:00 of day 2 are the same as they are for day 1.

When several batches are produced in a day, the expected waste is calculated by adding the expected waste from each batch. Even though the waste calculation can certainly be done without trying to visualize the interaction between inventory levels and cancellation probabilities, visualization affords additional insights. **Figure 6** shows batch inventory

for the original configuration using a 24-hour plot. Looking at the batch schedule this way makes it clear that, with the original configuration, the level of total inventory is high when the probability of cancellation is high as well. This observation led the operations management professionals on the team to examine how the level of expected waste is affected by the start time of batch preparation. Using the model, they found that, if the hospital were to continue with a single-daily batch, then waste would be minimized if batch preparation started at 20:00 (see **Figure 7**) rather than at 06:00.

The expected waste was calculated for a number of different batch production schedules. **Figure 8** shows the values for 3 schedules of particular interest. The single-batch schedule on the left is the original schedule; it leads, on average, to 24.8 hours of supply per cancelled order. This serves as the reference level for calculating the waste reduction benefit of different process changes. For example, eliminating virtual inventory saves 4.6 hours of supply in waste or approximately 18%. Moving the start of batch

Figure 7. 24-hour inventory for a single daily batch prepared starting at 20:00.

Figure 8. Expected compounded sterile products waste for an average cancelled order measured in hours of supply.

preparation to 20:00 reduces expected daily waste per order to 20 hours of supply, equivalent to about a 20% waste reduction. Waste reduction estimates in Figure 2 are calculated from the values listed in Figure 8. It is also worth noting that there can be additional reductions in waste if the CSPs are prepared in several small batches. However, there are diminishing returns to additional batches and the additional benefit of careful optimization of batch start times becomes ever less.²⁷

Because different interventions act on different sources of waste, the amounts of waste in Figure 8 are separated by the type of inventory. An improved IT system that allows easy removal of cancelled orders from the work queue can eliminate only the portion of waste that is due to virtual inventory. More sophisticated sequencing of batch preparation can affect only the waste associated with the inventory in preparation. Using a relatively simple analytical model, it was possible to estimate the impact of schedule changes and improved handling of cancelled orders. To estimate the impact of more sophisticated IT functionality, it was necessary to turn to a Monte Carlo simulation, as described in the next section.

USING MONTE CARLO SIMULATION TO ESTIMATE THE IMPACT OF CHANGING THE SEQUENCE OF MEDICATION PREPARATION

Intuitively it makes sense to delay the preparation of orders that are more expensive and/or more likely to get cancelled. Presumably, such functionality could easily be programmed into an IT system, and work queues could be sequenced by the product of *CSP cost* and *probability of cancellation*. The probability of cancellation can be estimated from past data, for example, using order age as the predictive variable.

Paradoxically, although the implementation of the functionality would be relatively simple, the estimation of savings is quite complex. An accurate estimate requires not only the probability distribution of cancellation times and a function to estimate the probability of cancellation based on age of the order, but also the probability distribution of order costs, the probability distribution of ages of orders, an estimate of correlation between costs and durations, etc.

To get an idea of possible savings, the operations management team used Microsoft Excel 2010 (the spreadsheet file is available from the corresponding author on request) to create a simple Monte Carlo

simulation. The simulation is initialized with the following input variables:

- The distribution of cancellation arrival times, as shown in Figure 3
- Upper ($kmax$) and lower ($kmin$) limits on the cost of raw materials needed in preparing a CSP dose
- Upper ($pmax$) and lower ($pmin$) limits on an order's probability of cancellation on a given day
- Number of orders in a batch, N
- Batch preparation start time, T_0
- Duration of batch preparation, ΔT
- Number of simulation trials

Each trial simulates the preparation of N doses. Each dose has the following attributes:

- Unique index $j \in \{1, 2, \dots, N\}$
- Random cost of ingredients, k_j , drawn from a uniform distribution on $[kmin, kmax]$
- Probability of dose being cancelled, p_j , drawn from a uniform distribution on $[pmin, pmax]$
- Random variable $s_j \in \{0, 1\}$ signifying whether the dose was cancelled; this variable is drawn from a Bernoulli distribution with success probability p_j
- Random arrival time of the cancellation order, t_j ; the hour of arrival of the cancellation is drawn from the distribution shown in Figure 3, time within the hour is distributed uniformly
- Flag $b_j \in \{0, 1\}$ indicating whether cancellation arrived during batch preparation time, ie, if $T_0 \leq t_j < T_0 + \Delta T$ then b_j is set to 1, otherwise it is set to 0
- Rank $r_j^2 \in \{1, 2, \dots, N\}$, ranking the dose relative to the other doses in the order of increasing cost k_j
- Rank $r_j^3 \in \{1, 2, \dots, N\}$, ranking the dose relative to the other doses in the order of probability of cancellation p_j
- Rank $r_j^4 \in \{1, 2, \dots, N\}$, ranking the dose relative to the other doses in the order of increasing index $p_j \cdot k_j$

The transformation $\tau(r) = T_0 + (\Delta T / N) \cdot (r - 1)$ converts a ranking r into the time the dose of this rank is scheduled to be produced. In a simulation trial, a dose j , scheduled to be produced at $\tau(r_j)$, is considered wasted during batch preparation when all 3 of the following conditions hold: (1) it is cancelled during the day, ie, $s_j = 1$, (2) the cancellation arrives during batch preparation time, ie, $b_j = 1$, and (3) the cancellation arrives after the production of the dose started, $t_j \geq \tau(r_j)$. So in each simulation trial, the number of doses wasted is calculated as

Table 1. Output statistics for Monte Carlo simulation of batch preparation waste

	Doses		Mean standard error	Dollars		
	Mean	SD		Mean	SD	Mean standard error
Waste with random ordering	37.50	5.90	0.13	373.87	61.84	1.38
Waste <i>reduction</i> relative to random ordering						
Ordering by cost	0.05	4.29	0.10	61.42	48.08	1.08
Ordering by probability of cancellation	4.09	4.43	0.10	40.32	47.08	1.05
Ordering by cost • probability of cancellation	2.14	4.35	0.10	74.77	48.56	1.09

$\sum_{i=1}^N b_i \cdot s_i \cdot \text{If}(t_i \geq t(r_i), 1, 0)$, and the cost of waste as

$$\sum_{i=1}^N k_i \cdot b_i \cdot s_i \cdot \text{If}(t_i \geq \tau(r_i), 1, 0).$$

The simulation was run with 2,000 trials with daily probabilities of cancellation uniformly distributed between 15% and 35%, and material costs uniformly distributed between \$4 and \$16. **Table 1** lists the statistics for a batch preparation scheduled between 06:00 and 14:00. Producing CSP doses in order of increasing cost does not reduce the amount of waste in terms of the number of doses, but it does decrease the cost of the waste by 16%. Sorting production by the probability of cancellation reduces both the number of doses wasted and thus the corresponding cost by 11%. Using as the index the product of cost and probability of cancellation reduces waste in doses by 6% and reduces costs by 20%. These results are incorporated in the summary shown in **Figure 2**.

DISCUSSION AND CONCLUSION

Recent articles describe efforts by in-hospital pharmacies to improve operations and to reduce CSP and other types of waste.^{8-10,28} Some institutions have attempted to reduce CSP waste by increasing the number of daily production batches. Reports of such initiatives have prompted other pharmacy managers to ask what is the optimal number of batches for their institutions,²⁹ as the answer has not been readily available. It turns out that there is no single opti-

mal solution – even for hospitals of the same size and case mix. The decision about the number of batches must trade off the reduction in CSP waste against the increase in employee hours needed for batch preparation and delivery. At least one pharmacy used a trial-and-error approach to find that waste reduction resulting from going to 6 batches per day was more than offset by the additional labor required.⁸ Often the long-term objective of lean process improvement is to eliminate all waste. In the short run, such an objective is rarely achievable. The models discussed here can easily estimate how much CSP waste can be realistically eliminated through straightforward process adjustments.

Most changes in pharmacy operations are evaluated empirically — with laborious data collection needed both pre and post implementation to assess their impact. Clearly this limits the number of process changes that can be considered. Also, a reliance on the collection and counting of physical waste to measure improvements cannot provide insights in advance of the implementation of an intervention. In introducing mathematical operations modeling to pharmacy managers, Dean et al²² wrote, “Mathematical modeling offers pharmacists a low-risk, low-cost tool for aiding decisions about pharmacy systems by predicting alternative futures.”^(p2491) Working in an in-hospital pharmacy, we demonstrated the usefulness of analytical mathematical modeling for managerial decision making in this health care setting.

There are certainly some important limitations in our model. For example, the model assumes that without a virtual queue system enabled by IT, all

orders cancelled during the batch preparation time are still produced. The model also assumed that the waste consists of all prepared doses scheduled to be administered after the order has been cancelled. The actual waste will be less than predicted if the hospital is able to reuse some discontinued doses for other patients or to stop the production of some of the cancelled orders. The model does not take into account the effect of batch schedule on the production of “first” doses or on the number of “missing” doses. While recognizing some limitations of a model, it is important to keep in mind the words of the renowned statistician George E. P. Box, “essentially, all models are wrong, but some are useful.”^{30(p424)}

We believe the insight and methodology used in this study could benefit many in-hospital pharmacies. Intelligent scheduling of the daily batch is likely to be most beneficial, because hourly cancellation probability is likely to vary significantly throughout the day, influenced as it is by the scheduling of providers’ rounds. Computing cancellation probabilities (as in Figure 3) should be straightforward for pharmacy IT specialists, because most hospital PIS record timestamps for order cancellations. Using such data from our hospital, we calculated that shifting batch preparation to later in the day could save over \$70,000 annually. If the same savings were achievable in the 1,100 other US teaching hospitals, nationwide annual savings could be close to \$80 million.

The analysis of Big Data (ie, petabytes of data) to gain new insights has garnered considerable attention recently. This study experience highlights opportunities to apply insights from much smaller operational data sets. Along with appropriate models, these represent the “low-hanging fruit” of data analytics. The use of these sorts of techniques can also help in the estimation of the potential savings, thus helping hospitals focus on the most promising areas and set realistic objectives.

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