Financial considerations when deciding on an IV dosage form

Part 2 of a multi-article series as we explore how premixed IV products can positively impact your pharmacy operation.

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Introduction

Pharmacy and healthcare leaders are charged with maintaining a progressive and contemporary medication formulary for their institution to meet the needs of their diverse patient population. For intravenous (IV) products approved and available on formulary, the decision to use a specific dosage form must also be decided. Table 1 outlines various dosage forms that are available for IV medications, including ready-to-administer (RTA), various ready-to-use (RTU) products and compounded sterile products (CSPs). In our previous article, "Efficiencies gained by using manufactured premixes," we explored variables that impact operational efficiency when deciding on an IV dosage form. In this article, we will discuss financial implications that must also be considered when deciding on an IV dosage form for your institution.

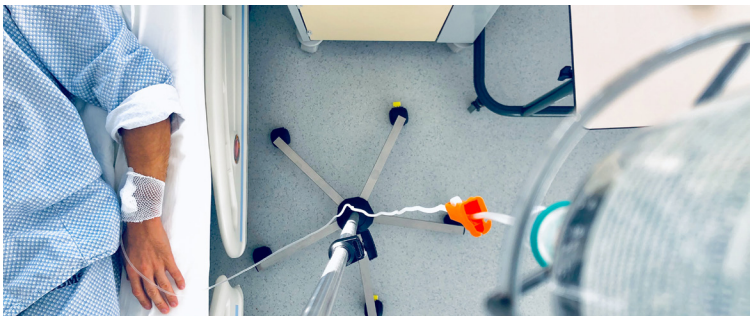


Table 1.

Dose Type	Meaning	Description
RTA	ready-to-administer	Premixed from manufacturer and can be administered without any further manipulation
RTU	ready-to-use	Premixed product requires activation prior to use or Premixed product requires thawing or some type of storage manipulation prior to use or Product requires both assembly and activation prior to use
CSP	compounded sterile product	Sterile product that is prepared using component ingredients by a qualified individual or device in a sterile environment Preparation options include: – Robotic preparation – Human preparation with assistive technology – Human preparation without assistive technology

Acquisition cost

The cost to purchase an IV medication from a distributor or directly from the manufacturer is an important part of the overall selection process for a specific product. Unfortunately, acquisition cost is often the only consideration given significant weight in the decision-making process. Undoubtedly an important part of the equation, however, acquisition cost alone should not drive the decision without taking a holistic approach of all the variables that are impacted by an IV dosage form decision.

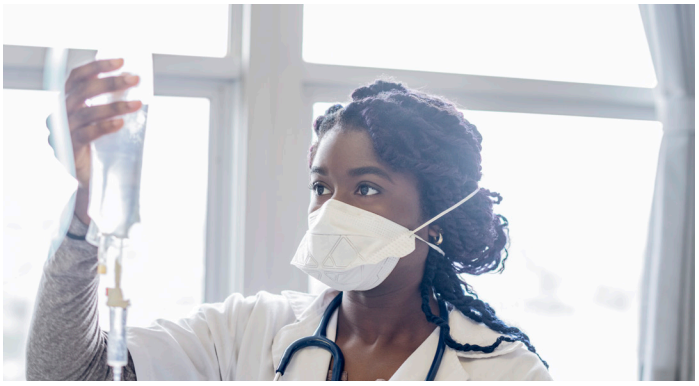
When comparing acquisition cost between products, it is important to ensure the comparison is on a level playing field. Important factors to incorporate into the comparison are wholesaler cost-minus discounts and 340B pricing (if applicable). Lastly, consideration should be given to evaluate a product's price over time. This strategy can mitigate price volatility due to shortages or other reasons.

Due to the black-and-white nature of this financial exercise, it is quite easy to stop after this acquisition cost analysis is completed. However, I would implore you to perform additional due diligence in the decision-making process to ensure that a comprehensive, robust process is utilized to identify the best choice for your overall business needs.

Ancillary Supplies

When preparing CSPs by any method, ancillary supplies such as IV bags, diluents, syringes, needles, alcohol swabs, port covers, caps, etc., will be needed. While generally inexpensive as compared to the pharmaceuticals being evaluated, it is important to include the costs of these supplies in your financial comparison.

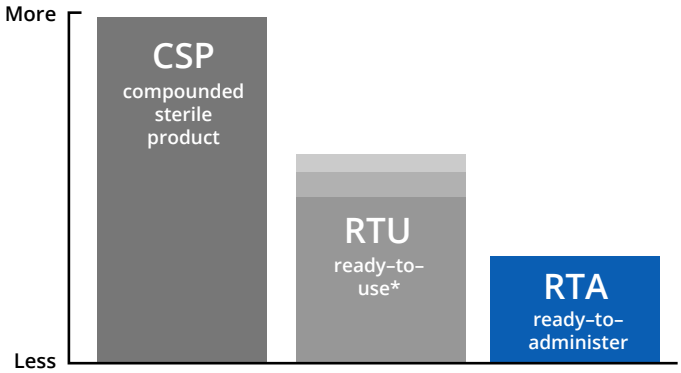
Preparing CSPs according to USP standards requires personnel to wear personal protective equipment (PPE), such as gowns, head and shoe covers, gloves, etc. While PPE is part of the necessary infrastructure to support routine compounding activities, making a large shift of products from CSP to RTA (and/or to RTU) may reduce overall PPE utilization and should be considered in the financial analysis.



Labor

Previously, we reviewed the impact of IV dosage type on labor for both pharmacy personnel and end-users, who are usually nurses. The labor impact trend can be represented by the following: RTA < RTU < CSP, with RTAs requiring the least labor and CSPs requiring the most labor.

Relative Amount of Labor Required



*Labor needed varies based on the specific type of RTU being used.

When performing a comprehensive financial analysis on IV dosage form selection, the associated labor impact should be considered. This is typically accomplished by performing a small time-motion study to determine the labor impact by job type or, alternatively, by using industry standard values, then incorporating this data into the decision matrix. Studies in the literature indicate the compounding time is between 5.6 to 9.1 minutes per preparation[1, 2, 3], which can be used as a representative value.

Financial pundits may argue that if you are not cutting full time equivalents (FTEs)/labor, then labor costs should not be part of the financial analysis since they are considered soft and not hard savings. An argument against that way of thinking is that your labor is a finite resource with a fixed capacity. By using an IV dosage form with less labor requirements, you are freeing up resources to perform additional functions, which may include insourcing 503B products or performing other critical functions.

Additional pharmacy technician resources may be required to manage product dating in central pharmacy storage locations, but especially for decentralized inventory located in automated dispensing cabinets (ADCs). Products with shorter dating, such as CSPs and certain RTUs with beyond-use dates, will require more time and resources to manage as compared to products with a manufacturer's expiration date (e.g., RTAs).

Safety

The Institute for Safe Medication Practices (ISMP) is well known and respected for their viewpoints and recommendation on medication safety. In their Guidelines for Safe Preparation of Compounded Sterile Preparations, ISMP recommends[4]:

To the maximum extent possible, COMMERCIALLY-PREPARED, premixed parenteral products and unit dose syringes are used versus compounded sterile products.

The American Society for Health-System Pharmacists (ASHP) also recommends to use premixed IV solutions in their guidance document entitled ASHP Guidelines on Preventing Medication Errors in Hospitals.[5]

The Joint Commission commonly recommends to standardize IV product concentrations and also to use premixed solutions to prevent errors.[6]

The Centers for Medicare and Medicaid Services (CMS) recommend that "whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer…".[7]

The guidance from our medication experts and regulatory agencies is clear. They recommend the use of RTA products over RTUs requiring assembly/activation and CSPs.

Data has shown that nearly 1 in 10 CSPs is not prepared within established guidelines.[8] Also, there is a lack of visibility with CSP errors as adverse drug events (ADEs) from compounding are increasing and under-reported.[9]

Given these facts as well as the strong ISMP, ASHP, JC and CMS recommendations, we must determine how to take this information into account as part of our financial analysis. Similar to the labor discussion, financial officers will indicate that any improvement in medication and patient safety will be soft savings, not a hard return on investment. However, given that safety and quality are almost always embedded into a health system's mission, vision and values, in addition to strategic themes, there is a strong argument that they should be considered in the evaluation process.

Assigning an occurrence frequency and dollar value to medication errors is not a straightforward task. Both IV medication error rates and specific dollar values associated with IV medication errors are not consistent in the literature. Rosselli et al[10] take a conservative approach and assign a value of $28 for a mild error, $1737 for a moderate error and a value of $1995 for a severe error, with respective frequency rates of 6.3%, 1.4% and 0.6%. These values are estimated from an expert panel with full acknowledgement that these costs are much lower than those reported in the literature. You can use these values as an initial starting point for the cost of poor quality and further refine percentages and quantitative values based on your individualized research.

Waste

Most hospital pharmacy operations do not prospectively monitor and evaluate IV product waste. Studies have shown that IV waste may represent up to 2.5% of a facility's total IV medication budget.[11,12] There are many variables that impact waste, such as pharmacy department hours of operation and whether IV products are batched as non-patient specific or prepared patient specific. IV dosage types that use a manufacturer's expiration date, such as RTA products that will have a longer shelf life than products with a beyond-use date (BUD), therefore, these products will have inherently less waste due to expiration. It is a common strategy to transition CSP dose types with a short BUD to an RTA product to minimize waste.[13]

Some RTAs and premixed RTUs can be returned to the manufacturer for full or partial credit once their expiration dates have been exceeded. Additional details regarding this process and the amount of credit available can be obtained from your reverse distribution vendor. Alternatively, CSPs and any RTU products requiring manipulation or assembly cannot be returned for partial credit.

Having specific data on IV product waste for your institution will be a valuable piece of the equation when deciding on a dose form for your facility. The general trend in waste based on expiration dating or BUD from the author's experience is: RTA < RTU < CSP, with RTA products having the least waste and CSPs having the highest amount of waste.

Storage Infrastructure

Excluding room temperature storage conditions, storage under frozen or refrigerated conditions may require additional infrastructure to support an IV dosage form. Commercial-grade storage devices are generally recommended due to minimal temperature variation as compared to non-commercial units. In addition, a near-real-time temperature monitor system should be leveraged to provide an alert for temperature excursions. Lastly, electrical supply redundancy should be considered as an additional safety net.

Generally, storage infrastructure is considered a one-time cost and expansion may not be needed when making a decision for a small number of IV dosage forms. Infrastracture decisions become more impactful when a large number of therapies are involved, such as the decision to utilize a full line of frozen RTU products.

Conclusion

Too often, pharmacy leaders look solely at acquisition cost when making important formulary dosage form decisions, without performing a holistic approach. The use of a comprehensive, multivariable modeling tool is recommended when making a decision on an IV dosage form for your institution. Financial variables such as acquisition cost, labor impact, ancillary supply cost, medication safety impact, waste and storage infrastructure must all be part of the equation (See example of Financial Decision Matrix displayed in Table 2). In addition, factors that impact operational efficiency such as medication distribution model, inventory control and dosage form standardization should be part of the financial decision-making process as well.

See our previous article "Efficiencies gained by using manufactured premixes." It is critical that pharmacy leaders take into account all of these variables, not just acquisition cost, when making important decisions on IV dosage form selection. These decisions have potential to make a sweeping impact on your operation.

Table 2.

Financial Variables*	Dosage Form A (compounded products)	Dosage Form B (RTA Products)
Acquisition Cost		
Labor Impact[a]		
Ancillary Supply Cost		
Medication Safety[b]		
Waste[c]		
Storage Infrastructure[d]		
Total Cost		

Data for each variable should be annualized

a. Impact of pharmacy technician and pharmacist labor. Can also include impact of end-user labor (e.g., nurse) if significant. *Example:* [(average hourly rate x time for one dose in hours) x (number of doses in one year)]

b. Utilize an occurrence frequency and a cost associated with adverse drug events. *Example:* [(frequency percentage x number of doses in one year) x (ADR cost)]

c. Identify a waste percentage for each dosage type. *Example:* [(waste percentage x number of doses in one year) x (acquisition cost)]

d. Cost of any additional commercial grade refrigerators or freezers and/or cost of a temperature monitoring system and/or cost of electrical system redundancy

*The equations for estimating costs were developed by the author.

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