Outsourcing unit dose packaging

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The need for reliable machine-readable unit dose packaging in health systems continues to expand as hospitals adopt bar-code-dependent technology in the pharmacy and at the bedside. In fact, nearly 40% of hospitals with 200 or more staffed beds have implemented bar-code-assisted medication administration (BCMA).[1] With most BCMA systems, it is often possible to utilize the bar-coded unit dose packaging provided directly from the manufacturer. However, there are many products and patient situations that require facilities to either package or repackage a medication to ensure BCMA system compatibility.

There are several possible solutions to this dilemma. It is often desirable to preferentially purchase from pharmaceutical manufacturers that provide compatible machine-readable bar codes in order to minimize the number of line items that must be repackaged. For the items that do require repackaging, facilities may choose to implement a set of processes onsite that provide an acceptable bar code. To achieve economies of scale, some multihospital health systems have developed centralized repackaging centers that distribute bar-coded unit dose packages to member facilities via a hub-and-spoke model. Another option is to outsource all or part of the bar-coding function to a third-party repackager.

In this issue of the *Journal*, Meller and colleagues[2] provide a commentary on some of the issues surrounding facility-based packaging and contrast that to the advantages of third-party vendors that provide packaging services. The authors describe a variety of third-party arrangements, cite results of a survey of 91 hospital pharmacy directors, and ultimately recommend utilizing such a service in lieu of onsite packaging.[3] The article also appropriately emphasizes the need for due diligence when selecting a repackaging vendor.

The commentary also raises some anecdotal concerns that are not evidence based. For example, it is suggested that hospital-based repackaging services are inefficient and costly and may not contain appropriate safeguards. Error rates in pharmacy-based repackaging services have been reported to be as high as 1.2% of the total doses packaged (with nearly half of the errors related to incorrect lot number), yet this same study found that the pharmacy's quality-assurance program was "necessary and effective at detecting [these] errors" before dispensing.[4] Other safe and effective hospital-based packaging programs have been previously described.[5,6]

It is further postulated that by virtue of increased regulatory requirements and adherence to good manufacturing practices, third-party repackagers provide an added safety benefit[2]; however, there are no published data to support these claims. Despite significant quality-control requirements, third-party repackagers—and even manufacturers of brand-name pharmaceuticals—occasionally provide products that are subject to recall due to error.[7,8] If a hospital chooses to outsource bar-code packaging to a third-party vendor, product accuracy cannot be assumed, and appropriate double-checks are warranted when the medication is received. This includes a check of the medication's overall packaging and quality, as well as ensuring the compatibility of the bar code with the BCMA system.

Meller et al.[2] also suggest that hospital automation designated for repackaging services may not be cost-effective due to low utilization and machine reliability. While this may be true in some facilities, many pharmacies effectively use packaging automation on a regular basis in a safe and economical manner. As a case in point, investigators at Veterans Affairs hospitals recently described a quality-monitoring program that addresses automation,

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packaging, and quality control.[9,10] The acquisition of any pharmacy automation requires a careful and objective assessment (which includes a return-on-investment analysis) and ongoing optimization and process integration after the system is implemented. There are certainly pharmacy directors who are frustrated by the challenges associated with packaging automation. On the contrary, there are many who have invested the time and effort necessary to operate inhouse packaging technology at peak performance.

Nevertheless, Meller and colleagues[2] provide a thought-provoking analysis that calls for an appropriate amount of introspection related to bar-code packaging services. Competition among third-party repackagers has driven improved economics around per-dose pricing, and it is quite possible for these vendors to provide a convenient, safe, and cost-effective alternative to pharmacy-based repackaging services.

The decision to outsource the production of any pharmacy-dispensed product requires cautious consideration and analysis. Variables such as hospital size, preparation complexity, available resources, delivery logistics, cost, product demand, patient safety benefits, and quality control must be evaluated. If the decision is made to use an external vendor, appropriate due diligence and negotiation of acceptable contract terms and conditions are essential. Ultimately, it is the pharmacist's responsibility to ensure safe and effective drug distribution processes, while thoughtfully and objectively contemplating how the medication is acquired.

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