Third-party repackaging in hospital pharmacy unit dose acquisition

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Medication errors can occur during every step of the medication-use process, but they occur most frequently during the prescribing and administration stages.[1] In fact, "when all types of errors are taken into account, a hospital patient can expect on average to be subjected to more than one medication error each day."[1] One way to prevent some types of medication errors is to administer medications in unit dose packages, as this ensures that the medication name, dosage, and other characteristics are available to the administering professional until the time of medication administration. As a result, administering medications in unit dose packaging is not only considered a best practice but is near universal in its application, with millions of unit dose medications dispensed in hospitals and health systems daily.[2]

Bar-code technology represents a promising solution to some medication dispensing errors. Bar-code technology saves time, improves accuracy, reduces errors, and is capable of identifying a rare event, something at which human beings are not proficient.[3] A study of medication dispensing errors that occurred before and after implementing bar-code technology revealed that bar-code technology in the pharmacy compares favorably with other patient safety interventions.[4] Given the high volume of medications dispensed in a hospital, even small reductions in errors will result in significant improvements in patient safety.

Unfortunately, not all hospitals have implemented this technology. One of the barriers is the substantial cost of adopting bar-code technology. A study conducted to evaluate the cost–benefit ratio of such an investment found that bar-code technology pays for itself within 5–10 years, primarily by decreasing adverse drug events.[5]

In order to further improve patient safety, some hospitals are implementing bar-code-enabled point-of-care (BPOC) systems.[6] In such a system, medications are administered in bar-coded unit dose packages, and patients must wear a bar-coded wristband. When a nurse administers the patient's medications, he or she must first scan the bar code on the medication and then the patient's wristband. These systems help ensure that the right medication reaches the right patient at the right time.[6]

In contrast to unit dose packaging, BPOC systems are not universally adopted, with approximately 25% of hospitals in 2008 using such a system.[7] The primary roadblocks cited to the implementation of BPOC systems are the information systems and infrastructure on the patient floors needed to read the bar codes on medications and wristbands. The roadblock that is not cited, however, is related to nurse "buy in," or the lack thereof, due to insufficiently designed systems. These systems can make nurses' jobs more difficult and time-consuming. With these roadblocks acknowledged and eventually addressed, we believe that the implementation of BPOC systems will increase. Only 15% of hospitals surveyed in 2008 had no plans to implement a BPOC system.[7] Thus,

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this commentary focuses on securing medications in unit dose packaging as a means to reduce medication errors.

According to a recent survey, 85% of hospital pharmacy directors preferred to acquire all pharmaceuticals in unit dose forms packaged by the manufacturer. This sentiment was supported by a ruling from the Food and Drug Administration (FDA) that became effective on April 26, 2004, requiring all drug and biological products acquired by hospitals to incorporate bar codes on their labels.[6] Drug manufacturers must place a bar code on the "immediate container" of the product, which is generally the smallest unit of packaging. Therefore, if drug manufacturers supply unit dose medications, each unit dose must have a bar code. The bar code must contain the medication's 10-digit National Drug Code number, which uniquely identifies each medication by drug name, drug strength, and manufacturer. The aim of this ruling was to make unit dose systems more widely adopted, but it did not require that manufacturers set the smallest unit of packaging as the unit dose level. Before FDA's ruling, only about one third of all medications were available from the manufacturer in bar-coded unit dose packages.[6] Currently, most hospitals are able to purchase at least 40% of their medications in unit dose packages directly from the manufacturer.[8]

Given hospital pharmacy directors' increasing demand for bar-coded unit dose medications, some repackaging will be required. This article reviews and compares the repackaging options available and provides a systems analysis of hospital pharmacy unit dose acquisition.

Multiple site visits and interviews with pharmacy directors and third-party repackagers provided in-depth background on hospital pharmacies' strategic, tactical, and operational methods. To ensure a thorough study and that all perspectives were considered, we visited and discussed operations at pharmacies that spanned the range of satisfaction with respect to their internal repackaging system. We conducted a survey in 2008 of hospital pharmacy directors to determine how and to what extent hospitals used unit dose medications to support BPOC practices.[8] The survey consisted of 22 questions and was administered online. In total, 91 valid survey responses were received from hospital pharmacy directors in 38 states. After collecting multiple types of responses, we utilized our expertise in systems engineering to arrive at our final recommendation. However, we acknowledge that no universal agreement will be reached due to specific pharmacy situations and circumstances.

Repackaging options. When medications are not available in bar-coded unit dose packages, hospital pharmacy directors have two main options: (1) repackage the medication themselves and (2) work with an external agent other than the manufacturer to acquire the medication in unit dose form.

Internal repackaging. Repackaging medications within the pharmacy has the advantages of flexibility, a low cost per unit of labor and supply, and a great deal of control over production. The disadvantages are that this option typically involves investment in equipment for repackaging (which is space consuming) and packaging in a one-size-fits-all model (resulting in larger packaging), as well as knowing that the process will be conducted by employees not likely to have been trained in industrial pharmacy practices.

The three basic repackaging process technology choices within the pharmacy include manual, semiautomated, and automated. A manual process typically uses a tray with bubble packs that are manually filled and then labeled and sealed. Manual labor is used for the repackaging and relabeling process. The equipment required tends to be inexpensive (generally hundreds of dollars). With a semiautomated process, a device for repackaging and relabeling is automatically controlled, but the induction of medications is performed manually. Semiautomated equipment costs more. Finally, with an automated process, the induction of medications, repackaging, and relabeling are all automated. The equipment consists of a set of canisters that are filled manually. Each canister holds one medication and is specific to the physical characteristics of that brand of medication. The equipment in such a system can be expensive. Our survey found that 88% of respondents used these systems four or fewer hours per day.[8] Therefore, the high infrastructure cost is often hard to justify given such low utilization, especially given the costs incurred when the machine breaks or is not working correctly. Many pharmacy directors have had issues with automated repackager unreliability, as well as the maintenance and upkeep of the technology because the number of technician hours required to support the repackaging was equal to or greater than the number of machine hours.[8] The three processes follow the typical cost–benefit tradeoff of a higher investment in capital for a decreased level of labor.

From our multiple site visits and pharmacy director interviews, we found that repackaging in hospitals is characterized by a system that is either labor intensive (for the manual or semiautomated options) and uses more employees than the full-time-equivalent count would indicate (due to the high activity levels needed for short periods of time each day) or less labor intensive but requires a significant investment in technology with low utilization (no more than four hours per day). More importantly, the internal repackaging process is typically not executed as an industrial process, which leads to the need for multiple checks of the work conducted. From a systems-design perspective, quality cannot be inspected into a

process; that is, the process itself must be designed to ensure quality, since manual inspection itself is not fail-safe. This is not an ideal situation.

External repackaging. Working with an external agent other than the manufacturer to acquire medications in unit dose form has the advantages of freeing clinically trained pharmacists and pharmacy technicians to work on clinical issues, knowing that the repackaging operations will be performed by staff trained in industrial pharmacy practices. Removing this operation from the pharmacy also frees up space in space-constrained pharmacy departments. The disadvantages of this option include increased coordination and possible delays, as well as less flexibility and control. The per-unit cost for this service is also a potential concern. In 2008, 13.4% of hospital pharmacies surveyed used an external repackager.[7]

The two basic partnering arrangements include a large wholesaler–distributor that buys medications in bulk and repackages them for sale and a third- party repackager that receives the hospital's medications and repackages them before sending them to the pharmacy. There is another arrangement of contracting with a third-party to conduct onsite packaging at the hospital, but this arrangement is not common, with only 2% of survey respondents currently using this practice.[8] The wholesaler–distributor arrangement most closely resembles purchasing directly from the manufacturer; however, hospital pharmacy directors noted concerns about the intermittent availability of medications, costs, and packaging characteristics of this arrangement. The third-party repackager arrangement is similar to the internal option in that the repackager is always working with "your medications."

Compared with the hospital pharmacy, the manufacturer may be less likely to mislabel or mispackage unit dose medications.[9] The quality of medications repackaged by a third-party repackager tends to fall in between the two groups.[10] This quality difference may be attributable to the fact that pharmaceutical manufacturers are subject to the stringent FDA Code of Federal Regulations (CFRs) and Current Good Manufacturing Practices (cGMPs).[9] Third-party repackagers are subject to a portion of the CFRs (e.g., packaging, labeling, cleaning, training), but the inspection process is less rigorous than that of the manufacturer.[9] Also, third-party repackagers are trained in industrial processes, which are not the core competencies of hospitals. In addition, repackaging in the hospital is regulated only by state regulatory agencies,[9] and requirements vary by state.

Whether a third-party repackager is used or the medications are repackaged inhouse, the medications are purchased from a wholesaler or distributor. In most cases, the medications are mailed directly to the repackager (as opposed to the hospital) with the third-party option. Thus, at no time does the third party own the inventory. In order to efficiently use a third-party repackager, a hospital's wholesaler or distributor must be able to provide "bill-to, ship-to" ordering.

Once the medications have arrived at the repackager, the repackaging operations at the third-party location differ from in-house repackaging in the following critical ways:

1. Dedicated production facilities with specialized production suites are used at a third-party repackager, which enhances quality by controlling for the risks of product mix-ups, cross-contamination, and staff interruptions or distractions.
2. The staff is dedicated to repackaging, which has implications relative to staff training, staff performance, and the monitoring of staff performance.
3. Due to the volume and multiple customers it serves, the third-party repackager typically uses technology-based solutions to retrieve information on incoming medications (versus manual keystroke entry), which can reduce errors.
4. Some third-party repackagers use sophisticated production software with several checks and validations (e.g., biometrics and drug databases for identification and handling information) that permits the repackager to associate a specific order with a machine and production worker at any time.
5. The automated repackaging technology discussed earlier is not used by third-party repackagers, because the third party keeps all inventory separate (i.e., one hospital's medications are handled separately from another's). Further, when a third-party repackager repackages a medication, it repackages the entire quantity and does not hold inventory of the medication in an "open, but not being processed" state.
6. The technology we observed at third-party repackaging facilities is not designed with a common chute; therefore, there is no cross-contamination issue like in the automated repackagers used at a hospital, because the unit at the third-party repackager is cleaned between each change of medication. One unit of this type (PentaPak) can vary the packaging size by medication, as flexible packaging size has advantages in stocking medical carts or automated dispensing cabinets.

In general, because the repackager is focused on repackaging at higher volumes, the equipment is used more frequently and requires replacement more often. As a result, the repackager will typically be a step or two ahead of hospitals and their staff in terms of the equipment and training available.

All repackagers use tabletop and manual units to repackage at least some oral solids, as is the case in most hospital pharmacies. The difference

that we saw in practice was that hospitals tended to completely wash the unit only between repackaging some medications, whereas the third-party repackagers washed the unit between all medication changes.

Once the medications are repackaged by a third party, they are delivered via a priority parcel delivery service, arriving the next morning after repackaging. The hospital then receives the medications through its normal receiving and induction process (i.e., with other medications that wholesalers or distributors ship in unit dose form).

Comparison of repackaging options. The two options for obtaining medications in unit dose form were compared in terms of the three highest-rated concerns of hospital pharmacy directors:turnaround time, cost, and quality.[8]

Turnaround time. It is typical for a hospital pharmacy to process a repackaged medication over two days. The bulk medications arrive on day 1, the medications can be repackaged on day 2, and the repackaged medications are available for orders on day 3. This schedule can be compressed to one day, when needed. For an external option, the bulk medications arrive at the repackager on day 1 and are repackaged that day, arriving at the hospital on day 2, and are made available for orders on day 3. This schedule can be compressed into two days, when needed. So, the difference in terms of timing is one day when the repackager promises same-day processing or up to two days when the repackager promises two-day processing. When weekends are considered, the internal option affords even more flexibility.

Cost. Another easy-to-quantify difference is the per-unit and additional shipping charges associated with the third-party repackaging options. Repackagers often offer tiered pricing based on a hospital's needs (e.g., dosage forms, volumes). For oral solids, the charge is $0.03–$0.12 per unit, with additional shipping charges of typically $9 per case (a case may contain 5000–7000 unit doses).[11] Thus, the total charge per dose may be about $0.06. This per-unit charge has to be balanced against the purchasing of technology, the labor involved in repackaging, and the additional staff needed to check the work. In addition, outsourcing unit dose packaging may eliminate the need for physical remodeling within the hospital and may result in a reduction in inventory.[12] This balance, from a strictly financial point of view, rarely favors the internal option when all aspects of the process are considered,[5,13] especially for very small pharmacies.

Quality. There are three main quality advantages the repackager can legitimately claim:

1. *The repackagers employ cGMPs.*[14] This can lead to small effects in the process (e.g., an employee is working on one repackaging lot at a time instead of multiple lots) to large ones (e.g., routine testing of equipment, not just when problems are identified).
2. *Additional quality-control checks are performed on the repackaged medication.* Repackagers keep one unit of each lot (referred to as a reserve or retention sample) and hold the unit in inventory for a year after the medication's expiration date for bioavailability and bioequivalence testing.[15] One repackager we interviewed conducted inproduction testing and sampling (e.g., verification of the 25th dose—the 25th dose has to pass an inspection before the process will continue). Also, third-party repackagers stay abreast of medication recalls and notices, passing this information on to the hospitals they service, providing another quality check in the system.
3. *Repackagers must be registered with FDA.* The registration process states that cGMPs have been established and that processes are in place to ensure compliance. FDA inspectors verify and validate the above by reading the standard operating principles and then observing the operations and record keeping. These visits are unannounced and typically occur over multiple days.

The third option: A hybrid model. A hybrid model occurs when a group of hospitals, typically part of the same network, pool their requirements so that they can take advantage of the volume and efficiencies of an external supplier while maintaining a tighter degree of control, as in the internal option. This strategy has been successfully used by Hospital Corporation of America hospitals in Tennessee[16] and Mercy Hospitals in the Arkansas, Oklahoma, Missouri, Kansas, and Texas areas.[17] Note that in this model, the central hospital repackager typically holds inventory of a core set of medications. In this situation, the automated repackagers used in a hospital pharmacy are viable options, with a typically higher rate of utilization.

Wholesaler–distributor-turned-repackager model. Some of the large medication wholesalers or distributors will supply some unit dose medications that they themselves have repackaged.[8] From the hospital's point of view, in theory, this is the next-best option other than buying direct from the manufacturer in unit dose packaging. However, hospital pharmacists with whom we discussed this scenario did not view this as the best option, since wholesalers and distributors charged too much for this service, the package size did not vary by medication (i.e., it tended to be too large), and, more importantly, medications were frequently unavailable.

State of the repackaging industry. The third-party repackaging industry is small and has not matured, with little market penetration.[8] The companies listed in Table 1 represent all known third-party repackagers with some repackaging capabilities and their respective websites.

If a *fully capable repackager* is defined as one that can repackage all dosage forms and will do so for medications purchased from any licensed provider, then there are only three to date: Safecor, Shamrock, and Unit Dose Solutions/Atlantic Biologicals. The observations of best practices noted above were based on visits and additional information from Safecor and Shamrock.

Nearly all hospitals would rather purchase all medications in unit dose form, as manufacturers are experts at this. When unit dose packages are not available, hospitals would rather repackage the medications themselves since they do not fully trust a third-party repackager. The largest challenge that the third-party repackaging industry faces is to raise that level of trust.

Moving forward: A better third-party repackaging industry. We recommend that due consideration should be given by hospital pharmacies to partnering with a third-party repackager. Because most hospitals are currently not partnering with a third-party repackager, we also present a set of concerns that must be satisfied before a hospital follows our recommendation. Finally, we present our thoughts on what hurdles need to be overcome before the third-party repackaging industry can achieve widespread market penetration.

Recommendation to partner with a third-party repackager. Most repackaging efforts performed in hospitals are labor-intensive, with approximately two thirds using manual or semiautomated systems.[8] Repackaging efforts are performed by pharmacy technicians, many of whom were never trained in industrial pharmacy practices. As a result, the process both is costly and requires a system with double-, triple-, and sometimes quadruple-checking of work.

Table 1.
Third-Party Repackagers[a]

Company	Website
American Health Packaging (Columbus, OH)	www.healthpack.com
Ameridose (Framingham, MA)	www.ameridose.com
Atlantic Biologicals[b] (Miami, FL)	www.atlanticbiologicals.com
Choice Rx, Inc. (Brentwood, TN)	www.choicerx.com
Murfreesboro Pharma Nursing Supply (Murfreesboro, TN)	www.unitdosesupply.com
PD-Rx Pharmaceuticals (Oklahoma City, OK)	www.pdrx.com
Redwood Unit Dose (San Francisco, CA)	www.redwoodunitdose.com
Safecor Health (formerly Regional Service Center) (Woburn, MA)	www.safecorhealth.com
Sandhills Packaging (Lexington, NE)	www.sandhillspackaging.com
Shamrock Medical Solutions Group (Lewis Center, OH)	www.medsolgroup.net
Unit Dose Solutions[b] (Morrisville, NC)	www.unitdoseinc.com

[a]As of April 2010.
[b]A strategic partnership exists between Atlantic Biologicals and Unit Dose Solutions.

One third of the hospital pharmacies that use an automated repackager do so because they believe or have been told that the automated repackager will improve patient safety.[8] However, all but one of the automated repackagers we have seen in practice or have heard about are considered failures. Many of the pharmacy directors we met with would "get rid of the repackager," if they deemed it possible, due to a wide variety of quality-related issues (e.g., no medication packaged, multiple medications packaged into one unit, crushed and broken medications, severe lack of technical support). Very similar sentiments were expressed in a recent report by Hess.[18]

In short, the point of unit dose administration is to increase patient safety by reducing medication-related errors. However, if the repackaging process produces medication packaging errors, these are very likely to be passed on to the patient.[3]

Evaluating a third-party repackager. Our interactions with hospital pharmacies have led us to the following criteria upon which to evaluate a third-party repackager:

1. The evaluation of the process should ensure quality throughout. In particular, beyond a third-party repackager utilizing cGMPs, there should be higher-quality processes in place that the hospital recognizes as processes that it is not utilizing.
2. Turnaround time is critical to the availability of medications. With the drop-shipment method, a hospital pharmacy orders from the wholesaler or distributor and then has it directly ship to the third-party repackager. This method allows the repackager to repackage on the same day that the medications are received. With expedited parcel delivery available in most locations, this translates into a one-day delay in most cases. This turnaround time appears to be acceptable as long as the repackager ensures that repackaging will occur within one day of receipt.[8]

3. The capability of the repackager to offer a variety of packaging solutions is critical, as most repackaged medications will ultimately be stored in multiple locations within a hospital (e.g., pharmacy shelves, carousel system, robotic system, medication cabinets on the floor). The most-sophisticated repackager that we visited was able to specify the size of the packaging to a greater degree than any inhospital operation that we visited. Also implicit in this criterion is the readability of the resulting one-dimensional or two-dimensional bar code applied by the repackager.
4. A full-scale move to a third-party repackager will require that the repackager is technically competent in many repackaging technologies and dosage forms. Not all third-party repackagers could handle all forms (e.g., oral solids, liquids in cups, syringes). However, some third-party repackagers can handle dosage forms that some hospitals cannot.
5. The cost of repackaging is another factor that should be considered. While numerous pharmacy directors shared the sentiment that the first three items listed above were more critical, the cost of third-party repackaging is also important. Although pharmacy directors would like the cost to be as low as possible, they understand that repackagers are performing a critical service, and a business model that allows the third-party repackagers to prosper is necessary. In addition, many third-party repackagers require contracts with minimum and maximum purchase requirements, "out clauses," and liability limitations.

In exchange for output that has fewer errors (based on a higher-quality system), hospital directors are willing to pay an upcharge that slightly exceeds their current operating costs as long as the repackaged product itself is of the same or better quality and the turnaround time is one or two days. In addition to the increased quality of the product, hospital pharmacy directors believe there will be increased job satisfaction and retention if pharmacists spend their time performing tasks they are trained to do, which correlates well with better patient care.[19,20]

If hospital pharmacy directors decide to partner with a third-party repackager, it is ultimately the responsibility of pharmacy directors to provide their patients with high-quality, contaminant-free products, even if these products are provided by an outsourced vendor.[19] Many of the same concerns that exist for outsourcing i.v. admixture products exist for outsourcing medication repackaging. Therefore, it behooves pharmacy directors to take the necessary steps to truly understand the quality of the services provided by these outsourcing vendors.[21] Before entering into any partnership with a drug repackager, the pharmacy director should ask each eligible vendor for the following information:

- Licensure and certifications,
- Description of repackaging processes,
- Description of quality-control processes,
- Samples of packaging and labeling,
- Bar-code capabilities, and
- List of customer references.

Once this information is obtained, the pharmacy director should conduct an onsite audit of any potential repackaging partners. The purpose of this visit is to receive a firsthand view of the facility, meet key leadership and management staff, conduct an onsite record review, and observe the processes in person. As part of the site audit visit, the pharmacy director should review the facility's standard operating procedures, staff training and competency assessment records, quality-control records and procedures, quality-assurance and quality-improvement documents, summaries of any actions by regulatory agencies, and any customer complaints and their resolution. The pharmacy director should also tour the facility to check for overall cleanliness and visit inventory areas (including drug preparation areas) and distribution and product quarantine areas, making sure that there are designated areas for each function. The director should also check building security, room-temperature monitoring, refrigerator- and freezer-temperature monitoring, and the security provided for controlled drugs. As part of the audit, the pharmacy director should ask to see all records for any particular product that has been repackaged recently.

Before finalizing the audit, the pharmacy director should ascertain what records will be provided to the hospital from the repackager and how frequently they will be provided. In addition, the director should reach an agreement with the repackager's leadership on how frequently onsite audits will occur. Both of these last steps are critical to help ensure that the hospital pharmacy will receive the highest-quality products from the third-party repackaging partner.

Hurdles for the third-party repackaging industry. Our survey of pharmacy directors provided some insight into their concerns with partnering with a third-party repackager.[8] In decreasing order of concern, cost, turnaround time or order fulfillment time, quality, product offerings, and insufficient bar-code capabilities were the top responses. With respect to acceptable turnaround time, 25% selected "1 day" as their preference, 34% selected "2 days," 39% selected "3–5 days," and 2% selected ">5 days." Additional feedback is available in the full survey report.

Interestingly, the primary consideration in choosing a third-party repackaging partner—product quality—was- not the top-rated response in our survey. This implies that product quality was not a top

concern for some pharmacy directors due to their current (positive) experience. However, because product quality is the primary consideration, the quality of the repackaging process will face significant evaluation. It is very difficult to imagine an outside organization caring as much, and having as much at stake, as the hospital pharmacy director; however, because third-party repackagers are competing for business, they do have an incentive to strive for quality.[10] In all cases, a significant amount of time and evaluation must be invested into the relationship. Although the third-party repackager is likely to be held liable in the case of a medication error, the hospital will likely not be viewed without fault. This step of the process will require site visits to the repackaging facility, which will likely involve interviewing multiple members of the repackager's staff. Pharmacy directors should expect continuous quality reports that detail any problems and the corrective actions taken.

To assist the repackagers in overcoming this hurdle, the pharmacy directors in our study group suggested meeting FDA requirements (as do manufacturers) or establishing an independent accreditation body that, in addition to specifying initial and ongoing requirements, would be directed to perform site visits to ensure compliance.

Summary. Currently, we found that fewer than 10% of hospital pharmacies are working with a third-party repackager.[8] The hospital pharmacies surveyed indicated that they would consider doing so if issues surrounding cost, turnaround time, and quality were addressed. This is a tremendous opportunity for the third-party repackaging industry, if it can overcome the hurdles outlined above. Our prediction is that with increased adoption of this practice, both quality and cost will improve, thus benefiting all participants of the health care system.

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