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Automating IV Dose Management

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The nature of a controlled environment pharmacy cleanroom is that it is a sterile space isolated from the rest of the activities of the pharmacy. By design, it is set apart, and combined with the fact that the activities taking place in cleanrooms are usually the most sensitive to exposure, this can be a challenging area to properly manage and supervise. Having a full-time pharmacist stationed inside a cleanroom is rarely a viable option, so there are times when the workload in the cleanroom can be a mystery, and without automated tracking tools, there is little recourse for strict monitoring of cleanroom activities. While these workflow issues can be difficult to negotiate, the lack of a standardized, automated process in an IV compounding cleanroom renders that controlled environment vulnerable to human error, thereby jeopardizing control over patient safety.

Fortunately, the last few years have seen an uptick in the number and type of IV workflow management tools and software that not only standardize and automate the process of IV preparation, but also introduce dynamic verification tools that allow a pharmacist located outside the cleanroom, and physically removed from that area, to accurately and precisely check all steps in the IV preparation process.

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Traditional IV Dose Management Shortfalls

At Indiana University Health, we instituted IV workflow management tools in November of 2010 at two sites—Riley Hospital for Children and Bloomington Hospital—serving a total of 772 licensed beds. Prior to adopting IV management tools, we employed the rather unsophisticated method for processing IV orders common in many hospitals. Labels were printed for individual IV doses or batches three or four times a day and a pharmacist would hand off the labels at the cleanroom pass-through window for a technician to sort by time. In the event of a stat order, a pharmacist would alert the cleanroom technician accordingly, otherwise technicians were vaguely instructed to prepare all other doses two to three hours before they were due; a situation that inherently challenged standardization. In addition, we have multiple pharmacists entering orders independent of each other, including stat orders, so the technician was usually the only one aware of the full workload at any given time and thus was relied upon to make priority decisions. Furthermore, we had no way of knowing when extra support was needed in the cleanroom. Recognizing these shortfalls, we set a goal of fostering a figuratively transparent view of the workflow to enable us to codify the compounding process and fortify our patient safety initiatives.

The lack of a clear and detailed patient safety mechanism in our previous process created the greatest concern. Like many other facilities, to verify that an IV dose was prepared correctly, the cleanroom technician placed the completed dose in a basket along with the empty vial and the syringe with the plunger pulled back to the volume supposedly injected into the bag. The basket was placed outside the cleanroom and a pharmacist would review the empty vial and the pulled back syringe, and then initial the dose as verified. Clearly the risk of human error in such a process is substantial, and we were not satisfied that this approach could consistently assure proper dose preparation.

Converting to Automated IV Workflow Processes

Patient injuries and fatalities due to IV mixing errors tend to make the news, and this only worsens a nightmare scenario for any pharmacy director. To exacerbate this risk by relying on a

system with clear verification deficiencies is certainly at odds with the mission of hospital pharmacy operations. When we began to discuss possible remedies for this process, we started by reviewing our other bar code scanning processes. We realized we were scanning all other medications multiple times before administration, but there were no scanning checks for the most critical, high-risk doses prepared in the IV cleanroom. Effectively, we had better safety measures in place for stool softeners than we did for chemotherapy doses. After first seeing some of the available IV workflow management tools at a conference, we decided to investigate them further.

Once we began to review IV dose management tools, it became clear such technology could provide the solution we needed to bridge the gap between our overall bar code scanning protocol and our IV dose preparation process. Though it required implementing new hardware and software, these additions were relatively minimal. Our existing PCs remained for order entry and dose verification, but we ultimately added three workstations, each with a label printer, scanner, and camera in the cleanroom. Once in place, the benefits of the system quickly became apparent. Under the current system, all doses to be prepared are shown in a queue on the workstation, and an ordered dose label is not printed until the technician is ready to prepare that specific dose and touches that item on the touchscreen. This real-time queue is also visible to the supervising pharmacist and based on that information, the pharmacist can make informed, supplementary staffing decisions. We did not set a benchmark for when extra staff are needed, rather the supervising pharmacist remains cognizant of the number and type of stat orders in the system and makes decisions accordingly. If the pharmacist sees that there are 12 stats, then we need to send additional staff into the cleanroom. Alternatively, if there are only three stat orders, but the orders are complex and will take longer to complete, that also is grounds for additional staff.

Create a Better Process

We have several racks of drugs in our cleanroom and many of the drugs sound alike and their packages look alike. In the past, it was easy for a technician to grab the wrong product when preparing an IV dose. Under the new system, the technician will collect all necessary ingredients indicated on the printed dose label, but in order to proceed, the bar code on each product must be scanned, and if a product is incorrect, the system will issue a hard stop. This ensures that the right ingredients are selected at the onset thereby reducing wasted doses. While waste reduction was not a primary driver in acquiring the system, it has proven to be a distinct advantage. Avoiding an improperly prepared chemotherapy or monoclonal antibody dose could mean a few thousand dollars in savings.

Bar code scanning also helps codify technique. Variances in compounding technique among staff is always an area of concern, and while all technicians receive standardized training, they usually work independently in the cleanroom and develop different habits and work patterns that tend to diverge from training. For example, previously, our technicians were taught to only mix one IV dose at a time, but there was always the temptation to start mixing multiple doses at once in an effort to save time. With no real restrictions in place to prevent this, it introduced yet another level of error risk. Now, our IV management system forces every technician to follow step-by-step, systematic instructions for every dose and the technician cannot begin another dose preparation until the previous one has been completed through the system.

Setting up the systematic steps is a facility-dependent operation and our vendor provided a process that was both canned and customized to our facility. The initial processes were fairly straightforward and applied to the bulk of our preparations. Most of the changes we made were done up front, including adding a few drugs to the formulary that have special mixing instructions, but the software does allow for other changes to be made for specific dose preparations whenever necessary.

Ensure Accountability for IV Preparations

We are currently processing approximately 350 doses through the system per day. Of these, 130 are compounded sterile preparations (CSPs), 210 are premixed doses, and six are chemotherapy doses. While our staffing model has not changed as a result of implementing IV dose management tools, we did add an extra technician and pharmacist for three weeks after go-live until everyone became comfortable with the process.

We have a designated pharmacist in charge of IV preparation during all shifts and that person is primarily responsible for monitoring IV workload and performing dose verifications. One staffing area that did benefit greatly from the new system is the night shift when we normally have only one pharmacist and two technicians working. Previously, the pharmacist would have to physically move to the IV room and verify each dose or batch of doses as they came out. For chemotherapy doses, the pharmacist would have to enter the anteroom to pre-check the dose causing further disruptions. Now, the night pharmacist can remotely verify doses based on the images captured during the preparation process by the cleanroom technician (see Figure 1). As with the rest of the program, our IV management software can be programed to force the technician to take a specific series of images for verification. For example, if the dose requires a diluent to be added to the drug to dissolve it, the system requires a scan of that diluent. Now, the standard image captures include the drug, the diluent, and the IV fluid. For the drug itself, the technician will take an extra image of the lot number and the expiration date.

Figure 1. Standard Dose Preparation Images

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Addressing Unavoidable Circumstances

As with all unique medication preparations, there will always be mitigating circumstances that affect whether those preparations are actually administered. It is not uncommon for doses to be returned to the pharmacy for any number of reasons. This is an area where computerized tracking of doses can provide another big advantage. Our IV management system is capable of supporting a returned-dose scanning protocol. In such a system, all returned doses would be scanned again and placed in an electronic queue according to the expiration date established when the dose was prepared. The system will issue a hard stop when scanned if the dose has surpassed its expiration. While we do not currently have an automatic scan-upon-return process in place, we are considering implementing one. At this point, we keep all returned doses in a bin and will scan the individual dose to determine viability if a new order comes in for the same preparation. Fortunately, some preparations have a fairly large window of use, such as 48 hours. See figure 2 for a list of our commonly reused doses.

Figure 2. Commonly Reused Doses

Vancomycin	Levetiracetam
Gentamicin	Insulin infusion
Ondansetron	Norepinephrine infusion

Currently, the only compounded products we do not run through the system are TPN doses because a special module is required, which we are planning to implement in the near future. Some facilities may decide to only run high-risk preparations through the management system, such as chemotherapy, and while we debated this early on, we ultimately decided that we wanted the same level of safety for premixed doses as we do for CSPs.

Negotiating Staff Push Back

Implementing a new system and new processes will invariably cause some discomfort and require time and proper management to become ingrained. While we did a good job of managing the physical aspects of implementation, we did a poor job of managing the changeover for our staff. This failure became evident just a few days into the go-live period when we had staff display significant resistance to the new system. This brings up an important point: Just because a new program or system is intended to ease staff workflow or improve quality does not mean it will be embraced instantly, so avoid short cuts when preparing for change.

To adjust for this resistance, we took a few steps back and assembled an optimization program during our second week of go-live, including an all-staff presentation that primarily talked about how to adjust to a major change. By then, we had also gathered some data on preventable errors that proved powerful. As a result, by weeks three and four, we saw a vast turnaround in attitude toward adoption of the new IV workflow management. What we initially failed to qualify was our staff's awareness of how many errors were being made under the old system since there was no way to account for them. Under the old system, because a verifying pharmacist might not see a single error on a shift, or even a month of shifts, it was easy to assume we were not making any errors. In reality, we were making at least as many errors before implementing the system as we were after, but it was with automated dose tracking that we had a way to quantify those errors

and use that knowledge to propel improvement initiatives. In retrospect, we should have spent considerably more time preparing staff for the change over.

Data and Reports

One of the greatest differences between preand post-implementation of IV workflow management tools is the breadth and depth of reporting. Pre-implementation, data reporting was very poor and we did not have hard data on how many doses were being made, how long they took to make, or how many errors were being prevented. To get an idea of how many doses we were preparing, I had to have a technician count the labels each day. Now, reporting capabilities are quite robust. The report that generates the greatest impact is on prevented errors, which is tracked weekly. This remains a dramatic report, because we know we are preventing an average of 27 errors per week and about two-thirds of those are prevented by the bar code scanning of dose ingredients. Among other information, the report lists who is making errors and what compounds are most problematic. As a result, we have gone back and changed the way we store certain premixed drugs to avoid confusion and have reinforced training for those individuals with higher error rates.

Another area of reporting involves user compliance, which consists of two primary points—how many times a user bypasses the system and how many doses are dispensed without the final bar code scan that logs the dose out of the system and indicates it has been completed. In the case of the former, if the scanner fails to recognize an NDC code on a particular ingredient, the user can bypass the system and have the pharmacist verify the compound in the traditional manner as opposed to bar code scan and photograph. The system records every instance of bypass including the user that was logged in at the time. Currently, there are only two approved reasons for bypassing the system—an NDC scan fails and the oversight pharmacist is not available to repair it, or non-formulary drugs are used. Both cases are infrequent, however.

The third main report addresses turn-around time. As the system logs a time stamp at each step in the preparation process, it is easy to determine how long it takes to prepare a dose and deliver it to the nursing unit. Since implementing the system, we have seen a slight increase in the time it takes to prepare a single dose, owed largely to the standardized steps including bar code scanning and image capture. However, overall turn around time has improved, and that is largely due to faster pharmacist verification. Under the old system, we had no automated way to alert the verifying pharmacist that a dose needed to be checked, so it might sit on the counter for 20 minutes before review. Now, there is both an audible and visual alert on the pharmacist's computer when doses are ready to be checked. There is also a central status board that lists the doses at their various stages, so anyone can check the status of the queue at any time (see Figure 3). These measures have resulted in a decrease of chemo turn around time from 60 minutes to 45, a decrease for CSPs from 15 to 14 minutes, and a decrease of premixed doses from 15 minutes to 12. Although the greatest single turn around decrease was for chemo, given the volume of CSPs and premix doses, a decrease of even a few minutes can add up quickly to significant time savings.

Looking Forward

Among the improvements we are looking to implement in the near future include the aforementioned TPN processing capability as well as the ability to process oral liquids through

the system. We draw up patient-specific doses for pediatric patients in oral syringes, and the same risks that applied to our IV doses under the old system apply to these doses made for our most fragile patients.

In general, adding bar code scanning and standardization to our IV preparation process has greatly benefited our facility. Given the number and sophistication of bar code supported processes now available, this type of scanning should become the standard of care for all facilities with compounding processes in place.

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