Congress, FDA Should Make Pharmacy Compounding Safer

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Last fall’s deadly meningitis outbreak linked to contaminated steroid injections is a tragic reminder of the risk of errors inherent in manual pharmacy medication compounding. Unsanitary conditions at the Massachusetts compounding pharmacy that made the injections resulted in fungal contamination of the drugs. The resulting outbreak sickened nearly 700 people in 19 states, and killed more than 40.

Although this outbreak is an egregious example of medication compounding gone awry, it is hardly an isolated incident. In December, the journal American Health & Drug Benefits reported that medication errors from injectable drugs harm more than 1 million patients annually in U.S. hospitals. Adverse drug events (ADEs) due to injectable medications cost U.S. healthcare payers between $2.7 billion to $5.1 billion annually, an average of $600,000 per hospital.

If we were beset by a contagious disease with such devastating consequences and costs, we would put all available resources toward eradicating it. Yet this epidemic of medication errors goes largely unchallenged. What is perhaps most tragic is that the technology to prevent it is already available. Automated pharmacy compounding systems have existed for more than a decade — it’s just that too few pharmacies use them.

Medication compounding is a common practice in hospitals and pharmacies.

Physicians prescribe combinations of medicines that are mixed in a single syringe or IV bag for a specific patient. To make these compounds accurately and safely, pharmacists must measure and combine drugs with meticulous care – for example, diluting a few milliliters of one drug and adding an equally small quantity of another. But despite the best efforts of pharmacy workers to mix medications perfectly, humans are not perfect.

One of the biggest advantages automated pharmacy compounding technology provides is removing the primary source of contamination and error — humans — from the compounding process. And automated compounding systems deliver many more benefits than the ability to make highly-precise sterile compounds exactly right every time.

Automated compounders have an aseptic chamber where medications are mixed. Vials are photographed and their barcodes are scanned; both are then matched to a product database to ensure the right product is being used in each step. As compounding progresses, pulsed UV light provides extra disinfection to critical puncture sites, needles are automatically capped (reducing the risk of needle sticks), and the finished product is dispensed in a syringe or IV bag with an electronic barcode label for documentation. The result is a sterile and accurate medication compound that is verifiably safe for the patient.

By increasing safety, the technology also saves money. Automation lowers the cost-per-dose of medication and reduces the need for medication outsourcing. Equally important, automated compounding minimizes the risk of medication errors that can result in patient injury, emergency intervention, extended hospitalizations and tort liability — critical considerations for hospitals already burdened with more than a half-million dollars in costs from adverse drug events every year.

Some will say that automated compounding systems are expensive, but that's relative. CT scanners, MRI machines and many other types of healthcare technology can be considered expensive, but they are an investment in a higher standard of patient care. Fortunately, through enhanced safety and lower medication costs, even the most expensive automated compounding systems have paid for themselves in less than three years.

Last fall following the meningitis outbreak, Congress held hearings about how the FDA can better regulate compounding pharmacies. Rep. Ed Markey introduced legislation to enhance pharmacy safety, and plans to reintroduce it in the new Congress. It is imperative that any effort to regulate pharmacy compounding include a discussion of the available technology that is proven to make it safer. Congress and the FDA must seize this opportunity to put medical technology to its highest and best use, not just improving the quality of patients' lives, but saving them.

What’s your take? Please feel free to comment below!

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