Cleveland Clinic International IV Robotics Summit

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Purpose. The proceedings of an international summit on the current and desired future state of use of robotic systems to compound intravenous (IV) solutions are summarized.

Summary. The International IV Robotics Summit was held at the Cleveland Clinic main campus in Cleveland, OH, on April 29 and 30, 2019. The purpose of the summit was 2-fold: (1) to define the current state of robotic IV compounding and (2) to develop a guide for automation companies, pharmacy departments, and drug manufacturers to improve the technology and expand the use of IV robotics in health systems in the future. The first day of the summit included 45-minute presentations by each of the speakers. Each lecturer recounted a different hospital's experience implementing and using IV robotics. On day 2 of the summit, an expert panel dedicated to mapping the future of IV robotics was convened to determine barriers to widespread adoption of IV robotics in health systems and offer potential solutions to remove these barriers. The expert panel targeted 3 specific audiences: robot manufacturers, drug manufacturers, and fellow pharmacy leaders.

Conclusion. It is the hope of the international faculty that the information that emerged from the summit can be used by others to successfully implement IV compounding robotics in their sterile products areas to maximize patient safety. The summit also served as a call to action for pharmacy leaders, drug manufacturers, and robotic companies to develop a safer, more efficient future for patients by working together to optimize the development and operation of IV robotics.

Keywords: compounding, intravenous medications, medication safety, robotic technology, robots

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Medication errors resulting from incorrect compounding of intravenous (IV) or parenteral solutions have led to catastrophic consequences for patients over time. There have been cases described in the lay press of IV medication errors leading to unfortunate fatalities.[1-3]

In 2006, 2-year-old Emily Jerry was the victim of an IV medication compounding error when she was infused with her final dose of etoposide, which was incorrectly compounded in hypertonic saline instead of normal saline.[1] Emily's dose was fatal and she passed away several days later.

In 2014, Loretta McPherson died unexpectedly in an Oregon hospital emergency room after her IV bag was accidentally filled with a solution of rocuronium, a neuromuscular blocker, instead of fosphenytoin, an anticonvulsant. She passed away 2 days later when she was taken off life support.[2]

The goal of implementing IV compounding robotics or automation systems in sterile products preparation is to prevent these types of errors from reaching the patient. IV compounding robots have been shown to safely and accurately prepare IV medications in hospitals since the first study on the topic was published in 2012.[4] Many earlier adopters of IV robotics internationally have focused on preparing hazardous drugs, given their high-risk nature and strict requirements. Multiple publications have demonstrated that current IV robotic systems compound safely while protecting both the patient and the caregiver preparing the medication.[4-12]

While the use of IV robotics has steadily increased, the adoption of these systems is still relatively low. The 2017 ASHP national survey of hospital pharmacy practices found that

2.3% of all hospitals surveyed used IV robotics for nonhazardous sterile compounding and 0.9% used an IV robot for hazardous (chemotherapy) sterile compounding.

Summit background, objectives, and format

The Cleveland Clinic pharmacy enterprise has been an innovator and early adopter of IV robotics. The International IV Robotics Summit was held at the Cleveland Clinic main campus in Cleveland, OH, on April 29 and 30, 2019. The Cleveland Clinic pharmacy department implemented its first chemotherapy compounding robot in 2012, followed by a nonchemotherapy compounding robot in 2015 and a pediatrics compounding robot in 2018. The Cleveland Clinic pharmacy department is also currently testing the products of multiple manufacturers of robots for preparing high-volume syringes. The team has also published a number of peer-reviewed articles on IV robotics since 2013.[9,10]

Based upon a desire to increase the widespread adoption of IV sterile compounding automation to improve patient safety, the Cleveland Clinic pharmacy department hosted the International IV Robotics Summit and called on peer leaders in IV robotics to speak on their experiences.

The purpose of the summit was 2-fold: (1) to define the current state of IV robotic compounding and (2) to develop a guide for automation companies, pharmacy departments, and drug manufacturers to improve the technology and expand the use of IV robotics in health systems in the future.

The summit was divided into 2 events. On day 1, international speakers gave presentations on the current state of IV robotics at their sites, focusing on implementation, production and throughput, accuracy, and downtime. To minimize potential biases, speakers were chosen from sites with differing IV robot systems. Approximately 100 guests

from 50 institutions and 7 countries attended the summit. On day 2 of the summit, an expert panel dedicated to mapping the future of IV robotics was convened. The desired output from this event was to determine barriers to widespread adoption of IV robotics in health systems and offer potential solutions to remove these barriers. The expert panel targeted 3 specific audiences: robot manufacturers, drug manufacturers, and fellow pharmacy leaders.

Day 1: expert presentations

The first day of the summit included 45-minute presentations by each of the speakers. Each lecturer recounted a different hospital's experience implementing and using IV robotics.

The end of the first day concluded with 2 additional sessions. First there was a presentation by the conference host, Dr. Scott Knoer, then serving as chief pharmacy officer at Cleveland Clinic, who presented his vision for the future of IV robotics. The second presentation was a panel discussion including all the speakers, during which audience members were allowed to ask questions about the presentations they had attended throughout the day or to ask other questions of interest.

A conference steering committee selected the panel of international speakers to represent the significant manufacturers of IV robotic systems on the market.

Each faculty member spoke about their experience with a specific robotic devices and discussed the future of IV robotics.

The following objectives were provided to ensure uniformity among the presentations:

1. Apply strategies for the effective and efficient use of IV compounding robotics.
2. Understand the state of IV robotic compounding internationally.
3. Discuss strategies to measure the utilization of IV compounding robotics.
4. Discuss the practice limitations of IV compounding robotics.
5. Discuss the future of IV compounding robotics.

From the stated objectives, 5 themes emerged from the presentations and discussion:

1. The primary reason for the use of IV robotics is safety. While relatively rare, high-profile cases of compounding errors and unsafe compounding practices leading to patient fatalities have plagued the profession of pharmacy. Use of IV robotics, although currently slower than manual compounding, is an important step to increase patient and employee safety during the compounding process.
2. Safe sterile IV compounding is a goal of pharmacy departments around the world. All speakers represented hospitals that have adopted IV robotics to ensure safety.
3. Benefits of IV robotics vs manual compounding include precision, accuracy, extensive documentation, safety features, and the sterile advantages of the systems.
4. Although the expert users embrace robotic technology, there are opportunities for improvement that are also current barriers to widespread adoption. The cost of the IV robots is seen as a factor limiting their utilization; moreover, technicians are required to operate the systems, which does not provide a net labor cost offset to help defray the costs of automated systems. The current rate at which IV robots compound products is not financially sustainable for widespread adoption relative to manual compounding.

5. There was a resounding call to action for current and future users of IV robotics. Only through partnerships between health systems and manufacturer partners can the development of new, enhanced IV robots that overcome the current efficiency challenges while maintaining safety be ensured.

Day 2: expert panel recommendations

Recommendations for drug manufacturers. One of the largest barriers to widespread adoption of IV robotics is the speed at which robots compound sterile products (ie, throughput) compared to humans performing manual compounding. This limited throughput was identified by all user groups. The size and relative lack of dexterity of the robots also hinders the ability to compound all IV sterile products through the robot. Expert users unanimously agreed on the need for a faster next generation of IV robots (while maintaining similar safety endpoints) if their use is to become standard practice in hospitals.

To run efficiently and effectively, IV robots require both human and supply resources. Pharmacy staff are responsible for the loading, unloading, cleaning, and general upkeep required to operate an IV robot. IV robot supplies include the drug product, diluent solution, container used for the final product, and necessary ancillary supplies required for compounding (eg, needles, syringes). The general design of these materials, specifically the packaging and labeling, have presented challenges to both robot users and manufacturers.

Generic medications are often manufactured by multiple drug companies, which results in the same medication being available in multiple different vial sizes and shapes. Many manufacturers also change vial sizes and shapes on their marketed products without forewarning. For IV robots, these presents specific challenges, as a robot cannot automatically learn the new vial sizes. Rather, some IV robot users rely on the vendor to

input the new vial sizes into the robotics software, which can cause significant delays in use of different or adapted products. While waiting on the vendor to update its software, the throughput of the machine is reduced t. Drug shortages can further complicate the issue because they generally require switches in products that might not be readily available in the robot database. With this in mind, the expert panel recommended that manufacturers develop standards for vial dimensions for both Food and Drug Administration (FDA)–approved medications and investigational drugs; this will allow easier programming of robots to better adapt to changes in manufacturer products to maximize efficiency.

Another role of the manufacturer is to ensure proper labeling of their product including FDA required elements such as: barcode, lot numbers, and expiration dates. In the current state, most of this labeling does not automatically extract into the IV robotic software and requires the manual input of lot numbers and expirations for the product. With the implementation of the Drug Supply Chain Security Act (DSCSA) in the United States, manufacturers are required to update their barcodes to be 2D (ensuring the lot and expiration date would be readily extractable); however, compliance for the entire supply chain is not required until 2023. In order to make the processes for both manual and robotic compounding more efficient, the expert panel recommended that drug manufacturers embed lot number and expiration date data in barcodes.

Most compounding robots use gravimetric techniques to achieve the high level of precision required for IV sterile compounding and to ensure the correct amount of medication is prepared. If this information is not readily available from the manufacturer, then the pharmacist must determine the correct specifications for the drug. For sterile compounding, it is also important to understand the stability of the drug after the vial is first punctured and how long the drug is stable once the drug is prepared with diluent. In order

to ensure that the robot is using the correct specifications for a manufactured product, the expert panel recommends that drug manufacturers include in-depth product information, including but not limited to: stability, specific gravity, and accurate concentrations in the package insert that could easily be programmed into the IV robotic systems.

Recommendations for pharmacists. Pharmacists and technicians are the frontline users of automated IV technologies. While pharmacy staff directly benefit from the use of IV robots, they also have to contend with the limitations of the current technology and manufacturer practices. Even though they cannot change the specifications of current IV robots or drug products, standardization of practices, policies, and procedures within the hospital setting can help improve processes.

One such practice is the setup of standardized dosing for individual drugs and/or dose banding. Within the hospital setting, pharmacy departments can work with physician leaderships to determine dosing protocols as well as standard concentrations for medications. Most of the time, these standards are to ensure consistency across the hospital and improve medication safety. Standardization within the IV robotic system can increase productivity while minimizing the potential for errors. For patient-specific medications, there is an ability to use dose banding (ie, rounding doses up or downing according to patient and situational factors) to prepare common doses. The expert panel recommended that hospitals adopt standardized drug concentration and dose banding guidelines to better serve patient needs efficiently.

Training and competency assessment of the pharmacy technicians and pharmacists operating the robots is an area for improvement. Often pharmacy technicians and pharmacists who work on the IV robot have sterile compounding experience but do not have significant experience with IV robotics technology. Given the complexities of the

system, staff need specific training in this technology in order to optimize the use of IV robots. These trained staff members should be given specific titles and position grading that adequately reflects the requirements of the position. These positions should also require specialized certification on the use of advanced IV robotics, including initial educational requirements whose completion is overseen by an accrediting body (eg, Pharmacy Technician Certification Board), by a certified pharmacy technician school, or directly by the employer.

Pharmacy leaders must better integrate IV robots into daily workflow and cleanroom infrastructure. It is critical to appropriately integrate the robot to maximize workflow. Sterile compounding pharmacists and pharmacy leaders must consider how the IV robotic systems will be used, such as for batching or patient-specific compounding. They also must consider that IV robotics occasionally have downtimes for various reasons (eg, routine maintenance, cleaning, certification, relocation, and repairs). Pharmacy leaders need to develop scheduled and emergency downtime contingency plans.

There are limited publications and data in the literature to guide pharmacists in putting an IV robot system into place. Sterile products pharmacists who have implemented IV robotic systems or are considering their use should be involved in user groups to help share best practices for implementation, use, and optimization. Leaders should prioritize publishing their experiences with IV robotics, including head-to-head comparisons, cost-benefit analyses, and case studies for specific robots.

Recommendations for robotics manufacturers. Robotics manufacturers and vendors are in a unique position to impact the use and growth of IV robotics in the future. They ultimately control how these robots are designed and manufactured. They also impact how the robotic technology interacts with other technologies used by hospital pharmacy

departments. These companies are the experts when it comes to support of these technologies, including diagnosis, repair, and prevention of issues encountered in their operation.

Current IV robots are designed for functionality and many have large articulating arms that swing and rotate inside the compounding area. They have segregated areas for loading and unloading and areas for storage of byproducts from the compounding process. Although necessary, these various areas take up a lot of space, resulting in large pieces of equipment for pharmacy departments to integrate into limited IV compounding space.

Since robots are relatively new to sterile compounding, most sterile product IV compounding rooms must be retrofitted to accommodate them. The ideal situation is to create an IV compounding room that incorporates IV robots and other sterile products technologies, which is not always possible. It is quite challenging to install a large robot (or any significant equipment) in an established IV compounding room; this makes designing IV robots to minimize square footage a high priority for users. In order for installation of robots to be feasible in the majority of IV rooms, manufacturers must minimize square footage requirements while making them more ergonomically designed for loading, unloading, cleaning, and repair.

In order for IV robots to reach their full potential, manufacturers must communicate, collaborate, and consult with drug and supply manufacturers, software developers, and pharmacy sterile products leaders.

IV robots must to be programmed to perform the tasks that are required of them. These tasks include the ability to identify medications, incorporate the vial size for each medication profile, and the final container that will be used (syringe, bag, vial, etc). In order for this to happen, robotic manufacturers need to collaborate with drug manufacturers to

program IV robots with new drugs that are being released into the market and the final containers that may be used in compounding in advance of the products' commercial release. This will require the IV robot manufacturers to incorporate real-time data on availability of new products into the drug library of their IV robot software. Manufacturers should actively collaborate with other software developers to ensure interfaces between the robot software and electronic health records, IV workflow platforms, and other pharmacy automation systems that customers use in their hospitals are created and maintained. Robot vendors must partner with hospital leaders, especially in the area of service contracts. These service contracts must measure key performance indicators such as service response times, number of site visits, robotic uptime and downtime tracking, maintenance plans, database management, and ongoing staff training. The robotics vendor is best equipped to draft goals for these key measurements.

As a primary engineering control, the compounding area of the IV robot must be regularly decontaminated and disinfected to ensure there is no contamination. Current cleaning processes require significant human interaction, leaving staff members exposed to potentially hazardous drugs and chemicals. The current cleaning processes create hazardous waste that must be disposed of, potentially exposing staff to harmful waste products. The optimal solution is to equip robots with automated self-cleaning features, including the ability to decontaminate and disinfect the compounding area and dispose of byproducts. Another way to improve this process is to design the compounding area to be more accessible and easier to clean in order to minimize time required for manual cleaning processes.

There are several key features that robot manufacturers must focus on in order to improve efficiency and throughput. Robots must be designed to limit human interaction.

Robotics manufacturers must focus on optimizing the autonomy of the robot, decreasing the need for human interaction, and freeing staff to work on other tasks. The ideal robot would be able to independently perform loading of products, programming, unloading of final products and waste, cleaning, and labeling. These are all important tasks that currently rely heavily on human interaction.

The IV robots must be able to work more efficiently when it comes to output. This means robot manufacturers must design devices with increased speed while maintaining precision. Many robots are currently designed by modeling the human compounding process, which involves the use of an articulated arm. The robotic arm currently used in many IV robots on the market limits the ability to multitask and quickly move products through the compounding process. Manufacturers need to focus on innovative solutions to help increase the productivity of the IV robot by decreasing the necessity of human interaction while increasing production speed.

Summary

The International IV Robotics Summit at the Cleveland Clinic brought together thought leaders and experts in the area of IV robotics use to share the current state of IV robotics and to develop a path for the future. The proceedings of this summit outline the importance of this technology for the future of pharmacy practice. They also highlight the need to overcome the barriers of the current technology in order to gain widespread adoption.

The feedback from summit participants was overwhelmingly positive with regard to the structure, execution, and content of the conference. This success can be attributed to the dedicated faculty members and their willingness to share their experiences.

Conclusion

It is the hope of the summit faculty that the information presented here can be used by others to successfully implement IV compounding robotics in their sterile products areas to maximize patient safety. The summit also served as a call to action for pharmacy leaders, drug manufacturers, and robotic companies to develop a safer, more efficient future for patients by working together to optimize the development and operation of IV robotics.

Disclosures

The authors have declared no potential conflicts of interest.

Previous affiliations

At the time of writing Dr. Knoer was affiliated with Cleveland Clinic, Cleveland, OH.

References

1. Emily Jerry Foundation. Emily's story. Accessed July 25, 2020. http://emilyjerryfoundation.org/emilys-story/
2. Newschannel 21. 'Tragic error': St. Charles probing wrong-drug death. Updated September 1, 2016. Accessed July 25, 2020. https://ktvz.com/news/2014/12/05/tragic-error-st-charles-probing-wrong-drug-death/
3. Vivian J. Criminalization of medication errors. *US Pharm*. 2009;34(11):66-68.
4. Volpe G, Cohen S, Capps RC, et al. Robotics in acute care hospitals. *Am J Health-Syst Pharm*. 2012;69(18):1601.
5. Chen WH, Shen LJ, Guan RJ, Wu FL. Assessment of an automatic robotic arm for dispensing of chemotherapy in a 2500-bed medical center. *J Formos Med Assoc*. 2013;112(4):193-200.
6. Masini C, Nanni O, Antaridi S, et al. Automated preparation of chemotherapy: quality improvement and economic sustainability. *Am J Health-Syst Pharm*. 2014;71:579-585.
7. Palma E, Bufarini C. Robotized compounding of oncology drugs in a hospital pharmacy. *Int J Pharm Compd*. 2014;18:358-364.
8. Nurgat Z, Faris D, Mominah M, et al. A three-year study of a first-generation chemotherapy-compounding robot. *Am J Health-Syst Pharm*. 2015;72:1036-1045.
9. Yaniv AW, Knoer SJ. Implementation of an i.v.-compounding robot in a hospital-based cancer center pharmacy. *Am J Health-Syst Pharm*. 2013;70:2030-2037.
10. Yaniv AW, Orsborn A, Bonkowski JJ, et al. Robotic i.v. medication compounding: recommendations from the international community of APOTECAchemo users. *Am J Health-Syst Pharm*. 2017;74(1):e40-e46.

11. Milibari L, Cotugno M, Belisle C, et al. Single center experience with robot technologies for sterile compounding: a retrospective review. *Intl J Pharm Compd*. 2020;24(4):346-351.
12. Boyd AM, Chaffee BW. Critical evaluation of pharmacy automation and robotic systems: a call to action. *Hosp Pharm*. 2019;54(1):4-11.

Box 1. Recommendations of Summit Participants

Recommendations for Robotic Manufacturers and/or Vendors

1. Establish service contracts for key performance indicators including but not limited to response time, site visits, uptime, maintenance plans, database management, and supervised training.
2. Develop a bidirectional interface that communicates with the EHR, IV workflow systems, and other automation systems as determined by health systems.
3. Ensure interoperability with different manufacturers' consumables without the need for customization.
4. Implement real-time calibration of new medications into the database.
5. Optimize self-cleaning module that performs decontamination, disinfection, and disposal to reduce worker exposure.
6. Minimize the necessity for human intervention.
7. Develop systems for final product labeling within the robotic process.
8. Design the IV robot with minimal footprint and optimal ergonomics.
9. Develop system to target compounding of 80 to 90 products per hour while still maintaining patient safety.

Recommendations for Drug Manufacturers

10. Embed barcodes with lot numbers and expiration dates (as mandated by, eg, DSCSA).
11. Standardize vial dimensions for investigational and FDA-approved medications.
12. Provide product description (eg, stability, specific gravity) in the package insert or prescriber information.

Recommendations for Hospital Leaders

13. Adopt standard concentrations for specific populations (eg, neonates, pediatric patients, adults) when appropriate.
14. Adopt dose banding, if appropriate, to minimize preparation of custom doses.
15. Develop specialized roles and advanced certifications for staff who maintain IV robotics systems.
16. Develop adequate contingency plans for both planned and unplanned downtimes.
17. Ensure adequate facilities to accommodate IV robotics in future expansion plans.
18. Participate in end-user groups and publish available data to increase transparency and sharing of best practices.

Abbreviations: DSCSA, Drug Supply Chain Security Act; EHR, electronic health record; FDA, Food and Drug Administration; IV, intravenous.