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Intravenous Smart Pumps During Actual Clinical Use

A Descriptive Comparison of Primary and Secondary Infusion Practices

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ABSTRACT

This descriptive observational study was conducted to increase understanding of medication administration practices during actual clinical use between 2 commonly used, different types of intravenous (IV) smart pumps. Compliance with manufacturer-recommended setup requirements for both primary and secondary infusions and secondary medication administration delay was compared between a head-height differential system and a cassette system. A total of 301 medication administration observations were included in this study: 102 (34%) for the linear peristaltic IV smart pump (medical–surgical: N = 51; critical care: N = 51) and 199 (66%) for the cassette pump (medical–surgical: N = 88; critical care: N = 111). Results found a 0% compliance for primary line setup and 84% compliance for secondary line setup and 1 omitted medication due to a closed clamp with the linear peristaltic system. For the cassette system, there are no head-height requirements. Two roller clamps were found to be in the closed position on initiation of the secondary infusion, but the clinician was alerted by an alarm, so no medication delays occurred. These findings support that the current system requirements for flow rate accuracy using head-height differential systems are difficult to achieve consistently at the point of care. There is a need for additional human factor designed technology to replace manual actions to improve the process of care for nurses and the safety of care for patients.

Key words: IV infusion, IV smart pump, medication error, patient safety, quality improvement

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With an estimated 90% of hospitalized patients receiving intravenous (IV) medications, IV infusion pumps are ubiquitous in health care.[1] Although there are different types of infusion pumps, large-volume IV smart pumps are the most widely used in US acute care hospitals because they can administer large amounts of both fluids and medications.[2-4] Through our experiences as practicing nurses, we know the difficulty first hand in trying to juggle multiple patient care tasks while simultaneously having to safely administer potent IV medications with significant potential side effects. The reality of programming an IV smart pump is that the delivery of even a single dose of medication involves multiple steps and keystrokes, each of which introduces a potential opportunity for error. A recent study compared some of the differences in IV smart pump usability with various brands of IV smart pumps and examples of findings were that the time to power on ranged from 7.1 to 13.8 seconds, and the number of keystrokes required to initiate a primary infusion ranged from 10 to 17.[5]

IV smart pumps have built-in drug libraries, interchangeably referred to as a dose error reduction system or dose error reduction software (DERS), which are intended to reduce medication administration errors. These errors are mitigated by drug-associated DERS programming limits, which provide various alerts to users if the programmed dose is outside of the acceptable range. Soft dosing limits provide a warning that the dose may be out of the acceptable range, but this limit can be bypassed by the user. When hard-dosing limit alerts are triggered, the IV smart pump must be reprogrammed to a different dose before the IV medication administration can proceed. While data support that the use of IV smart pumps has been associated with reductions in medication administration errors, they have not eliminated errors, including serious adverse drug events with high-alert medications.[6-12] *High-alert medications* are defined by the Institute for Safe Medication Practices (ISMP) as medications that bear a heightened risk of significant patient harm when used in error.[13] In our previous research, we found the majority of IV smart pump alerts were bypassed by clinicians at the point of care, regardless of whether the medication was high alert or non-high alert, a symptom of alert fatigue and a clear limitation of IV smart pump safety features.[14,15] Considering the frequency and importance of IV medication administration in acute care, it is noteworthy that few studies have investigated the root causes of these serious adverse drug events and whether differences in medication administration errors exist among different IV smart pump types.

Of the work that has been done, weight-based infusions, secondary infusions, and IV boluses have been identified as particularly high risk and error prone.[2,16] These IV medication administration tasks place additional cognitive demands on users, are not well standardized within hospital protocols, vary among IV smart pump user interfaces, and have associated failure modes that are not easily detected.[16] Unfortunately, available data comparing the workflow and usability for the user interfaces of different IV smart pump types are scarce.[3,16,17] As a result, limited empiric data exist about what can and should be required by manufacturers to help make their products safer and easier to use.

SECONDARY MEDICATION ADMINISTRATION

Secondary medication infusion by large-volume IV smart pump is used extensively in US acute care for administering IV medications ordered for one-time or intermittent dosing. Secondary administration is designed to allow the primary continuous infusion to pause during the secondary infusion and then resume automatically after the secondary infusion is complete.[16-18]

In US acute care, anti-infectives and electrolyte replacement for adult patients are commonly delivered by secondary infusion. Secondary medications are often time sensitive, and the following are examples of potentially serious clinical consequences that can result from secondary medication administration delay:

- In a patient receiving an antibiotic as treatment for sepsis, antibiotic administration delay is associated with increased mortality.[19,20]
- For patients receiving an antibiotic to prevent surgical site infection (SSI), a delay results in increased SSI risk, a common hospital-acquired infection.[21]
- For patients receiving crucial electrolyte replacements, such as magnesium or potassium replacement, numerous serious consequences, including cardiac arrest, are possible.

HEAD-HEIGHT DIFFERENTIAL SYSTEM

Secondary medication administration using a head-height differential system requires a head-height differential between the primary and secondary fluid containers and a primary line back-check valve. *Head-height differential* refers to the difference between the top of the fluid level in the primary and secondary fluid containers. With a US market share of >50%, the Becton Dickinson (BD) Alaris Pump (Becton, Dickinson and Company, Franklin Lakes, NJ) is the most common large-volume IV smart pump using this technique.[4,22] The setup requirements are described below and also shown in Figure 1.[23]

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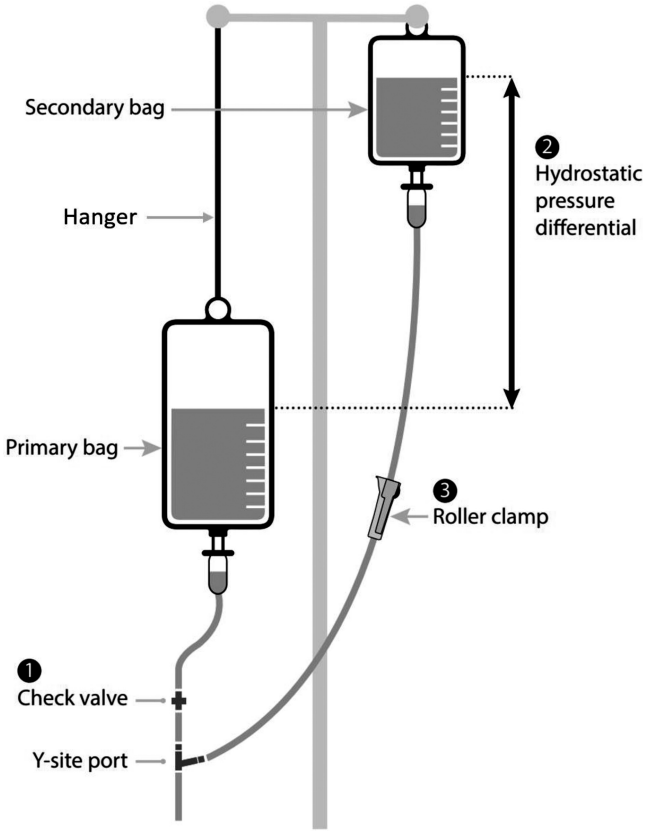

Figure 1 Required components for secondary medication infusion using the head-height differential method. Figure used with permission from Karen K. Giuliano, PhD, RN.

1. The IV smart pump is placed on the IV pole in a position that is level with the patient's heart, and the top of the fluid in the primary container is 20 inches above the top of the pump.[23]
2. A head-height differential of at least 9.5 inches between the primary fluid level and secondary fluid level for IV bags and a head-height differential of at least 9.5 inches between the primary fluid level and the fluid level in the drip chamber for vented IV bottles are required for adequate infusion. These head-height differentials are achieved by lowering the primary with a hanger and are necessary to create the hydrostatic pressure differential required for secondary medications to infuse.
3. If the secondary container is >50 or 100 mL or the flow rate is high, it is recommended to check the primary container for flow and, if necessary, add a second hanger to further lower the primary container.
4. The hydrostatic pressure differential closes a back-check valve in the primary tubing, which is required to prevent unintended primary flow or reverse flow from the secondary container into the primary container instead of into the patient.
5. The roller clamp on the secondary tubing should be open during secondary infusion and closed during the primary infusion. If the roller clamp is inadvertently closed during secondary infusion, no pump alarm will sound, and the fluid will be pulled from the primary bag at the programmed secondary flow rate.

Because the medication administration process using linear peristaltic pumps has so many manual setup requirements, secondary infusions in particular are prone to user errors.[2,16,17] If setup specifications are not adhered to during clinical use, the secondary medication may not infuse at all, may infuse into the primary bag instead of the patient, or may infuse concurrently into the patient with the primary at a different rate than intended. Furthermore, all reported flow rate accuracy testing results (±5%) provided with the product labeling and included in regulatory submissions are obtained using the manufacturer's setup specifications. Data support that deviations from manufacturer recommendations decrease both flow rate and flow rate accuracy.[16,17,24]

Three specific secondary infusion setup errors that have been found to occur include:[1,2,16,17,25]

1. The use of tubing without a primary line back-check valve, which can cause backflow into the primary bag instead of directly into the patient.
2. Back-check valve failure because of inadequate head-height differentials, high secondary flow rates, and partial opening of needle-free connectors. All of these conditions may lead to unintended flow from the primary container or backflow into the primary bag instead of directly into the patient.
3. Leaving the roller clamp closed, which prevents the secondary medication from infusing at all.

Following is an example from the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience database, which provides an example of back-check valve failure.

> *"The patient was to receive IV albumin piggybacked onto a normal saline infusion through an infusion pump. The nurse set up the infusion. When she checked in on the patient approximately 20 minutes later, she noted that the bottom of the saline bag had discolored to amber brown, indicating that the albumin was emptying out of the piggybacked bag and flowing into the primary bag. The piggybacked infusion had been set up correctly, with the secondary bag hung higher than the primary bag. The back-check valve in the primary tubing should have prohibited flow of the secondary infusion into the primary bag."*[26]

In this case, the backflow into the primary was detectable because of the discoloration. However, secondary medication backflow due to back-check valve failure is generally not detectable. Additionally, once the primary infusion resumes, the rate of delivery of the secondary medication (which is now actually in the primary bag and not in the patient) is determined by the programmed primary rate.

Lack of secondary medication delivery due to an inadvertently closed clamp is often not detected until the next dose is due. Both of these errors result in either a medication administration delay or a completely missed dose.[2,16,17]

CASSETTE SYSTEM

Primary and secondary medication administration using a cassette system is regulated by valves in the cassette. These cassette valves eliminate the need for head-height differentials and a primary line back-check valve for secondary medication administration. Because the secondary medication has its own fluid path, if the roller clamp is inadvertently engaged during secondary medication administration, an alarm will provide notification to the clinician. Thus, cassette systems provide a technical mitigation for the 3 reasons identified above for secondary medication administration error that exist on the head-height differential systems.[27]

OBJECTIVE

Concerning secondary medication administration, this need has already been recognized by ISMP in their recent guidelines for optimizing IV smart pumps safely, where they recommend the use of systems for secondary medication infusion that do not require a head-height differential.[13] The objective of this study was to measure the impact of medication administration practices between 2 types of IV smart pumps during actual clinical use. The BD/Alaris pump was used as the representative head-height differential system and the ICU Medical Plum 360 (ICU Medical, Inc., San Clemente, CA) was used as the representative cassette system.

RESEARCH AIMS AND HYPOTHESES

Aim 1

What is the adherence with the requirement of pump–primary IV head-height differential of 20 inches for the head-height differential system during actual clinical use?

> Because of the complex setup requirements and limited physical space during actual clinical use, we hypothesized that the pump–primary IV head-height differential for appropriate medication administration will be insufficient at least 50% of the time during actual clinical use.

Aim 2

What is the adherence with the 9.5-inches secondary head-height requirement with the head-height differential system pump during actual clinical use?

> We hypothesized that the required primary–secondary head-height differential for appropriate medication administration will be insufficient at least 20% of the time during actual clinical use.

Aim 3

Is there a difference in secondary medication administration delay between the head-height differential system and cassette system during actual clinical use?

> Because of the requirements for a primary line back-check valve and the need to manually open the roller clamp during secondary infusion with linear peristaltic technology, we hypothesized that there would be fewer secondary medication administration delays with the cassette system as compared with the head-height differential system.

STUDY DESIGN AND METHODOLOGY

Setting

The study design was observational and noninterventional. Two large (600- and 800-bed) urban hospitals were used as study sites, one that used the head-height differential system and one that used the cassette system. Observational data collection occurred in both the critical care and general medical–surgical clinical units in both study sites. Institutional review board approval was obtained at each site before beginning data collection, and data were collected at each site by a single observer.

Sample

Using a point prevalence methodology, data were collected on a minimum of 100 medication observations at each site (50 in medical–surgical and 50 critical care), which occurred over a consecutive 2-day period. Observations using convenience sampling were recorded real-time using a case report form (CRF).

Inclusion Criteria

All adult patients (18 years or older) hospitalized in either a medical–surgical or critical care unit and who had at least 1 active IV secondary medication order were eligible for inclusion in the study.

Exclusion Criteria

Adult patients on the study units who did not have at least 1 active IV secondary medication order were excluded.

Procedures

1. Data collection was completed on 2 consecutive weekdays between the hours of 6:00 AM and midnight to capture medication administration at various times during the 24-hour cycle.
2. First, the individual site investigators at each site reviewed all current secondary medication orders in the electronic health record (EHR) for patients on the critical care and medical–surgical study units.
3. Secondary bag volume, infusion duration, and type of secondary medication were collected as descriptive data.
4. Direct observation of each secondary medication administration at the point of care was done at the site using the head-height differential system only to assess the setup by:
   a. Measuring the distance between the top of the IV smart pump and the primary fluid level (which should be 20 inches)

b. The secondary head-height differential measured as the distance from the top of the primary fluid level to the top of the secondary fluid level (which should be at least 9.5 inches).
c. Confirming the presence of a back-check valve on the primary line
d. Observing the position (open/closed) of the secondary medication tubing roller clamp

5. Direct observation of each secondary medication administration at the point of care was then done on both IV smart pump types to confirm the actual time of secondary medication administration.
6. Patient identification was confirmed for all observations only to verify the EHR medication orders, but no protected health information was collected on the CRF.
7. Each secondary medication observation was assigned a study number, as this was considered as the unit of analysis.
8. Using the ISMP guidance, medications were recorded as given on time (±30 minutes from order time) or delayed (administered outside of the ±30-minute time window).[28]
9. A medication was recorded as *omitted medication* only if dosing was not completed before the time of the next scheduled dose.
10. The names of all ordered medications were collected.

RESULTS

A total of 301 medication administration observations were included in this study: 102 (34%) for the head-height differential system (medical–surgical: N = 51; critical care: N = 51) and 199 (66%) for the cassette system (medical–surgical: N = 88; critical care: N = 111). Table 1 summarizes the descriptive data for secondary bag volume, infusion duration, and medication type.

Aim 1

What is the adherence with the requirement of pump–primary IV head-height differential of 20 inches for the head-height differential system during actual clinical use? Tables 2 and 3 summarize the total and clinical unit-specific data on the measured pump–primary IV head-height differentials, including 5 instances where the primary fluid level

TABLE 1

Summarized Frequency Data for Secondary Bag Volume, Infusion Duration, and Medication Type by Therapeutic Class

	Total		Head-height differential system		Cassette system	
Secondary bag volume (mL)	N	%	N	%	N	%
50	70	23.0%	29	28.4%	41	20.6%
100	182	60.0%	57	55.9%	125	62.8%
150	6	2.0%	0	0.0%	6	3.0%
250	39	13.0%	15	14.7%	24	12.1%
400	1	0.3%	1	1.0%	0	0.0%
500	3	1.0%	0	0.0%	3	1.5%
Secondary infusion duration (min)	**N**	**%**	**N**	**%**	**N**	**%**
15	3	1.0%	3	2.9%	0	0.0%
30	152	50.0%	36	35.3%	116	58.3%
60	79	26.0%	19	18.6%	60	30.2%
90	24	8.0%	9	1.0%	15	7.7%
120	8	3.0%	1	1.0%	7	3.5%
180	4	1.0%	3	0.2%	1	0.0%
240	31	10.0%	31	30.4%	0	0.0%
Medication therapeutic class	**N**	**%**	**N**	**%**	**N**	**%**
Antibiotic	216	72.0%	81	79.4%	135	67.8%
Other anti-infective	23	8.0%	5	4.9%	18	9.0%
Electrolyte/vitamin	40	13.0%	13	12.7%	27	13.6%
Other	22	7.0%	3	2.9%	19	9.5%

TABLE 2

Measured Primary Head-Height Differentials

Inches	Total sample (N = 102)	Medical-surgical (N = 51)	Critical care (N = 51)
Mean	5.8	5.1	6.5
Median	5.2	5.0	6.0
SD	4.9	5.0	4.9
Minimum	–4.0	–3.5	–4.0
Maximum	16.0	15.0	16.0

was located below the pump (4 in medical–surgical and 1 in critical care). Data show that none of the observations for the primary infusion setup were compliant with the head-height differential system setup requirements of 20 inches between the pump and the primary IV head height.

Aim 2

What is the adherence with the 9.5-inch secondary head-height requirement with the head-height differential system during actual clinical use? Tables 4 and 5 summarize the total and clinical unit-specific data on secondary head-height differentials. Overall, 16% (N = 17/102) of the secondary head-height differentials were found to be <9.5 inches, with only minor differences between medical–surgical and critical care. Of the 17 secondary infusions that did not meet the recommended head-height differential, 2 infusions in medical–surgical were found to have a head-height differential of 0 inches, whereas the remaining heights were between 7 and 9 inches (Table 6).

Aim 3

Is there a difference in secondary medication administration delay between the 2 IV smart pump types during actual clinical use?

Back-check Valve

For the head-height differential system, it was found that 100% of the primary lines did contain a back-check valve. For the cassette system, there is no need for a back-check valve because the cassette prevents backflow.

TABLE 3

Adherence With Required Primary Head-Height Differentials

	Total frequency (%)		Medical-surgical frequency (%)		Critical care frequency (%)	
Yes	0	0%	0	0%	0	0%
No	102	100%	102	100%	102	100%

TABLE 4

Measured Secondary Head-Height Differentials

Inches	Total sample (N = 102)	Medical-surgical (N = 51)	Critical care (N = 51)
Mean	12.3	12.5	12.2
Median	12.0	12.0	12.0
SD	3.6	4.0	3.1
Minimum	0.0	0.0	7.0
Maximum	21.0	21.0	20.0

Roller Clamp

For the head-height differential system, 1 clamp (1% of observations) on the secondary line was found in the closed position, resulting in an omitted secondary medication dose that was not detected. For the cassette system, 2 clamps (1%) were found to be in the closed position on initiation of the secondary infusion. In both cases, the clinician was alerted by the alarm, and no medication delay occurred.

DISCUSSION

The findings from Aim 1, primary head-height compliance, should be of concern to all practicing clinicians in the acute care setting. There were no observations where the primary head-height requirements were met, and 5 of the primary infusion bags were found to be hanging below the pump. Since flow rate accuracy and delivery of primary and secondary infusions are dependent on adhering to the manufacturers' recommendations for the system setup, the impact of these findings on the accuracy of medication delivery is unknown. In the busy setting of acute care, nurses are required to continually balance complex and ever-changing patients care requirements. Any time a technical versus a manual solution can be used to improve the safety and efficiency of patient care, it should be considered. Based on these findings, cassette IV infusion technology provides an example of a technical solution that can improve both the quality and process of care for secondary medication administration.

TABLE 5

Adherence With Required Secondary Head-Height Differentials

	Total frequency (%)		Medical-surgical frequency (%)		Critical care frequency (%)	
Yes	86	84%	45	88%	41	78%
No	16	16%	6	12%	11	22%

TABLE 6

Head-Height Differentials for Nonadherent Secondary Infusions

Inches	Medical-surgical	Critical care
0	2	0
7	1	1
8	1	2
9	2	8

For Aim 2, while the majority (84%) of secondary medication infusion setups did meet the 9.5-inch head-height differential requirement, 16% did not, which is a considerable degree of error. The 2 observations of a 0-inch differential very likely led to delayed administration of the secondary medication, while the remaining inadequate head heights had variable and unknown impacts on flow rate. More recent 2017 BD/Alaris product recommendations do not specify 9.5 inches as the differential needed to achieve the hydrostatic pressure for secondary flow but alternatively describe the secondary more generally as needing to be sufficiently higher.[29] This open-ended recommendation may lead to further inconsistency at the bedside, since no clinical guidance is provided in those recommendations for any operational definition of what sufficient means.

These findings provide evidence that it is difficult, if not impossible in some situations, to comply with the recommendations for head height during actual clinical use of head-height IV smart pump systems. Clinical realities, such as limitations on space at the bedside, the availability and type of IV poles, and head-height requirements that make it impossible for most nurses to reach the IV bags without standing on a stool, all contribute to the lack of compliance with recommended head-height differential system setup. To illustrate this point, Figure 2 shows the implications of these setup requirements from the perspective of a frontline nurse. The middle photo depicts the 9.5-inch secondary setup requirement. These recommendations require frontline nurses to conform to physical setup requirements that are often not possible at the bedside, which likely accounts for the 0% compliance with primary head-height recommendations.

For Aim 3, we found a total of 3 closed clamps, 1 with the head-height differential system that resulted in a missed dose and 2 with the cassette system, both of which alarmed, alerted the clinician, and did not result in missed doses.

Based on what is known regarding medication administration error with secondary infusion, errors of varying severity are occurring during actual clinical use without detection.[16,17] These likely include reduced flow accuracy of the secondary infusion due to inadequate hydrostatic pressure, concurrent flow of primary and secondary infusions, backflow from the secondary into the primary due to backcheck valve failure, and, in this small sample, 1 documented occurrence of a missed dose due to a closed clamp. While data on the position of the pump relative to the patient were not collected in this study, anecdotal observations noted by the data collector found that the pumps were positioned in a variety of locations relative to the patient, including below the patient.

The impact on the delivery of antibiotics is concerning, because the majority of medications (72%) administered by secondary infusion were antibiotics (Table 1). When other anti-infectives are included, the total is 80%. Incomplete dosing of antibiotics not only decreases the therapeutic benefit to the patient but also contributes to antibiotic resistance due to the resultant subtherapeutic levels, which foster bacterial mutation.[30] While appropriate and timely antibiotic administration as prescribed is always important, in certain clinical situations like sepsis, where every hour delay in antibiotic administration results in an 8% increase in mortality,[19] it can literally make the difference between life and death.[20,31,32]

Figure 2 Using a commonly available intravenous pole and the 9.5-inch secondary hanger, if the recommendations for primary and secondary head heights are followed, it is not possible for this 5′5″ nurse to reach the secondary medication bag. Images used with permission from Melody Bennett, MN, RN.

LIMITATIONS

This study was conducted in 2 hospitals that were chosen to be similar in bed size, urban location, patient acuity, and annual patient discharges. The findings from these 2 hospitals are not necessarily representative of the practices in all US hospitals. The authors acknowledge that the study used a point-prevalence, convenience sample design, and observational approach with data collected over a 2-day period, so the findings should be interpreted in that context. As the study was primarily descriptive in nature, a larger-scale trial with multiple sites, additional IV smart pump types, different size hospitals, and a larger sample size is needed to more thoroughly describe IV smart pump medication administration practices in a way that is more generalizable. This is especially important to study the issue of medication delay. Even with these limitations, it is the authors' hope that this study provides an example of the type of practice-based research that can generate data from the point of care to support improvement in IV medication administration safety and inform future recommendations for implementation science.

CONCLUSION AND IMPLICATIONS FOR FUTURE RESEARCH

In addition to a larger-scale study, a knowledge assessment of direct care nurses on the topic is warranted. It is important to learn more about the overall knowledge level of these professionals concerning the technical requirements, limitations, and clinical effects of secondary medication administration and the potential for error. This information is important for the development and implementation of educational materials that may, at least in the short term, help improve the secondary medication administration process. However, even if frontline caregivers are provided with all the relevant knowledge, the current system requirements for flow rate accuracy using head-height differential systems are simply not possible to achieve consistently at the point of care. There is a need for additional human-factors designed technology to replace manual processes to improve the process of care for nurses and the safety of care for patients.

Much more research is needed to understand the variations in flow rate accuracy under the conditions that actually exist in acute care, as reported data are generally limited to manufacturer recommendations and requirements. Because most IV smart pumps were developed before the current FDA requirements for human-factors safety testing, there is a lack of practice-based flow rate data to help guide clinical decision-making. ECRI, a noncommercial organization for health care technology assessment, regularly publishes IV infusion comparative effectiveness reports and issues recommendations. Their recent IV infusion report was released on March 18, 2020. Unfortunately, the ECRI testing process uses only manufacturers' recommendations for setup, which provides no insight into what actually happens in the clinical settings. Practice-based research on flow rate accuracy using a variety of realistic clinical scenarios is needed to help clinicians understand which patient safety and usability tradeoffs exist among the different IV smart pump systems.

Finally, innovation in IV smart pumps to develop technical solutions for as many usability issues as possible is needed, including the development of additional choices that do not require a head-height differential for secondary medication infusion.[3,32] With the high level of demand for clinicians at the point of care, manufacturers have the responsibility to improve both clinical workflow and patient safety by creating innovative technology solutions to improve IV smart pump usability in this very important area of patient safety.

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