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Give Intravenous Bolus Overdose a Brake: User Experience and Perception of Safety Device

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Objectives: Drugs can come in concentrated solutions that require dilution before intravenous bolus administration. Upon dilution, the syringe can contain more than the required amount of drug. The user may mistakenly administer the full contents of the syringe, resulting in an overdose. In this cross-sectional study, we evaluated user experience and perception of Syringe Brake, a dosage flow restrictor device, as part of the intravenous morphine bolus administration workflow.

Methods: From December 2018 to January 2019, doctors and nurses working in the emergency department of 3 public tertiary hospitals in Singapore were invited to complete a paper-based 11-item 5-point Likert scale survey questionnaire after 3 months of Syringe Brake implementation.

Results: Overall, 77.5% (290/374; 4.11 ± 0.83) of participants were satisfied with the use of Syringe Brake to prevent medication error. Our survey results showed that the top features of Syringe Brake were ease of setting the desired volume to be administered (86.1%; 4.21 ± 0.72), allowing the drug to be titrated safely (84.8%; 4.26 ± 0.77), and giving users the confidence to avoid overdosing the patient (82.1%; 4.21 ± 0.78). Those with hands-on experience with Syringe Brake rated significantly higher for all survey statements except on the perceived ability to prevent error arising from miscommunication (adjusted odds ratio, 1.58 [0.98–2.57]; $P = 0.062$).

Conclusions: Syringe Brake shows promising potential for adoption to prevent medication errors. The device serves as a constraint to prevent accidental overdose, caused by user unfamiliarity or autopilot administration.

Key Words: bolus administration, intravenous administration, intravenous push medication, medication error, medication safety, device

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Not all medication errors are created equal. The intravenous (IV) route of administration for medications often results in the most serious outcomes of medication errors.[1,2] Harm can easily result from IV medication administration because of the immediate bioavailability of intravenously administered drugs, the narrow therapeutic dose range of many IV medications, and the limitations in reversing systemic effects after IV administration.[3,4]

Besides, IV medications pose particular risks because of their greater complexity and the multiple steps required in their preparation, administration, and monitoring. In one study[2] on IV medication administration errors, 4 error types (wrong diluent mixture, wrong diluent volume, wrong bolus rate, and drug incompatibility) accounted for more than 91% of the errors; 27% of these errors were considered serious.

In 2015, the Institute for Safe Medication Practices developed consensus safe practice guidelines for adult IV push medications.[5] According to the guidance document, medication errors associated with the administration of the wrong dose and/or wrong concentration are believed to be more prevalent when frontline users are provided with a parenteral product that requires additional manipulation (partial doses, reconstitution, or dilution) at the bedside.

To minimize the need for manipulation outside the pharmacy sterile compounding area, the Institute for Safe Medication Practices recommends acquiring IV push medications in a ready-to-administer form to the greatest extent possible. The use of commercially available prefilled syringes or pharmacy-prepared syringes compared with routine provider-prepared medications has also been endorsed as a safer practice[6,7] and associated with fewer observed preparation and administration errors.[8]

However, concerns have been expressed about the perceived barriers to implementing this strategy, including unavailability of a pharmacy 24–7 compounding service, limited shelf life, high cost, and shortages of commercially available products.[5,9,10]

Where there are no commercially available ready-to-administer drugs suitable for IV push administration, using a more concentrated solution potentially increases the risk of an overdose.[10] The consequences of an overdose are more devastating when a high-alert medication[11] such as morphine is involved. In Singapore, morphine comes in a 10 mg in 1 mL solution and would typically need to be diluted to 10 mg/10 mL before IV administration. The medication is usually given in titrated doses of 1 to 2 mg, and the full 10-mg dose is rarely given all at once because this can result in serious or life-threatening respiratory depression.

In the haste of administration, a slip and lapse can occur. The user may mistakenly administer an incorrect dose or the entire contents of the syringe, resulting in a drug overdose. This error can also arise in a high-risk setting such as the emergency department where there is a need to simultaneously care for multiple patients.[12] With the many interruptions and distractions, communication failures in handoffs can happen. This can result in medication error,[13] especially when the drug is prepared and administered by different personnel.

Existing processes to safeguard administration errors include standardizing the medication use processes[14] such as having the user prepare his or her medication to avoid handoff issues (rules and policies), incorporating an independent double check by a second person (redundancy) before administration[15,16] and/or preparing the exact dose (fail-safe) with clear labeling.[17]

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FIGURE 1. Syringe Brake packaged in a Tyvek bag.

However, these interventions rely on staff experience and effective communication. For the latter workflow where excess medication is to be discarded to obtain the intended exact dose, the process may be made more tedious when a controlled drug (CD) such as morphine is involved. This is because time will be taken to procure the CD from the locked CD cupboard, document in the CD register, and prepare and purge the excess medication repeatedly.

An ideal safety measure would be one that takes into consideration the aforementioned factors, is easy to implement, and does not make the existing workflow more cumbersome. To improve medication safety, Changi General Hospital (CGH) in collaboration with the Singapore University of Technology and Design developed Syringe Brake, a disposable dosage flow restrictor to control the amount of medication delivered.

We introduce Syringe Brake as part of the IV morphine bolus administration workflow and aim to explore user experience and perception of its safety effectiveness in the emergency department through a survey questionnaire.

METHODS

Doctors and registered nurses working in the emergency department of 3 public tertiary hospitals in Singapore, namely, CGH, Sengkang General Hospital, and Singapore General Hospital, were recruited in the cross-sectional survey study. Before implementation, study participants were briefed and given an information sheet on the study protocol. The study protocol contained information such as the background and aim of the study, how it would be conducted, and how Syringe Brake should be used. A short product demonstration video on how Syringe Brake works was also shown to the users.

Materials

Syringe Brake, made from Styron 666H (Trinseo, Cilegon, Indonesia), is a disposable dosage flow restrictor device that can be attached onto a 10-mL Terumo syringe (Terumo Corporation, Binan, Philippines). It is packaged individually in a Tyvek bag (DuPont, Richmond, Virginia) after sterilization with ethylene oxide (Fig. 1).

Before the use of Syringe Brake, the drug, that is, morphine 10 mg, is first diluted with normal saline to 10 mL in a 10-mL syringe. Syringe Brake is then inserted with the ridge of the plunger and numbering facing up (Fig. 2A). The fitting should be securely mounted on the syringe plunger, with the device cap enveloping the plunger head (Fig. 2B).

Figure 3 shows the process of administration using Syringe Brake. The numbers on the section members or tabs "1" to "9" reflect the volume to be administered. The person who administers the drug sets the dose by breaking the tab corresponding to the different volume or dosage of medication. To administer 1 mL (morphine 1 mg), the user breaks the first tab numbered "1" and pushes the plunger till the next tab forms a mechanical barrier to the barrel flange. This also provides tactile feedback to the user to indicate that the desired volume has been delivered. To administer 2 mL, the user breaks the tabs numbered "1" and "2." The user should always refer to the graduation markings on the syringe barrel during drug administration to ensure an accurate dose delivery. When the drug administration has been completed and no further dose is required, Syringe Brake is then disposed of after use.

Survey Development

The survey was developed by the investigators based on user experience questionnaire samples, literature,[18,19] and expert consultation. The short questionnaire consisted of 3 parts with a total of 14 questions. The first part of the questionnaire asked participants about their demographic characteristics and involvement in morphine administration. For the second part, participants were asked to rate 11 survey items on a 5-point Likert scale, their experience, and perception of the safety effectiveness of Syringe Brake, with a rating of 1 being "strongly disagree" and 5 being "strongly agree." The last part of the survey was an optional open-ended question where participants were asked for their concerns or feedback on Syringe Brake design.

A 5-point Likert scale was specifically chosen to allow for a neutral response so that participants would not be compelled to leave the question unanswered, should they neither agree or disagree with it. Survey item 3 was reversed to keep respondents from answering carelessly and correct for agreement bias. A pilot survey was tested on 8 respondents to confirm that the questions were understood as intended, and subsequently revised according to the feedback received. Our Cronbach α revealed a score of 0.91, which suggested an excellent internal consistency of this 11-item survey questionnaire.

Implementation

Syringe Brakes were provided for use for a minimum 3-month period from September 1, 2018, to December 10, 2018. When an order for IV morphine bolus was placed, nurses would procure the morphine ampoule from the CD cupboard and obtain the

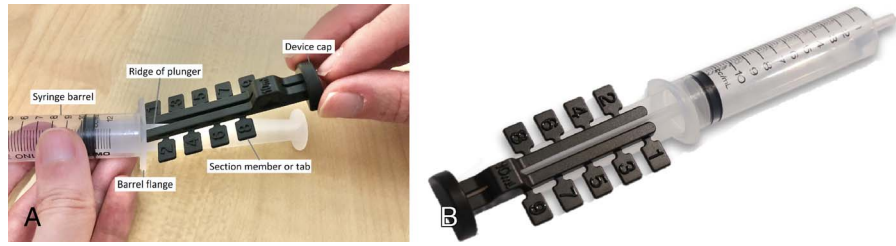

FIGURE 2. A, How Syringe Brake is inserted. B, Syringe Brake mounted on a 10-mL Terumo syringe.

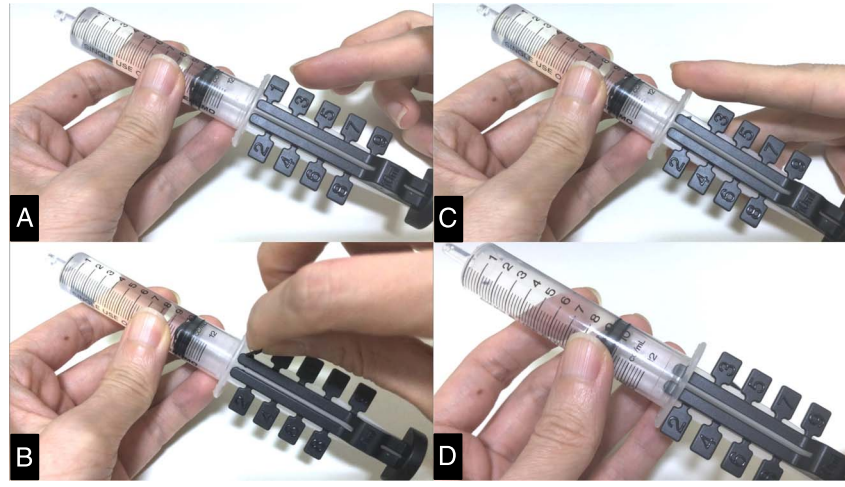

FIGURE 3. How to administer 1 mL using Syringe Brake. A, Locate the tab numbered "1." B, Lift the tab numbered "1" to break it. C, Push the plunger into the syringe barrel to administer 1 mL. D, The tab numbered "2" forms a mechanical barrier, limiting further administration.

necessary requisites for drug dilution. Syringe Brakes were stored close to the CD cupboard to improve user compliance and to minimize walking for the nurses during drug preparation. Except for CGH where purging of excess morphine was no longer required in the new workflow, existing medication use processes such as drug dilution, labeling of drug name and concentration, double checks, and drug administration by doctors in the hospitals were not affected with the implementation of Syringe Brake.

After 3 months of Syringe Brake implementation, paper-based questionnaires were distributed to study participants between December 10, 2018, and January 15, 2019. Because survey participation was on a voluntary basis, the questionnaire was kept short and anonymous to encourage participation. Reminders were sent at the end of December 2018 to obtain more responses. The collection of the survey questionnaires ceased mid-January 2019.

Sample Determination and Data Analysis

The total number of target respondents from the 3 sites was 665. With an estimated response rate of 50%, a margin of error of 4%, and a confidence interval (CI) of 95%, the minimum sample size required for this survey study was 316. Categorical data were presented as frequencies (percentage) where appropriate. Ratings of 1 and 2 on the Likert scale were grouped as "disagree," whereas 4 and 5 grouped as "agree." The Likert scale response was presented as frequency (percentage) with means score and its SD. Mixed-effects logistic regression was used to examine the association between the fixed effects of response ("agree" or "disagree") and the outcome of Syringe Brake hands-on experience ("yes" or "no") with the hospital as a random effect, to account for site differences. Adjusted odds ratio (aOR) with 95% CI was presented. Missing data were excluded from the analysis. Sensitivity analysis was performed by imputing the nonresponse with the best and worst scenarios, and there was no nonresponse bias. A 2-tailed P value of <0.05 was considered statistically significant. Statistical analysis was performed with SPSS statistical software, version 19.0 (IBM Corp, Armonk, New York).

Ethical Approval

The study was submitted to the Centralised Institutional Review Board of SingHealth under CIRB2018/2633 and was exempted from a formal review, as the participants were not subjected to additional risks or burdens beyond usual clinical practice. There was no direct patient contact, nor were patient data collected.

RESULTS

There were 380 responses received from the 3 hospitals, indicative of a response rate of 57.1% (380/665). A total of 377 participants were eligible and included in the study, as 3 participants had answered less than 50% of the questions. Table 1 shows the

TABLE 1. Characteristics of Participants (N = 377)

Variable	n (%)
Hospital	
CGH	182 (48.3)
SGH	108 (28.6)
SKH	87 (23.1)
Profession	
Nurse	265 (70.3)
Doctor	112 (29.7)
Years of experience*	
<2	87 (24.0)
2 to <5	113 (31.2)
≥5	162 (44.8)
Involved in morphine administration using Syringe Brake†	
Yes‡	279 (83.0)
No	57 (17.0)
Number of times involved in morphine administration using Syringe Brake§	
1 time	64 (23.7)
2 to 4 times	156 (57.8)
≥5 times	50 (18.5)
Hands-on experience with Syringe Brake†	
Yes	204 (60.7)
No	132 (39.3)

*Fifteen missing data.

†Forty-one missing data.

‡Includes those who witnessed but no hands-on experience with Syringe Brake.

§Nine missing data.

SGH, Singapore General Hospital; SKH, Sengkang General Hospital.

characteristics of participants and their involvement in morphine administration using Syringe Brake.

Table 2 shows the response of participants to the survey questionnaire. Overall, 77.5% of participants were satisfied with the use of Syringe Brake to prevent medication error (statement 11). The top features were ease of setting the desired volume to be administered (statement 2; 86.1%), allowing the drug to be titrated safely (statement 4; 84.8%), and giving users the confidence to avoid overdosing the patient (statement 5; 82.1%).

All the survey statements achieved at least a 72.9% agreement rate, except for statements 8 and 10. These 2 survey statements had the highest proportion of participants expressing neutrality.

When the questions were further analyzed based on participants' involvement with morphine administration using Syringe Brake (Table 3), those with hands-on experience with Syringe Brake rated significantly higher for all survey statements except on the perceived ability to prevent error arising from miscommunication (aOR, 1.58 [0.98–2.57]; $P = 0.062$).

Twenty participants provided additional feedback regarding their concerns and how Syringe Brake's design can be improved. Comments with the same theme were grouped and summarized in Table 4.

DISCUSSION

Our study findings revealed that doctors and nurses showed positive responses in their experience and perception of Syringe Brake safety effectiveness. According to Kirwan,[20] the nominal rate of human unreliability for generic tasks is highest when there is a totally unfamiliar task, performed at speed, with no real idea of likely consequence. We believe Syringe Brake prevents medication errors caused by unfamiliarity, haste, or accidental administration as the user would need to pause and think about the number of tabs to break before he or she can proceed to administer the desired dose. Even if the user were to be distracted by other tasks during the drug administration, an overdose can be prevented by the mechanical barrier of the tabs.

The intended benefit of Syringe Brake preventing wrong dose administration arising from miscommunication did not score as well compared with other safety features. One possible reason why the participants think otherwise could be that if there was a miscommunication on the concentration of the diluted drug, the person administering the drug may break the wrong number of tabs and still give the wrong dose. Thus, the use of Syringe Brake does not replace adequate communication and proper labeling. Another reason could be that the user may disregard the presence of Syringe Brake and break all the tabs to deliver the wrong medication dose. However, from the perspective of the person interacting with the device and administering the drug, this may seem counterintuitive. We consider the probability of users consciously breaking all the tabs without questioning is low and unlikely.

There were a few comments that the implementation of Syringe Brake does not take away the need for the user to know the drug dilution. Although we agree with the statement in general, we would also like to highlight that Syringe Brake does not require the user to have knowledge or experience of drug preparation to prevent medication error. In the event of an incorrect dilution, the presence of the device can still serve as a red flag to prompt the user to recheck the dilution process, as it is designed for 10 mL final volume administration. For example, if the user had used a smaller 5-mL syringe and diluted the medication wrongly, Syringe Brake would not have fit the plunger. Even if a 10-mL syringe was used and the user erroneously diluted to 5 mL, the plunger would need to be drawn far back to the 10-mL graduation marking on the barrel to allow for device insertion, making the preparation and administration seemingly odd.

The intent of survey statement 8 was to find out if participants would think using Syringe Brake would save the overall time

TABLE 2. Response of Participants Toward Use of Syringe Brake (N = 377)*

	Survey Statements	Disagree, n (%)	Neutral, n (%)	Agree, n (%)	Mean ± SD
	Ease of use				
1	It is easy to fit Syringe Brake onto the syringe.	4 (1.1)	78 (21.1)	288 (77.8)	4.10 ± 0.76
2	It is easy to set the desired volume to be administered.	5 (1.3)	47 (12.6)	322 (86.1)	4.21 ± 0.72
3	It is difficult to learn how to use Syringe Brake. (reverse)	32 (8.6)	53 (14.2)	289 (77.3)	4.01 ± 1.02
	Safety aspects				
4	Syringe Brake allows the drug to be titrated safely.	8 (2.1)	49 (13.0)	319 (84.8)	4.26 ± 0.77
5	Syringe Brake gives users the confidence to avoid overdosing patient.	7 (1.9)	60 (16.0)	307 (82.1)	4.21 ± 0.78
6	Using Syringe Brake can prevent medication error when the user does not realize diluted morphine (10 mg/10 mL) 1 mg equates 1 mL.	14 (3.7)	59 (15.6)	304 (80.6)	4.16 ± 0.83
7	Syringe Brake can prevent wrong dose administration arising from miscommunication when the drug is prepared and administered by a different person.	19 (5.0)	83 (22.0)	275 (72.9)	3.96 ± 0.87
	Efficiency				
8	For a process that requires excess dose to be discarded before administration, e.g., discards 9 mL when only 1 mg is required, Syringe Brake saves time by removing the necessity to discard excess morphine.	26 (7.0)	95 (25.4)	253 (67.6)	3.86 ± 0.91
	Acceptance				
9	I am willing to use Syringe Brake.	14 (3.7)	71 (18.9)	290 (77.3)	4.08 ± 0.87
10	I prefer using Syringe Brake compared with the previous workflow.	23 (6.1)	108 (28.8)	244 (65.1)	3.90 ± 0.96
11	Overall, I am satisfied with the use of Syringe Brake to prevent medication error.	9 (2.4)	75 (20.1)	290 (77.5)	4.11 ± 0.83

*Numbers may not add to 377 because of missing data.

TABLE 3. Agreement Response of Participants With Hands-on Experience (n = 204)* and No Hands-on Experience (n = 132)* With Syringe Brake

	Survey Statements	Agree, n (%)		aOR (95% CI)	*P*
		Hands-on	No Hands-on		
	Ease of use				
1	It is easy to fit Syringe Brake onto the syringe.	171 (86.4)	79 (60.3)	4.36 (2.53–7.53)	<0.001
2	It is easy to set the desired volume to be administered.	191 (94.1)	92 (70.8)	7.25 (3.55–14.81)	<0.001
3	It is difficult to learn how to use Syringe Brake. (reverse)	178 (88.1)	80 (61.1)	4.97 (2.83–8.72)	<0.001
	Safety aspects				
4	Syringe Brake allows the drug to be titrated safely.	186 (91.6)	96 (72.7)	4.22 (2.24–7.96)	<0.001
5	Syringe Brake gives users the confidence to avoid overdosing patient.	179 (88.2)	90 (68.7)	3.38 (1.92–5.95)	<0.001
6	Using Syringe Brake can prevent medication error when the user does not realize diluted morphine (10 mg/10 mL) 1 mg equates 1 mL.	171 (83.8)	95 (72.0)	2.03 (1.19–3.46)	0.010
7	Syringe Brake can prevent wrong dose administration arising from miscommunication when the drug is prepared and administered by a different person.	154 (75.5)	87 (65.9)	1.58 (0.98–2.57)	0.062
	Efficiency				
8	For a process that requires excess dose to be discarded before administration, for example, discards 9 mL when only 1 mg is required, Syringe Brake saves time by removing the necessity to discard excess morphine.	139 (68.8)	76 (58.0)	1.65 (1.03–2.65)	0.037
	Acceptance				
9	I am willing to use Syringe Brake.	169 (83.3)	85 (64.9)	2.72 (1.62–4.58)	<0.001
10	I prefer using Syringe Brake compared with the previous workflow.	134 (66.3)	74 (56.1)	1.60 (1.01–2.52)	0.046
11	Overall, I am satisfied with the use of Syringe Brake to prevent medication error.	174 (86.1)	80 (61.1)	4.04 (2.36–6.92)	<0.001

*Percentage presented is from total available responses and may not add up to n value because of missing data.

during the administration of a CD if the excess dose had to be discarded. We included this question on efficiency as part of the survey, as the emergency department is a busy and fast-paced working environment, and thereby, it can affect user adoption of Syringe Brake. Our study showed that 67.6% agreed with the survey statement, whereas 25.4% remained neutral. This could be, in part, due to some patients requiring only 1 dose of morphine. Hence, the use of Syringe Brake would be an additional step if the patient did not further require morphine doses. Conversely, for patients who required subsequent doses, Syringe Brake saves time, as it would obviate the need for the retrieval, documentation, and preparation of the CD repeatedly.

TABLE 4. Feedback (Optional) on Syringe Brake

Characteristics	Comments
Fitting	Loose-fitting on the syringe plunger (n = 3)
	May be difficult to fit (n = 1)
Numbering	Numbering on tabs to be clearer, e.g., color differentiation (n = 4)
	Numbering can be confusing (n = 1)
Material	Use material that is easier to break (n = 1)
	Tabs easily broke if a strong force is exerted on the plunger head (n = 2)
Knowledge	Need to know how to dilute the drug when using Syringe Brake (n = 2)
	More of familiarization since not all nurses handle morphine (n = 1)
Workflow	The person who administers should dilute the drug and apply device (n = 2)
	Bit of a hassle but overall improves safety (n = 1)
	Delays administration of opioids (n = 1)
Others	Acceptable device (n = 1)
	Cost concern (n = 1)
	Well done (n = 1)

It was interesting to find that, although most participants with hands-on experience were willing to use (83.3%) and satisfied with Syringe Brake to prevent medication error (86.1%), a smaller percentage of participants (66.3%) preferred using Syringe Brake to the previous workflow (statement 10). This finding is consistent with a phenomenon known as the knowledge-attitude-practice gap, which often occurs for preventive innovations: those that mitigate or avoid the possible occurrence of an unwanted future event.[21] The users may have gained awareness of the innovation and formed positive attitudes toward Syringe Brake but are not ready to act upon them. This is because the benefits of such innovations may not be immediately visible because the undesirable event of morphine overdose does not occur every day.

We did not find any significant relationship between the preference of using Syringe Brake with years of experience. Preference of workflow could be influenced by other factors. The incorporation of Syringe Brake into the workflow is seen as an additional step that slows down drug administration, especially if the hospital's previous workflow did not require purging of the excess dose. This could potentially compromise work efficiency, which is a competing priority against safety for doctors and nurses working in the busy emergency departments. Moreover, the users may already be used to the existing process and therefore not keen to adopt new ones. Concern for the additional cost of a device could be another factor. Compatibility with the values and needs of the users are known to affect the adoption of an innovation.[21]

One common feedback from our qualitative data was for Syringe Brake to have a clearer differentiation of numbering from the black background for different doses, for example, use of color. There was also a suggestion to use a material that is easier

to break. However, this would need to be balanced with the device material strength such that the tabs do not break easily as commented by 2 other participants. We also recognized that Syringe Brakes did not fit as well on 1 batch of syringes in CGH because of a slight variation of 10-mL Terumo syringe productions.

The applicability of Syringe Brake may be extended to other concentrated drugs besides morphine 10 mg/mL. For example, midazolam 5 mg/mL diluted to 10 mL to obtain a concentration of 0.5 mg/mL. Other potential drugs that may also be used include prediluted drugs that come in 10 mL such as oxycodone 10 mg/10 mL and phenylephrine 1 mg/10 mL. Given the varied drug concentrations that may be encountered, we reiterate the importance of labeling, that is, drug name and concentration.

There are some limitations in the study. Because not every participant had an official e-mail address, we chose not to administer an online survey. This resulted in paper-based questionnaires being administered with inevitably missing data when questions were skipped. Another challenge faced was the different shifts that participants were working, which made the collection of responses difficult. The response rate of 57.1% might have introduced selection bias and led to a higher-than-expected satisfaction survey. Because of normal staff turnover and postings of new doctors in public hospitals, some of the staff had less than 3 months' exposure to Syringe Brake implementation.

Finally, we did not further explore if there was any difference in response among the 3 hospitals; this may be investigated in future studies. Factors such as workplace culture,[22,23] medication error rate, morphine dose used per patient, and workflow among others may influence results.

CONCLUSIONS

Syringe Brake shows promising potential for adoption to prevent medication errors. In the absence of ready-to-administer injectable products, it is applicable for any drug diluted to a final volume of 10 mL, containing multiple individual doses. The device is designed to build in pauses and prevent accidental overdose, caused by user unfamiliarity or autopilot administration. The top features of Syringe Brake as perceived by our participants were ease of use, allowing the drug to be titrated safely, and giving users the confidence to avoid overdosing the patient. Perceptions of Syringe Brake were more favorable when users had hands-on experience. Preference for using Syringe Brake as part of the workflow could be influenced by other factors other than safety.

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