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# High-alert medication administration and intravenous smart pumps: A descriptive analysis of clinical practice

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ABSTRACT

*Background:* The Institute for Safe Medication Practices (ISMP) describes high alert medications (HAM) as medications that represent a heightened risk of patient harm when used in error. IV smart pumps with dose error reduction systems (DERS) were created to help address medication administration errors. Compliance with DERS provides a measure of how accurately a hospital uses smart pump technology to reduce IV medication error.
*Objective:* The primary purpose of this research was to use the REMEDI dataset, an aggregate, multi-hospital database inclusive of smart pump analytics, to improve the current understanding of clinical practices for IV HAM administration.
*Methods:* Descriptive analyses and analysis of variance (ANOVA) were used to test for differences in the mean DERS alert override rate, and mean DERS alert override to reprogram ratio between non-HAM and HAM overall, by hospital system, and by pump type.
*Results:* High mean override rates for non-HAM (73.8%) and HAM (75.8%) and high override to reprogram ratios for both non-HAM (7.30) and HAM (9.92) were seen. No significant differences were found in override rates ($p = 0.23$) and override to reprogram ratios ($p = 0.06$) between non-HAM and HAM. By hospital system, significant variability in override rates and override to reprogram ratios were seen. By pump type, there were no significant differences in the mean override rates (Baxter: $p = 0.09$; BD $p = 0.34$; ICU Medical $p = 0.18$) and the mean override to reprogram ratios (Baxter $p = 0.84$; BD $p = 0.03$; ICU Medical $p = 0.63$) between non-HAM and HAM.
*Conclusions:* These findings indicate that the majority of alerts generated are bypassed by clinicians at the point of care, a symptom of alert fatigue. Given the potential for significant patient harm with HAM and the high DERS alert override rates that routinely occur during IV medication administration, this study provides further support for clinician-driven IV smart pump innovation to improve alert fatigue.

## Introduction

IV smart infusion pumps (IV smart pumps) equipped with dose-error reduction system (DERS) were created and implemented across hospitals to help address the errors associated with intravenous medication administration. While smart infusion pumps have been shown to improve safety and prevent IV medication administration errors, a problem described extensively in the literature, the use of these pumps requires continuous monitoring and ongoing improvements in their clinical use to achieve optimal safety benefits.[1–10]

*Abbreviations:* (RCHE), Regenstrief Center for Healthcare Engineering; (REMEDI), Regenstrief National Center for Medical Device Informatics; Dose-error reduction system, (DERS); High alert medications, (HAMs)

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The Institute for Safe Medication Practices (ISMP) provides an annual list of *Targeted Medication Safety Practices for Hospitals*.[11] The 2018–2019 list contained a recommendation regarding the use of programmable infusion pumps with DERS specifically for all high alert medication (HAM) infusions.[11] HAMs are specific medications that when used in error, have the potential to cause the greatest patient harm.[12] Examples of HAMs include heparin, insulin, and opioids.[12]

IV smart pumps with DERS include drug libraries, which are designed to be customized for different patient care areas. Most institutions that use IV smart pumps implement a combination of soft limits and hard limits for generating alerts. While hard limits provide definite stopping points without exception, soft limits serve as a guideline, as the clinician can choose to override the alert, reprogram, or cancel the intended infusion. Cancelation and reprogram clinical actions often represent the intention of the clinician to review and hopefully correct the potential mistake. Conversely, an override clinical action represents the clinician ignoring the generated alert which creates the potential for a medication error. Since IV smart pump alert data do not provide enough information on what exactly happened after a clinician cancels a soft alert, this study focused on the actions of reprogramming and overriding which have more interpretable consequences.

Although DERS alerts can help safeguard infusion safety, misaligned drug limit settings can contribute to alert fatigue.[13] A report in 2015 from Intermountain Healthcare identified two common contributing factors to infusion pump related patient care errors: alert fatigue and poorly managed alert settings. An analysis of more than 113,000 alerts identified a significant number of alerts that were overridden and characterized as “nuisance” alerts that could desensitize nurses to potentially important information.[14]

ISMP has also recommended that hospitals review and revise drug library settings and analyze smart pump informatics data to ensure that their institutions’ actions reflect changes in clinical practice.[15] ISMP surveyed nurses and pharmacists who use smart pumps. One in ten respondents reported that smart pump data is never analyzed within their organizations. Additionally, only half of the respondents that analyze pump data actually review the actions taken by a user in response to an alert.[16] From these results, it is evident that there is room for improvement by utilizing smart pump analytics to improve infusion workflows and patient safety.

The primary purpose of this research was to use the Regenstrief National Center for Medical Device Informatics (REMEDI) dataset to better understand the current clinical practices of soft alerts for high alert IV medication administration using IV smart pumps. In support of the primary purpose, the following research aims were developed:

Aim 1 Describe the number of alerts, DERS alert override rates, and DERS alert override to reprogram ratios by individual medications commonly used across multiple hospital systems.

Aim 2 Determine if there is a difference in the mean number of alerts, mean DERS alert override rates, and mean DERS alert override to reprogram ratios between non-HAM and HAM overall and by hospital system.

Aim 3 Determine if there is difference in the mean number of alerts, mean DERS alert override rates, and mean DERS alert override to reprogram ratios for HAM generated between three commonly used large volume IV smart pump types (Becton Dickinson/Alaris (BD), Baxter/Sigma; and ICU Medical/Plum A).

## Materials and methods

### Data source

The infusion alert data for this study were obtained from the REMEDI alert database. REMEDI is a community of practice supported by the Regenstrief Center for Healthcare Engineering (RCHE) at Purdue University. The REMEDI infrastructure was created by and is maintained by RCHE and Information Technology at Purdue (ITaP), all of which is made possible with primary funding from the Regenstrief Foundation. Prior literature has described the REMEDI database in detail.[17]

As of July 2018, REMEDI membership represented 417 facilities in 31 states, Costa Rica, India, and the United Arab Emirates. Available data in the REMEDI system includes detailed information on 37 million DERS programming alerts as well as DERS compliance percentages, and drug limit libraries.

### Data preparation

The Institutional Review Board protocol (#1805020629) was submitted and given exempt status by Purdue University. IV smart pump alert data available for the 2016 calendar year were used, and initially included 17 hospital systems each with 12-months of relevant alerts data. In order to make the most clinically relevant comparisons, a list of common medications that were used by all of the 17 the hospital systems were identified. This list was reviewed and verified by two pharmacists prior to conducting the analysis. Through this process, a list of 36 medications, which were common to 15 out of the 17 hospital systems, were compiled, resulting in a final sample for analysis of 15 hospital systems with 46 individual hospitals. Of the 15 hospital systems included in the analyses, 10 hospital systems used BD IV smart pumps, 3 used Baxter/Sigma IV smart pumps, and 2 used ICU Medical/Plum A IV smart pumps. Of the 36 common drugs on our list, 19 were identified as HAM and 17 were identified non-HAM based on the ISMP classification.[12]

### Methods

Data from all 15 hospital systems on the total number of alerts per month, the associated clinical actions, categorized as DERS alert override or DERS alert reprogram action, were obtained from the REMEDI dataset. These data were used to calculate: (1) DERS alert override rate (number of override alerts divided by number of total alerts[1]), and (2) DERS alert override to reprogram ratio (number of override alerts divided by number of reprogram alerts) by hospital system, by medication, and by pump type. The higher the override rate and override to reprogram ratio are, the greater the number of alert override clinical actions were performed by the end users.

An analysis of variance (ANOVA) (alpha = 0.025) was performed using STATA 14.2 (StataCorp LP, Texas, USA) to compare differences in the DERS alert override rate and DERS alert override to reprogram ratio in HAM versus non-HAM. Since the sample size of each medication varied within each hospital system, the weighted override rates for two-group samples were calculated. The weighed override rates were defined as the original rates multiplied by the weighted coefficient, which is the ratio of the sample size of a specific medication to that of all medications within each hospital system.

## Results

Overall, 247,792 non-HAM alerts and 242,481 HAM alerts were analyzed. The weighted mean DERS alert override rate for all non-HAM was 73.8% and for all HAM was 75.8% (p-value 0.23). The mean DERS alert override to reprogram ratio for all non-HAM was 7.30 (95% CI 5.54–9.05) and for all HAM was 9.92 (95% CI 7.86–11.98) (p-value = 0.06).

The DERS mean override rate for individual non-HAM ranged between 48.7% (pantoprazole) and 83.8% (blood products). Similarly, the

[1] Total alerts include number of alerts associated with three clinical actions: override, reprogram, and cancel.

**Table 1**
Weighted DERS alert override rate and override to reprogram ratio comparison of non-HAM and HAM for each hospital.

| Hospital ID | Category | N alerts | Weighted Mean Override Rate | Weighted p-value | Override to Reprogram Ratio | p-value |
|---|---|---|---|---|---|---|
| 1 | Non-HAM | 12,278 | 91.7% | 0.47 | 12.90 | 0.68 |
| | HAM | 4933 | 87.1% | | 16.44 | |
| 2 | Non-HAM | 50,341 | 65.8% | 0.61 | 1.94 | 0.73 |
| | HAM | 25,567 | 61.1% | | 2.28 | |
| 3 | Non-HAM | 9954 | 68.9% | 0.10 | 4.84 | 0.16 |
| | HAM | 19,584 | 77.2% | | 7.94 | |
| 4 | Non-HAM | 3201 | 80.9% | 0.02 | 3.84 | 0.26 |
| | HAM | 1006 | 64.9% | | 1.74 | |
| 5 | Non-HAM | 7103 | 78.8% | 0.09 | 7.24 | 0.22 |
| | HAM | 12,806 | 83.4% | | 12.29 | |
| 6 | Non-HAM | 3980 | 72.3% | 0.00 | 21.23 | 0.94 |
| | HAM | 5401 | 88.2% | | 20.36 | |
| 7 | Non-HAM | 1921 | 83.0% | 0.06 | 10.85 | 0.33 |
| | HAM | 4059 | 91.9% | | 19.09 | |
| 8 | Non-HAM | 1128 | 70.2% | 0.97 | 5.67 | 0.48 |
| | HAM | 2179 | 70.4% | | 9.37 | |
| 9 | Non-HAM | 1835 | 67.9% | 0.02 | 7.83 | 0.93 |
| | HAM | 1637 | 82.7% | | 8.11 | |
| 10 | Non-HAM | 41,025 | 59.3% | 0.00 | 6.01 | 0.33 |
| | HAM | 67,059 | 76.4% | | 8.00 | |
| 11 | Non-HAM | 88,538 | 83.9% | 0.33 | 8.51 | 0.49 |
| | HAM | 70,129 | 80.9% | | 12.70 | |
| 12 | Non-HAM | 2891 | 80.3% | 0.24 | 5.89 | 0.09 |
| | HAM | 3985 | 87.1% | | 14.51 | |
| 13 | Non-HAM | 15,870 | 72.0% | 0.70 | 6.55 | 0.30 |
| | HAM | 20,824 | 73.7% | | 11.25 | |
| 14 | Non-HAM | 11,291 | 61.4% | 0.05 | 2.68 | 0.54 |
| | HAM | 8884 | 41.0% | | 1.96 | |
| 15 | Non-HAM | 6520 | 79.6% | 0.65 | 6.05 | 0.76 |
| | HAM | 4284 | 76.0% | | 4.94 | |

DERS mean override rate for individual HAM ranged from 49.6% (potassium phosphate) to 83.3% (morphine). The DERS mean override to reprogram ratio ranged from 2.8 (pantoprazole) to 18.5 (nitroglycerin) for non-HAM and ranged from 2.6 (potassium phosphate) to 23.3 (morphine, oxytocin) for HAM. The full table of medications with mean DERS override rates and mean DERS override to reprogram ratios are located in Appendix 1.

The weighted mean DERS alert override rates and mean DERS alert override to reprogram ratio for each of the 15 hospital systems are displayed in Table 1 (unweighted comparisons in Appendix 2). The highest mean override rate for non-HAM was 91.7% in hospital ID 1. The highest mean override rate for HAM was 91.9% in hospital ID 7. Hospital 6 had the highest mean override to reprogram ratios for both non-HAM and HAM at 20.36 and 21.23, respectively. Statistically significant differences were seen between non-HAM and HAM mean override rates for hospital IDs 4,6,9, and 10.

Table 2 describes the number of alerts, DERS override rate, and DERS override to reprogram ratio by smart pump type. DERS alert override rates ranged between 48.9% for ICU Medical/Plum A pumps (n = 30,982 alerts) and 72.7% for BD pumps (n = 381,908 alerts). Additionally, a comparison of HAM and non-HAM DERS override rates and override to reprogram ratios were calculated by pump type. There were no statistically significant differences in mean override rates and mean override to reprogram ratios between non-HAM and HAM by pump type. These results are listed in Table 3.

**Table 2**
Descriptive data comparing IV smart pump type by DERS alert override rate, and DERS alert override to reprogram ratio.

| Pump Type | N pumps | Total number of alerts | Override rate | Override to reprogram ratio |
|---|---|---|---|---|
| Baxter | 108 | 97,326 | 61.6% | 6.45 |
| BD | 360 | 381,908 | 72.7% | 10.42 |
| ICU Medical | 72 | 30,982 | 48.9% | 3.88 |
| Total | 540 | 510,216 | 67.3% | 8.69 |

**Table 3**
Comparison of Non-HAM and HAM by pump type.

| Pump Type | Category | Mean Override Rate | p-value | Mean Override to reprogram ratio | p-value |
|---|---|---|---|---|---|
| Baxter | Non-HAM | 56.30% | 0.09 | 6.14 | 0.84 |
| | HAM | 66.37% | | 6.74 | |
| BD | Non-HAM | 71.67% | 0.34 | 8.32 | 0.03 |
| | HAM | 73.62% | | 12.21 | |
| ICU Medical | Non-HAM | 43.00% | 0.18 | 4.36 | 0.63 |
| | HAM | 54.19% | | 3.45 | |

## Discussion

These results support that high DERS alert override rates and high DERS alert override to reprogram ratios were common in hospitals, occurred with different medications, and included all IV smart pump types analyzed in this review. There were limited differences in these measurements between non-HAM and HAM even though HAMs are recommended to be used with a greater situational awareness. The intended purpose of soft limits in IV smart pumps is to warn the user about the possibility of an impending medication dosing error and these findings indicate that the majority of the IV smart pump alerts generated are being bypassed.

These bypassed alerts did not result in IV medication error reduction because they did not change the clinician's intended medication administration. The presence of such a high degree of bypassed alerts adds to the complexity of IV smart pump programming by contributing to the problem of alert fatigue. This is evidenced by the lessons learned from studies on alarm fatigue from routine physiological monitoring.[18]

In comparing the DERS alert override rates and DERS alert override to reprogram ratios between non-HAM and HAM, three hospital systems, IDs 6, 9, and 10, saw significantly higher mean DERS alert

override rates for HAMs. These results demonstrate the variability for DERS alert overrides and the need for quality improvement at the hospital level. Since institutions often set their own drug libraries and alerting practices, clinicians could benefit from examining which HAM alerts are more often overridden at their institution to better inform how these institution-specific alerts should be set and changed. Once equipped with this information regarding alerts, hospitals can elect to update their drug library limits, provide nurse education, and communicate with smart pump users regarding the trends identified during this analysis.[19]

In comparing the differences in the total number of DERS alerts, DERS alert override rates and DERS alert override to reprogram ratios between the three IV smart pump types, no significant differences were seen.[20] However, differences were recognized in the total number of alerts. Even after accounting for the higher number of hospitals in this sample that used BD pumps, BD pumps still produced the largest number of alerts (N = 1061 alerts per pump).

Interestingly, BD also had the highest mean DERS alert override to reprogram ratio among the three pump types. Thus, from the broader perspective of alert fatigue, the BD pump generated the largest number of non-actionable IV smart pump alerts. It is possible that there is a positive relationship between total alerts and high alert override rates. These hypotheses are worthy of future empiric inquiry.

### *Strengths and limitations*

While this was an informatics-driven, multi-hospital study of selected hospital members of the REMEDI community, several limitations are worthy of consideration. First, there are differences in the ways that the three pump manufacturers define one unique infusion, which consequently affects how alerts are generated for the pump users. These differences become even more complicated when multiple alerts occur during a single infusion. Because this study was a secondary analysis of existing data, accounting for these differences was not possible. Another limitation is that there were differences in drug limit settings for the same drug across the different hospital systems, which could contribute to varying levels of alerts between systems. Next, these analyses were not able to consider any special events, such as clinical policy changes or process improvement initiatives that may have occurred during the period in which data were generated. Finally, these analyses focused specifically on actions of alert override or infusion reprogram after an alert was generated. Therefore, the results of this study do not capture any infusions that were cancelled as a result of the generated alert and conclusions cannot be made on the impact of cancellation clinical action on alert fatigue and patient safety.

Even with these limitations, using widely available smart pump analytics to improve the understanding of infusion practice of both HAM and non-HAM across a large set of hospitals will help to improve understanding of clinical practice. This improved understanding can then help to inform meaningful improvements in IV smart pump medication administration, enhanced patient safety, and inform future research.

## Conclusion

The Food and Drug Administration (FDA) has been advocating for the inclusion of human factors engineering as part of the medical device design process since the release of their guidance document in 2000. The FDA now requires usability testing as a vital part of the product development and the approval process.[21] The goal of this approach is to minimize user-related errors, and to promote the design of medical devices that can be used safely and effectively in the environment for which they are intended.[21] While these requirements exist for any new devices being introduced into the market, most of these requirements were not in effect during the design and approval of the current IV smart pump technology.[20]

This study further demonstrates the limited human factors engineering involved in IV smart pump technology by describing the frequency and clinical actions of high alert and non-high alert medication infusion alerts among a large set of hospitals. The results of this study support the need to improve the system of alerts in IV smart pumps.

Future studies linking infusion alerts and clinical quality measures may provide further insight into improving the safety of infusion practice. There is a clear need for innovation in IV smart pumps in order to improve both overall usability and decrease unnecessary alerts. If the majority of bypassed, non-actionable IV smart pump alerts could be eliminated, both alert fatigue and IV smart pump medical error would likely be improved. While it is the responsibility of current IV smart pump manufactures to develop technology that is designed using a human factors approach, clinicians should carefully examine their current IV smart pump alert practices to in order to minimize the high level of alert bypassing and the impact of alert fatigue.

## Declarations of interest

None.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sapharm.2019.02.007.

## Appendix

*Appendix 1a. Total Alerts, Mean DERS alert override rate and DERS alert override to reprogram ratio for non-HAMs*

| Drug name | Total alerts | Mean DERS Override Rate | DERS Override SD | DERS Override to reprogram | DERS Override to Reprogram SD |
|---|---|---|---|---|---|
| Acetylcysteine | 2607 | 63.9% | 31.4% | 6.9 | 5.8 |
| Acyclovir | 4711 | 56.9% | 26.6% | 3.1 | 3.3 |
| Blood products | 36442 | 83.8% | 13.8% | 13.8 | 13.3 |

| | | | | | |
|---|---|---|---|---|---|
| Calcium gluconate | 8239 | 65.2% | 34.1% | 9.3 | 12.4 |
| Furosemide | 6739 | 68.8% | 21.9% | 5.4 | 5.3 |
| IV fluids | 79406 | 70.6% | 28.2% | 9.0 | 8.2 |
| IVIG | 6368 | 79.7% | 19.9% | 13.7 | 12.7 |
| Levetiracetam | 5985 | 68.9% | 28.9% | 6.6 | 5.9 |
| Methylprednisolone | 5231 | 74.0% | 20.1% | 12.4 | 15.6 |
| Nicardipine | 3771 | 68.2% | 26.3% | 5.7 | 8.1 |
| Nitroglycerin | 2233 | 72.8% | 25.2% | 18.5 | 48.7 |
| Pantoprazole | 11345 | 48.7% | 28.8% | 2.8 | 2.7 |
| Phytonadione | 1336 | 50.1% | 34.8% | 3.0 | 3.9 |
| Pipercillin/tazobactam | 34931 | 51.9% | 31.8% | 4.2 | 5.0 |
| Sodium phosphate | 4963 | 53.1% | 34.3% | 4.1 | 4.5 |
| Valproate | 2616 | 68.5% | 24.7% | 5.8 | 5.4 |
| Vancomycin | 40869 | 58.6% | 23.9% | 3.3 | 2.7 |

*Appendix 1b. Total alerts, mean DERS alert override rate and DERS alert override to reprogram ratio for HAMs*

| Drug name | Total alerts | DERS Mean Override Rate | DERS Override SD | DERS Override to reprogram | DERS Override to Reprogram SD |
|---|---|---|---|---|---|
| Amiodarone | 7686 | 51.5% | 21.5% | 3.2 | 3.1 |
| Diltiazem | 6653 | 69.1% | 17.8% | 4.5 | 3.2 |
| Dobutamine | 6865 | 79.0% | 20.9% | 16.0 | 32.8 |
| Dopamine | 3245 | 69.0% | 16.8% | 7.9 | 17.0 |
| Epinephrine | 10 | 74.3% | 24.4% | 12.2 | 9.3 |
| Fentanyl | 11964 | 75.8% | 14.4% | 7.9 | 9.4 |
| Heparin | 24386 | 68.2% | 14.1% | 6.8 | 7.1 |
| Insulin | 12789 | 75.3% | 21.2% | 7.4 | 6.6 |
| Magnesium sulfate | 23989 | 66.6% | 24.1% | 7.3 | 8.4 |
| Morphine | 12904 | 83.3% | 17.4% | 23.3 | 37.4 |
| Norepinephrine | 15971 | 78.6% | 16.8% | 14.5 | 17.9 |
| Oxytocin | 18829 | 64.7% | 28.7% | 23.3 | 36.1 |
| Phenylephrine | 9341 | 76.4% | 23.5% | 8.8 | 7.0 |
| Potassium chloride | 32528 | 51.1% | 23.8% | 2.9 | 3.5 |
| Potassium phosphate | 7088 | 49.6% | 28.2% | 2.6 | 2.6 |
| Propofol | 27115 | 81.3% | 10.3% | 7.1 | 5.4 |
| Rituximab | 6242 | 77.0% | 27.5% | 15.5 | 15.1 |
| Sodium chloride 3% | 4246 | 65.9% | 34.1% | 15.7 | 23.6 |
| TPN | 10630 | 64.9% | 25.0% | 7.5 | 9.0 |

**Appendix 2. Unweighted DERS alert override rate and override to reprogram ratio comparison of non-HAM and HAM for each hospital**

| Hospital ID | Category | N alerts | Unweighted Mean Override Rate | Unweighted p-value |
|---|---|---|---|---|
| 1 | Non-HAM | 12,278 | 80.2% | 0.73 |
| | HAM | 4933 | 82.9% | |
| 2 | Non-HAM | 50,341 | 32.7% | **0.02** |
| | HAM | 25,567 | 57.0% | |
| 3 | Non-HAM | 9954 | 69.7% | 0.57 |
| | HAM | 19,584 | 73.0% | |
| 4 | Non-HAM | 3201 | 55.9% | 0.74 |
| | HAM | 1006 | 59.2% | |
| 5 | Non-HAM | 7103 | 78.6% | 0.55 |
| | HAM | 12,806 | 80.2% | |
| 6 | Non-HAM | 3980 | 74.9% | 0.45 |
| | HAM | 5401 | 78.8% | |
| 7 | Non-HAM | 1921 | 78.6% | 0.88 |
| | HAM | 4059 | 77.2% | |
| 8 | Non-HAM | 1128 | 67.8% | 0.93 |
| | HAM | 2179 | 68.3% | |
| 9 | Non-HAM | 1835 | 65.0% | 0.44 |
| | HAM | 1637 | 58.1% | |
| 10 | Non-HAM | 41,025 | 65.9% | 0.15 |
| | HAM | 67,059 | 73.1% | |
| 11 | Non-HAM | 88,538 | 80.1% | 0.81 |
| | HAM | 70,129 | 79.4% | |
| 12 | Non-HAM | 2891 | 67.9% | 0.26 |
| | HAM | 3985 | 78.1% | |
| 13 | Non-HAM | 15,870 | 68.1% | 0.81 |
| | HAM | 20,824 | 69.4% | |
| 14 | Non-HAM | 11,291 | 40.5% | 0.98 |
| | HAM | 8884 | 40.8% | |
| 15 | Non-HAM | 6520 | 45.5% | 0.05 |
| | HAM | 4284 | 67.6% | |

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