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UNITED STATES ARMY AEROMEDICAL RESEARCH LABORATORY

Efficacy of Medical Device Alarm Integration into a Simulated H-60 Integrated Communication System

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U.S. Army critical care flight paramedics were recruited as subjects for this study. Subjects participated in two testing scenarios: one with patient monitor alarms integrated into their communication lines and one without integrated alarms (the control condition). Testing took place in a simulated HH-60 interior with two priority-level patients per testing scenario, one on either side of the interior. Subjects provided care to these two patients for 30 minutes per scenario. After both scenarios were complete, the subjects were given a questionnaire to obtain their feedback on alarm integration.

15. SUBJECT TERMS

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14. Abstract (continued)
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The feedback obtained from the subjects provided a list of perceived benefits, drawbacks, and improvements related to the integration of medical device alarms into the intercommunication set.

Conclusions
Although the study was underpowered, the trends in the data indicate a benefit to the medics when integrating medical device alarms. When coupled with strongly favorable end-user feedback, the results provide justification for pursuing the effort of integrating alarms and performing future studies with improved integration systems to optimize the potential of the system.

15. Subject Terms (continued)
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Efficacy of Medical Device Alarm Integration into a Simulated H-60 Integrated Communication System

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INTRODUCTION

During en route care in the aeromedical environment, medics regularly use standard-issue medical devices, such as patient monitors and ventilators, to monitor patient vital signs and provide treatment. These medical devices use visual and audible alarms to alert medics to issues with the patient or the device itself; however, in the aeromedical environment, these alarms are rendered ineffective by the conditions in the cabin. The audible alarms cannot be heard over the ambient noise, as the average noise level in the cabin with closed windows and doors was measured by the U.S. Army Aeromedical Research Laboratory's (USAARL, pronounced yoo-suh-rul) Warfighter Performance Group (WPG) to be 110 decibels A-weighted (dBA), whereas the loudest audible alarm on the patient monitor was measured at 81.6 dBA from a distance of approximately (∼) 3 feet. In the absence of audible alarms, medics must rely on visual alarms. However, these visual cues are often difficult or impossible to perceive because of several potential factors: lighting conditions, such as glare from the sun or flickering light caused by the rotating helicopter blades make it difficult to perceive visual alarms, the position of the medic or the device may be such that the medic cannot see the visual alarm, and in blackout conditions medics will place a blanket over medical devices specifically to block out lights. In these situations, the medic has no method of being notified that an alarm is sounding and that their patient may be decompensating.

The Enroute Care Group (ECG) at USAARL performs Airworthiness Certification and Evaluation testing to ensure that all equipment that is intended for use aboard U.S. Army rotary-wing aircraft is reasonably functional and durable in the unique conditions of the extreme environment. Part of Airworthiness Certification and Evaluation testing

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includes a risk assessment, the results of which are published in the Aeromedical Certification Memorandum (ACM) (Department of the Army. Aeromedical Certification Memorandum for Patient Movement Items Aboard Army H-60, UH-72, CH-47, and MH Rotary-Wing Aircraft. Unpublished report, ACM-2018 Revision 4, November 2021. U.S. Army Aeromedical Research Laboratory.), which lists all limitations and restrictions on Patient Movement Items used by medical personnel on U.S. Army rotary-wing aircraft. The following warning is listed in the ACM as a limitation/restriction for all patient movement items: "Auditory alarms or cues on medical devices are difficult to hear in the aviation environment. Care providers must know to rely on visual indications from the display to determine if there is an alarm condition or system malfunction." One of the common warnings for ventilators in the ACM reads, "Because auditory alarms are difficult to hear in the noisy aviation environment, care providers must rely on visual indications from the display screen to determine if there is an alarm condition or system malfunction. Failure to detect the visual alarm could severely compromise patient's condition and possibly lead to death. In order to mitigate risk to a negligible level, one-on-one monitoring is recommended." While one-on-one monitoring is ideal, it is not always the case for care providers. A 2019 online survey performed by the ECG gathered feedback from active duty military medical specialists.[1] One of the questions in that survey asked how many patients the respondents typically cared for at once, and 51 respondents replied. The respondents typically cared for one patient (49.0% of respondents), two patients (41.2% of respondents), or three patients (9.8% of respondents). A method must be developed by which care providers may monitor multiple patients at once and be notified quickly of events that could negatively affect patient mortality.

This study examined the effect that integrating medical device alarms into the medic's intercommunication set (ICS) headset had on care provided and time delegation. This study also gathered end-user feedback on the potential benefits, drawbacks, and necessary improvements when integrating the alarms.

METHODS

To meet the inclusion criteria, subjects had to be critical care flight paramedics, U.S. Army active duty members, reserves, or National Guard, in good health, and able to hear at a normal level. Each subject underwent a hearing test performed by the WPG after the consenting process, but before testing began, to ensure they met the inclusion criteria of having normal hearing. Note that the inclusion criteria did not control for medic experience level, although most participants were experienced medics.

During testing, subjects performed patient care tasks for two 30-minute (min) testing scenarios: In scenario (1), device alarms were integrated into a simulated aircraft ICS system; and in scenario (2), device alarms were not integrated into the ICS (control condition). These two scenarios were counterbalanced to avoid biasing the data.

Inside the ear cups built into the Head Gear Unit-56/personal helmets, the medics use small, wired, foam-encased earpieces called communication ear plugs (CEPs), which connect to the ICS system and, combined with the helmet's built-in microphone, allow the medic to communicate with the rest of the crew. For this study, multiple audio inputs were integrated into the medic's CEPs to mimic the communication conditions in an actual aircraft. For the integrated scenario only, medical device alarms were played in the medic's CEPs at ∼85 decibels (dB). During a typical flight, the medic will engage in communications with the rest of the crew and will hear the pilots over the ICS. To mimic this crew communication, a medical validator was connected to the ICS outside of the HH-60 simulator. They communicated information to the medics that they would be able to distinguish on a real patient, but not the manikins that were used as simulated patients, and to remind them to verbalize their treatments. The medical validator and the subject's microphone were set so that their speaking volume was ∼80 dB. In a regular aircraft, there is an abundance of ambient noise, mainly from the rotary blades. A recording of this ambient noise was played into the CEPs at ∼75 dB, which is adjusted from the 110 dBA of the cabin to account for noise reduction provided by the helmet ear cups and the foam of the CEPs. Safety was a priority when choosing the dB levels of the audio inputs subjects experienced during the study. The audio level of the ambient noise was chosen to replicate what is experienced in the actual aircraft, and the dB levels of the alarms and microphones were set within acceptable safety limits.[2–5]

Each scenario utilized two simulated patients, and each patient was preprogrammed to have four decompensation events to trigger device alarms, for a total of eight alarms per 30-min scenario. The four patients were programmed with unique injury patterns and decompensation events, and the patients were alternated in a defined pattern between the integrated and nonintegrated scenarios to prevent biasing the data. Testing took place in the interior of an HH-60 Black Hawk cabin simulator, which was custom-built for this and other projects by the USAARL Fabrication Shop. All subjects were provided all of the medical equipment and supplies listed in the current Army Air Ambulance Medical Equipment Set.

SimMan3G manikins were used as simulated patients and produced digital vital signs. The vitals from the SimMan3G Laerdal Learning Application software were transferred to a Dynasthetics VitalsBridge device that converted the vitals into a readable format for the Zoll Propaq MD patient monitors, which then displayed those vital signs for the medic. The Zoll Propaq MD is the patient monitor in the current Medical Equipment Set, ensuring medic familiarity with the monitor.

A custom ICS equivalent was built to allow the research team easy volume control and amplification for all audio

inputs. Audio levels within the headset were measured before each run using a test fixture and sound-level meter to ensure safe and correct sound levels.

After the subjects completed both testing scenarios, they were given a questionnaire that asked questions regarding the benefits and drawbacks of integration, how the scenarios compared to each other, how they experienced alarm integration, such as if it was a distraction or helpful, and if they perceived hearing the alarms to detract from patient care.

After testing was complete, experienced medics reviewed the video data and created an Excel spreadsheet with time stamps of the start and stop time of each of the subject's actions, linking actions to specific patients, specifying the type of action, and adding any notes the medic had for each action. The experienced medics also marked alarm time stamps in this sheet, as well as when the subjects reacted to each alarm and when they treated the source of the alarm. From this spreadsheet, all summations and calculations were made, and the statistical analysis for this study was performed in R Studio 4.1.1.

RESULTS

Although the initial recruitment goal was at least 15 subjects, based on a power analysis for this study design, only six completed data collection. This was due to the effects of the coronavirus disease 2019 (COVID-19) pandemic caused by Severe Acute Respiratory Syndrome Coronavirus 2, such as a travel radius that was put in place, which prevented medics from traveling to the test site, and multiple cancellations due to illness as well as rapidly changing schedules and regulations.

One of the metrics evaluated to compare the integrated and nonintegrated scenarios was average reaction time. Reaction time was measured from when the alarm sounded to when the medic acknowledged it. Acknowledgment was denoted when subjects either verbally indicated that they acknowledged the alarm or, if they forgot to verbally indicate acknowledgment, when the subject studied the alarming monitor and began treating the source of the alarm. The average reaction time of each subject is shown in Figure 1.

Overall, integrating alarms decreased the average reaction time for four subjects and increased it for two subjects, although the differences in averages between scenarios for subjects 2, 3, and 6 were small (1-7 seconds [sec]). The difference in average reaction time for the four subjects who had decreased reaction times in the integrated scenario ranged from 6 to 37 sec, and the difference in average reaction time for the two subjects who had faster reaction times in the nonintegrated scenario ranged from 1 to 28 sec.

Another metric that was used to compare the integration scenarios was time spent with monitors (Fig. 2).

Integrating alarms decreased time spent with the monitors for three subjects, had a minimal effect for two subjects, and increased it for one subject. Integrating the alarms either reduced time spent with the monitors or was approximately equal to the nonintegrated scenario for five of the six subjects.

Time spent with monitors was measured as time spent looking at or physically interacting with the monitors. Note that because of equipment failure on the day of testing, subject 1 had a different monitor interface than subjects 2-6. This monitor interface was approved by the institutional review board as a study backup and presented the same information as the Zoll Propaq MD, but the display was different. Subject 1 was given a demonstration with the new monitor before testing to familiarize them with the layout and alarms.

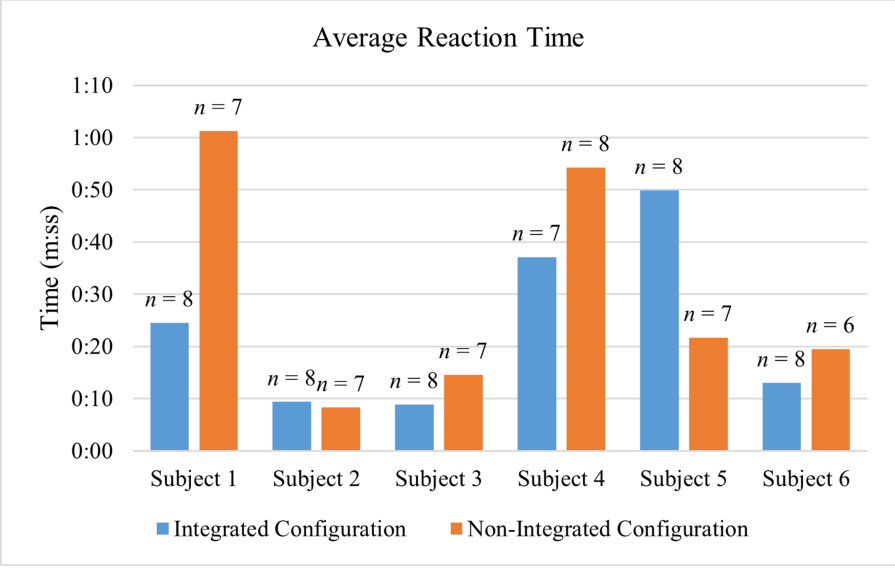

FIGURE 1. Average reaction time for each subject between integrated and nonintegrated scenarios. The *n* above each bar represents the number of alarms that each subject reacted to out of the eight programmed alarms for each scenario.

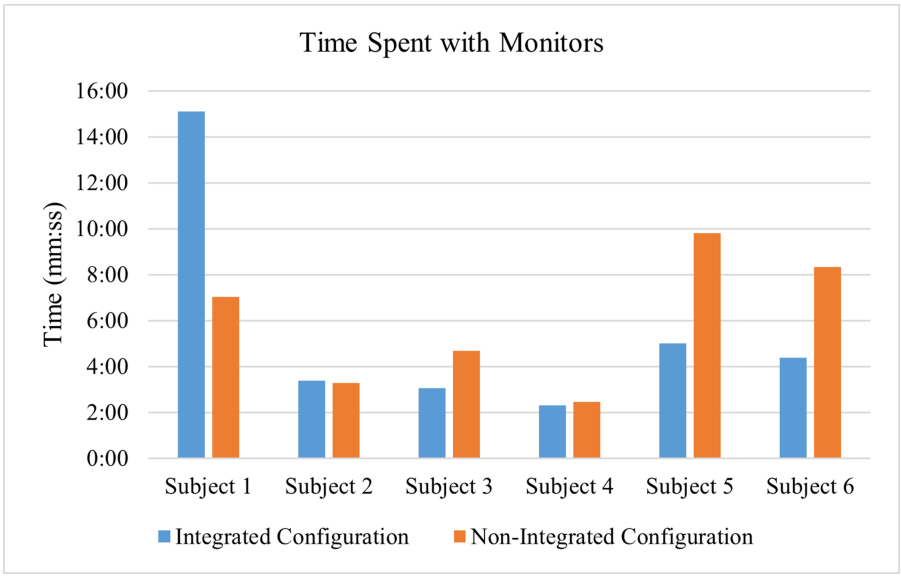

FIGURE 2. Sum of time spent looking at or interacting with the monitors for each subject between integrated and nonintegrated scenarios.

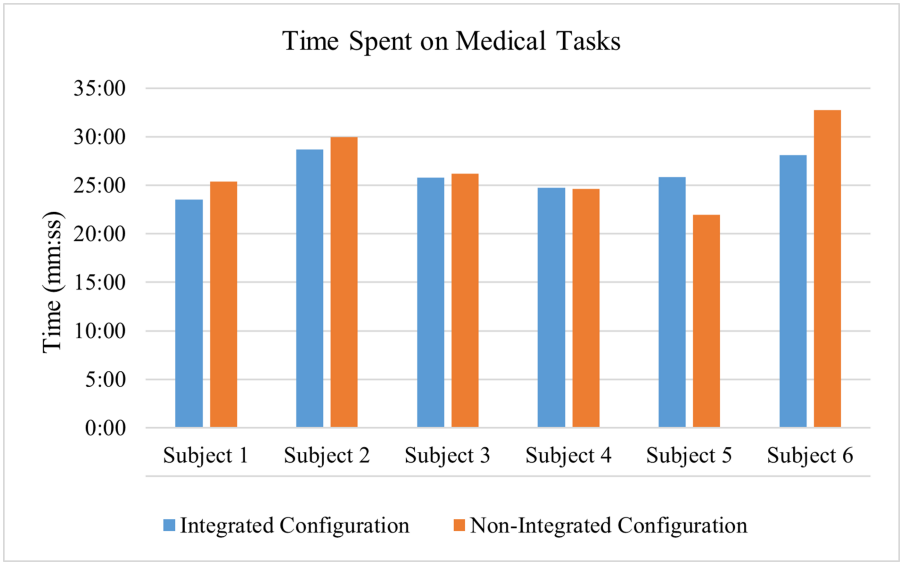

FIGURE 3. Sum of time spent providing care to patients for each subject between integrated and nonintegrated scenarios.

Another metric that was used to compare the two integration scenarios was the amount of time spent performing patient care tasks (Fig. 3).

The amount of time spent performing patient care tasks accounts for multitasking, such as when the medic is inflating the pressure infusion bag for an intravenous fluid bag while checking the patient's pulse. This makes the metric distinct from the amount of time spent with the patients and resulted in times exceeding the 30 min allotted for each testing scenario.

Whether the alarms were integrated or not, subjects spent most of their time in every scenario performing medical tasks and multitasked often. The time spent performing patient care tasks for all subjects ranged from 23 min 32 sec to 28 min 42 sec in the integrated scenario and from 21 min 57 sec to 32 min 43 sec in the nonintegrated scenario. The amount of time spent on medical tasks can exceed the 30 min of test time because of multitasking, and the sum of time spent with patients and time spent with the medical devices far exceeds the 30-min scenario. Four of the subjects spent more time on medical tasks in the nonintegrated scenario, with the time difference between scenarios ranging from 1 min 17 sec to 4 min 38 sec.

Per the study protocol, a statistical analysis was performed on the recorded time data. There was no statistically significant difference between scenarios shown in the time data. Subject 1 was excluded from the statistical analysis because of

the different monitors used in order to meet the assumptions of the paired-sample *t*-test used to evaluate the data.

The responses to the questionnaire were all open-ended. Because of this the research team found that many of the medics mentioned the same benefits, drawbacks, and improvements related to integrating alarms, but in answer to different questions. Since the content of the medics' responses overlapped frequently in response to different questions, an analysis was made of all the medic's answers to all questions to group common themes. Table I shows the breakdown of all the answers given in the questionnaire that pertain to benefits, drawbacks, and needed improvements.

The full questionnaire analysis and questions can be found in the USAARL technical report for this study (USAARL-TECH-FR-2023-10).[6]

DISCUSSION

Time Data

There were no statistically significant results found for the time metrics. Notifying the medic more quickly of a patient who is decompensating was one of the main goals of integrating alarms into the CEPs, so the decreased reaction time of four out of the six subjects was a promising sign that the idea of integration is worth pursuing, although it was not a statistically significant difference.

One of the concerns frequently expressed by the retired medics who were consulted when developing this study was that the incorporation of alarms would distract the subjects from patient care and that they would spend more time with the devices than they would normally. The medics tended to spend more time with the monitors in the nonintegrated configuration, which indicates that the concern that hearing the alarms would take the subject's attention away from the patient more often may not be the case for the majority of users. Again, the lack of statistical significance means that this is not a proven result of integration.

Average reaction time, time spent with monitors, and time spent with patients were the metrics that were analyzed for statistical significance; however, they are not representative of the full effect of integrating alarms. The amount of time spent on patient care tasks could represent more treatments

TABLE I. Questionnaire Response Summary

Category	Subcategory	Further subcategory	Percentage (#) of medics that provided response		Number of times response was given	
Benefits	[a]Improves patient care	Prevents vital sign negligence/improves attention	[a]100% (6)	83.3% (5)	[a]25	12
		Faster identification of change in patient status		83.3% (5)		9
		Assists in time delegation between patients		33.3% (2)		4
	Would be useful/crucial/essential/a game changer in real-world application	NA	50% (3)	NA	5	NA
	Confidence in hearing alarms/notification of patient status change	NA	50% (3)	NA	4	NA
	Medic felt less overwhelmed	NA	16.7% (1)	NA	1	NA
Drawbacks	Alarms were/could be distracting	NA	83.3% (5)	NA	7	NA
	[a]Alarm fatigue	Frequent or continuous alarms will be ignored	[a]16.7% (1)	16.7% (1)	[a]4	2
		False alarms occur frequently in the aircraft		16.7% (1)		2
	[a]Communication	Interferes with crew communication	[a]50% (3)	50% (3)	[a]4	3
		Would distract pilots/crew		16.7% (1)		1
	Focused on monitor, not patient	NA	33.3% (2)	NA	3	NA
	Usually only one monitor in the aircraft	NA	16.7% (1)	NA	1	NA
Improvements	Different alarms for different devices/vitals	NA	66.7% (4)	NA	5	NA
	Capability of remote control/silencing of alarms	NA	50% (3)	NA	4	NA
	Isolate alarms to specific communications	NA	33.3% (2)	NA	2	NA
	Integrate ventilator alarms	NA	33.3% (2)	NA	2	NA

[a]Subcategories are broken down into further subcategories in the right half of the response columns.

given, or it could represent that the tasks took longer for the subject to complete in one scenario than in the other. Several other metrics were calculated to evaluate the effect of integrating the alarms, such as time from reaction to treatment, time spent with individual patients, the number of untreated patient decompensation events, the number of tasks performed, and how the subjects reacted to the alarms. All of these analyses are published in this study's technical report (USAARL-TECH-FR-2023-10)[6].

Questionnaire Responses

Overall, the subjects had a strongly positive response to alarm integration. All the medics indicated that they perceived integration to improve patient care. The most frequently mentioned benefits were the prevention of inattention to vital signs and quick notification of patient status changes. Half of the subjects indicated that they felt that integrating the alarms gave them confidence that they would be notified of patient decompensation, and half of the subjects believed integration to be crucial to real-world applications.

Significant drawbacks were noted. All but one of the subjects thought that the alarms were or could be distracting, and half of the subjects mentioned that the alarms interfered with communication. In this study, the subject's communication was with a research team member, but in real-life application, it would be with the crew or pilots. Some of the noted drawbacks can be compensated for with the suggested improvements. Isolating the alarms only to the communication lines of those who need to hear them (the medic and possibly the crew chief if assisting) would be a necessity in real-world application to prevent distracting the rest of the crew, especially in the case of the pilots who need to be able to hear if the aircraft alarms are sounding. Having remote control of the alarms would also lessen the distractions caused by hearing them, as the medics currently have to silence the alarms on the monitor itself, which takes valuable time away from the patients, so the subjects in this study frequently let alarms ring instead of silencing them.

Another suggested improvement was to make alarm tones distinct, so that the medic immediately knows which monitor patient alarms are coming from and why. This would be especially helpful in the case where an alarm is already sounding from a second patient's device, so that the medic knows if there is a new alarm going off or a previous alarm has just become unsilenced. The final suggested improvement was to add the ventilator alarms into the ICS as well. While incorporating the ventilator alarms may lead to greater alarm fatigue in the medics, it could also provide that same confidence as hearing patient monitor alarms to the medics and could save patient lives by giving quick notice to medics in the event that an emergency such as a disconnected ventilator hose occurs.

Limitations

There were several limitations encountered during this study. The most restricting limitation was the sample size of participants. It is anticipated that further research using this same population as recruits will not encounter the same limitation, as the regulations related to COVID-19 have dissipated. Other limitations were due to the nature of the study. Since the study was designed as a proof of concept, it is laying the foundation and requires future studies to look at the effectiveness of utilizing salient alarms, the effects of alarm fatigue and false alarms, and the effect of incorporating other devices that have audible alarms such as the ventilator. These limitations and additional ones are detailed in the USAARL technical report[6].

Further Research

USAARL has just begun work on an approved follow-on study that will utilize three-dimensional audio as a means of providing patient-specific alarm notification to the medics.

CONCLUSIONS

Although there were no statistically significant results, there were some indications that integrating alarms could provide benefits to the medic shown in the data, which were supported by the subjects' feedback. The time data showed that most subjects had decreased reaction times, decreased or equivalent time spent with the devices, and similar amounts of time spent providing care to the patients when alarms were integrated. Coupled with the strongly favorable end-user feedback, the results of this study provide validation that the idea of alarm integration to benefit the care provider has merit, and further studies are needed to improve the concept and further develop the optimal alarm system.

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CONFLICT OF INTEREST STATEMENT

None declared.

DATA AVAILABILITY

The data underlying this article cannot be shared publicly because of data sharing restrictions placed by the organization's regulatory compliance office and institutional review board. The data will be shared on reasonable request to the corresponding author.

INSTITUTIONAL REVIEW BOARD (HUMAN STUDIES)/EXEMPT STUDIES

This study was designated as Research Involving Human Subjects by the USAARL Regulatory Compliance Office and received Institutional Review Board approval under the number M-10868.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (ANIMAL STUDIES)/EXEMPT STUDIES

Not applicable.

INDIVIDUAL AUTHOR CONTRIBUTION STATEMENT

USAARL collected and analyzed the data; designed this research; drafted the original classified reports; and drafted, reviewed, and edited this manuscript. All authors read and approved the final manuscript.

INSTITUTIONAL CLEARANCE

Institutional clearance approved.

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