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Major Article

Experiences when using different EHMR models: Implications for different designs and meeting user expectations

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Key Words:
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Background: New elastomeric half-mask respirator (EHMR) models without exhalation valves (EVs) or with exhalation valve filters (EVFs) are facilitating expanded use in health settings to reduce workers' exposure to airborne hazards while acting as source control to prevent pathogen spread. The physical comfort of new models has not been assessed in comparison to previously used EHMRs with EVs.

Methods: Researchers assessed 1,962 health care and emergency medical service personnels' self-reported adverse experiences from 2 cohorts while wearing EHMR models with EVs (cohort 1, n = 1,080) and without EVs or with EVFs (cohort 2, n = 882). Fisher exact test identified differences between the cohorts accounting for organizational factors when possible.

Results: Cohort 1 respondents experienced communication challenges and discomfort when wearing the EHMR > 1 hour statistically significantly more often than cohort 2. Cohort 2 respondents reported statistically significantly more instances of difficulty breathing, moisture buildup, being uncomfortable to wear < 1 hour, and being uncomfortably warm.

Conclusions: Discomfort is prevalent among end users and more often among those wearing EHMRs without an EV/with an EVF. As EHMR research and development advances, prevalence in use may increase for emergency and routine situations. Organizations may not only need guidance about respirator selection but also model-specific selection.

BACKGROUND

Although elastomeric half-mask respirators (EHMRs) are commonly used in industrial settings such as construction, mining, and manufacturing, their use in health delivery settings has been recommended during times of increased demand that have resulted in supply shortages for National Institute for Occupational Safety and Health (NIOSH) Approved N95 filtering facepiece respirators.[1,2] Because some health delivery settings have already transitioned to EHMRs for routine or emergency use, guidelines exist for their integration into the workplace, including strategies around disinfection, maintenance, and storage.[3,4] However, the exhalation valve (EV) on most NIOSH Approved models has limited the utility of EHMRs in some settings, such as sterile environments. Prior to 2020, EHMRs approved by NIOSH had an EV to allow for exhaled breath to escape from the respirator, providing more comfort for the wearer.[5] However, several manufacturers began redesigning EHMRs in 2020 to function as both respiratory protection for the user and source

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control to protect others (ie, to limit emission of infectious respiratory droplets in exhaled breath).[6]

To date, 25 NIOSH Approved models on the Certified Equipment List[7] have (1) no EV, where inhaled air and exhaled breath enters and exits through the same particulate filter, or (2) an exhalation valve filter (EVF) that is placed over the EV port to filter the breath.[8] With the availability of these NIOSH Approved EHMRs, it is plausible to think that health delivery settings may opt to (1) stockpile EHMRs to improve preparedness and response during shortages, or (2) provide EHMRs as a more routine respirator for use in their organization.

However, previous studies have found that physical comfort is a significant predictor to workers' adherence to respirator use in the workplace.[9–13] To date, research has assessed the comfort of EHMRs alone or in comparison to N95 FFRs and has revealed consistent findings. Some studies found that, although EHMRs are often described as less comfortable and offer communication challenges when compared with N95 FFRs, health care personnel (HCP) perceive EHMRs to offer superior protection and prefer them in higher-risk scenarios.[14,15] These findings suggest that perceived protection of EHMRs may drive user preference, but only during public health emergencies, hence minimizing adoption and use among organizations and employees.[16]

Notably, EHMR comfort studies to date have only involved EHMRs with EVs. A gap exists in user experiences with models that do not have an EV or have an EVF. The current study compared user experiences between 2 cohorts to answer: (1) *Are there differences in cohort experiences for users who wore the common EHMR with an EV compared with users who wore an EHMR without an EV or with an EVF?*; and (2) *Are there differences in user experiences based on whether their organization previously used EHMRs?* Based on results, it might be possible to promote expanded uses of NIOSH Approved EHMRs without EVs or with EVFs across health settings and provide considerations for EHMR prototypes focused on user comfort.

METHODS

This study examined adverse experiences while wearing EHMRs among health delivery workers (ie, HCP and emergency medical service [EMS] personnel) using 2 study cohorts. Cohorts received different EHMRs that either (1) had an EV or (2) did not have an EV or had an EVF. All participants received fit testing and training in accordance with the US Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard (29 CFR 1910.134).[17] For cohort 1, the study was reviewed and approved (via a certificate of exemption) by the Allegheny Health Network Research Institute's IRB and the University of Maryland Baltimore's IRB.[a] For cohort 2, this activity was reviewed and approved by the CDC as exempt human subjects research.[b]

Cohort 1: EHMRs with an EV

Cohort 1 involved 2 hospital systems in the Eastern, Mid-Atlantic part of the United States that purchased and distributed 2 models of EHMRs with an EV to a subset of employees. Because both hospital systems used EHMRs previously (one since 2009 and 2020, respectively), they already added EHMR fit testing and training into their respiratory protection program (RPP). Employees were routinely using EHMRs for 10 to 12 months at the time of data collection. No adaptations were made to the respirator body. However, hospital policy dictated that EVs needed to be covered to prevent possible illness spreading from employees to patients. This protection was normally achieved with a surgical mask being placed over the EV. See previous publications[18,19] for more information about cohort 1.

Cohort 2: EHMRs without an EV or with an EVF

Cohort 2 involved 32 health care and emergency medical settings across the United States that received EHMR models without an EV or with an EVF from the Strategic National Stockpile (SNS).[20] At the time of this study, only 3 EHMR models without an EV or with an EFV were approved by NIOSH. To ensure adequate supplies would be available, the SNS solicited proposals and purchased all 3 EHMR models for public distribution—1 had an EHMR with an EVF and the other 2 did not have an EV. Organizations that requested EHMRs from the SNS could request 1 or all 3 models for use at their organization (pending availability). Four health care and 1 emergency medical setting requested and distributed more than 1 model to employees. Organizations volunteered to provide employees who received an EHMR with NIOSH's online survey link. In many cases, organizations had no previous experience with EHMRs and had not yet incorporated them into their RPP. However, even if organizations had previous experience with EHMRs and incorporated them into their RPP, the EHMR models received (without an EV or with an EVF) were new to organizations and users. See previous publications for more information about cohort 2.[20,21]

Instrument

An anonymous online survey was available on the respective Research Electronic Data Capture (REDCap) portals to complete during both study periods. The survey for cohort 1 was open between April and June 2021, while the survey for cohort 2 was open between October 2021 and October 2022. Surveys took respondents from each cohort 15 to 20 minutes to complete. Some sections of the survey varied between cohorts, but one was the same for both. This section probed adverse experiences while wearing the EHMR (if applicable) using an abbreviated version of the Respirator Comfort, Wearing Experience, and Function Instrument (R-COMFI) scale.[22] Respondents were asked to check (Yes or No) adverse experiences from a list of 10 options: (1) difficulty speaking or being understood (ie, communication challenges); (2) difficult to breathe; (3) bothered by moisture buildup; (4) interferes with other personal protective equipment (PPE); (5) interferes with normal eyeglasses; (6) uncomfortable to wear less than 1 hour; (7) uncomfortable to wear more than 1 hour; (8) feels uncomfortably warm; (9) feels claustrophobic; and (10) causes skin irritation or acne.

Statistical analysis

Data cleaning and checking within and between the cohorts took place. Within cohort 2, respondents were from health care (53.7%) and emergency first-responder settings (46.3%). Fisher exact test results indicated that physical and physiological experiences that users encountered were not significantly different between these 2 occupational groups in cohort 2 (ie, health care and emergency responder settings), except for feeling claustrophobic while wearing an EHMR ($P < .001$). Consequently, researchers did not take occupation into account when considering this cohort and retained the group as one for the purposes of this analysis.

For the primary analysis, Fisher exact test was used as a more rigorous analysis for 2 × 2 nonparametric analyses. First, researchers assessed differences in user experiences between the cohorts and second, considered if organizational familiarity with EHMRs may have impacted experiences that were reported. The independent variables included EHMR model distributed (ie, with an EV or without an EV/with an EVF) and organizational experience

[a] See 45 C.F.R. part 46; 21 C.F.R. part 56.
[b] See 45 C.F.R. part 46.104.

with EHMRs. The dependent variables included the 10 adverse experiences. Phi coefficient informed the strength of each association tested. Analysis was performed using IBM SPSS 26.[23] A *P* value less than .05 with the Bonferroni adjustment where necessary represented statistical significance.

RESULTS

Demographics

The sample consisted of 1,962 respondents (cohort 1, n = 1,080 (55%); cohort 2, n = 882 (45%)). Respondents provided a variety of job titles, including physician, nurse, nursing assistant, environmental services, and facilities management working in intensive care units; emergency departments; operating rooms; pediatrics; and medical/surgical units, firefighter, safety engineer, dentist, dental hygienist, fire chief, industrial hygienist, and emergency paramedic. Table 1 shows job length reported (note minor differences in response options).

In cohort 1, both hospital systems had prior experience overseeing EHMR implementation. In cohort 2, 50% (n = 441) of respondents indicated their organization had prior experience overseeing EHMR use. In other words, 22.5% (n = 441) of the total sample represented organizations that had no prior experience with EHMRs, while the remaining 77.5% (n = 1,521) represented organizations that had experience. Table 2 shows the total time users reported wearing respiratory protection during their shifts.

Adverse experiences by model and organizational experience

Table 3 lists the frequency distributions for each statistically significant barrier experienced based on EHMR model and organizational experience. As Table 3 shows, respondents in cohort 1 (EHMR with an EV) were more likely to have communication challenges (82.2%) than were those in cohort 2 (52.8%). Communication challenges and model indicated a strong association (phi = 0.316). A weak but a statistically significant association was found between model and breathing difficulties (phi = − 0.066).

Users in cohort 2 experienced statistically significantly more instances of difficulty breathing, moisture buildup, other PPE interference, being uncomfortable to wear for less than 1 hour, and being uncomfortably warm when compared with cohort 1. Even though the strength of association between model and being uncomfortable to wear for more than 1 hour was statistically significant, the effect was small (phi = 0.121). Considering excess moisture buildup, respondents in cohort 2 reported more discomfort (44.6%) than those in cohort 1 (20.4%), showing a strong relationship between model and excess moisture buildup (phi = − 0.26). Similarly, users in cohort 2 were more likely to express discomfort due to being warm (38.9%) compared with users in cohort 1 (18.9%), rendering a medium effect size (phi = − 0.222).

Respondents who represented organizations with previous EHMR experience were more likely to have communication challenges (75%) than users with organizations that had no experience (48.5%). The association between communication challenges and organizational EHMR experience rendered a medium effect (phi = 0.239). Alternatively, users with organizations that had previous EHMR experience were less likely to express discomfort due to being warm (24.4%) compared with users with organizations that did not have experience (39.9%), indicating a small effect size (phi = − 0.144). Even though the other variables were statistically significant, the strength of association was small. Table 4 shows the significance levels and strength of the association.[24]

Table 1
Length of time in current job by cohort

Length of time in current job	Cohort 1, n = 1,077 (%)	Length of time in current job	Cohort 2, n = 848 (%)
Less than 1 y	8.1	Less than 1 y	14.2
1-2 y	11.6	1-2 y	15.2
3-4 y	24.2	3-5 y	18.3
5+ y	56.1	6+ y	52.3

Table 2
Total time respiratory protection was worn per shift

Total time	Cohort 1, n = 1,043 (%)	Cohort 2, n = 705 (%)
< 25% of shift	44.3	73.6
25%-50% of shift	39.4	6.4
50%-75% of shift	10.2	19.4
> 75% of shift	6.1	0.6

DISCUSSION

Although HCP experiences have been studied,[2-4,10-12,14-16] to the authors' knowledge, this is the first study that assessed user experiences for EHMRs without an EV or with an EVF. This study included additional job roles in health care and EMS settings that have not been included in other user studies (eg, dental, first responder). Generally, the results align with previous research assessing EHMR comfort and tolerability (with EVs) in clinical settings. For example, 1 intervention completed by Bryant and colleagues[25] found that, among approximately 1,400 HCP who wore EHMR models (with EVs), 64.5% experienced discomfort while wearing for their entire shift (defined as continuous wear for a minimum of 6 hours in the study) in comparison to 58% (cohort 1) and 45.8% (cohort 2). Further, 68% of HCP in Bryant's study[25] felt they were unable to effectively communicate while wearing their EHMR in comparison to 82% and 52%, respectively, for cohorts 1 and 2. Therefore, the results of the current study, even considering the limitations, appear to be a reliable indication of typical user experiences. However, there were significant differences in the results worth exploring, as detailed below.

Communication challenges

First, as research has thoroughly documented and been reconfirmed in the current study, communication challenges were the most prevalent, regardless of the EHMR model. In the current study, it is important to reinforce that employees in cohort 1 were instructed to wear surgical masks over their EV for source control, which may have introduced not only difficulties communicating but also other adverse effects. Although research[6] has shown that wearing a surgical mask over an EHMR does not produce clinically significant changes in heart rate and other physiological outcomes, it is possible that this temporary practice caused additional trouble communicating—particularly in being understood by others—as well as general discomfort over prolonged periods of use.

Despite this consideration within cohort 1, communication challenges were still the most prevalent adverse experience regardless of model and organizational experience with EHMRs. Mitigation strategies have been documented such as raising one's voice and speaking slower.[12,26] Likely due to these ongoing challenges, manufacturers have been exploring the development of EHMR models to improve speech intelligibility.[27] Recently, MSA manufactured the first NIOSH Approved EHMR that has a speaking diaphragm and no EV with the hopes of minimizing communication challenges while providing source control.[28]

Table 3
Statistically significant associations experienced while using EHMR models without an EV/with an EVF and EHMR models with an EV and organizational experience with EHMRs

EHMR model and organization experience	Challenges experienced (Yes)	
	Communication challenges	
	n	%
With an EV (ie, cohort 1)	888	82.2
Without an EV or with an EVF (ie, cohort 2)	466	52.8
Previous organizational experience with EHMRs	1,140	75.0
No previous organizational experience with EHMRs	214	48.5
	Breathing difficulties	
	n	%
With an EV (ie, cohort 1)	283	26.2
Without an EV or with an EVF (ie, cohort 2)	284	32.2
Previous organizational experience with EHMRs	428	28.1
No previous organizational experience with EHMRs	139	31.5
	Excess moisture buildup	
	n	%
With an EV (ie, cohort 1)	220	20.4
Without an EV or with an EVF (ie, cohort 2)	393	44.6
Previous organizational experience with EHMRs	440	28.9
No previous organizational experience with EHMRs	173	39.2
	Interference with other PPE	
	n	%
With an EV (ie, cohort 1)	255	23.6
Without an EV or with an EVF (ie, cohort 2)	318	36.1
Previous organizational experience with EHMRs	438	28.8
No previous organizational experience with EHMRs	135	30.6
	Uncomfortable to wear for < 1 h	
	n	%
With an EV (ie, cohort 1)	252	23.3
Without an EV or with an EVF (ie, cohort 2)	278	31.5
Previous organizational experience with EHMRs	383	25.2
No previous organizational experience with EHMRs	147	33.3
	Uncomfortable to wear for > 1 h	
	n	%
With an EV (ie, cohort 1)	626	58.0
Without an EV or with an EVF (ie, cohort 2)	404	45.8
Previous organizational experience with EHMRs	838	55.1
No previous organizational experience with EHMRs	192	43.5
	Uncomfortably warm	
	n	%
With an EV (ie, cohort 1)	204	18.9
Without an EV or with an EVF (ie, cohort 2)	343	38.9
Previous organizational experience with EHMRs	371	24.4
No previous organizational experience with EHMRs	176	39.9

NOTE. Significance level assessed using Bonferroni-adjusted *P* value < .005.
EHMR, elastomeric half-mask respirator; *EV*, exhalation valve; *EVF*, exhalation valve filter; *PPE*, personal protective equipment.
NOTE. All associations in the table are statistically significant, using Phi coefficient and considering a value > 0.25 as a strong association.[24]

Physical discomfort

The results showed that cohort 2 respondents (EHMRs without an EV or with an EVF) experienced more discomfort at a statistically significantly higher level. These barriers should be considered by both manufacturers and health delivery settings that are considering procurement and use. Specifically, being uncomfortably warm and experiencing excess moisture buildup was encountered by users in cohort 2 approximately 2 times more than those in cohort 1. Although this result may not be surprising and even unavoidable due

Table 4
Fisher exact test for association between variables and strength of association

Experiences while wearing EHMR	EHMR model	Strength of association*	Organizational experience with EHMRs	Strength of association*
Communication challenges	*P* < .001	0.316	*P* < .001	0.239
Breathing difficulties	*P* < .004	− 0.066	*P* = .170	-
Excess moisture buildup	*P* < .001	− 0.260	*P* < .001	− 0.093
Interference with other PPE	*P* < .001	− 0.136	*P* = .467	-
Interference with eyeglasses	*P* = .193	-	*P* = .720	-
Uncomfortable to wear < 1 h	*P* < .001	− 0.092	*P* = .001	− 0.077
Uncomfortable to wear > 1 h	*P* < .001	0.121	*P* < .001	0.097
Uncomfortably warm	*P* < .001	− 0.222	*P* < .001	− 0.144
Claustrophobic while wearing	*P* = .298	-	*P* = .381	-
Skin irritations	*P* = .924	-	*P* = .277	-

Significance level assessed using Bonferroni-adjusted *P* value < .005.
EHMR, elastomeric half-mask respirator; *PPE*, personal protective equipment.
* For statistically significant results only using phi coefficient. A value > .25 is considered a strong association.[24]

to some of the work-related scenarios that may require the use of respiratory protection, it demonstrates the need for additional education and expectations during fit testing and training pertaining to excess moisture buildup and potential difficulty breathing. Current OSHA RPP requirements indicate that basic information about EHMR maintenance and storage is required.[17] However, with the increase in models available, it is possible that organizations should include more specific user expectations training depending on the model(s) stockpiled and used by employees.

Also, cohort 1 predominately reported wearing their EHMR for more than 1 hour and reported statistically significantly higher levels of discomfort, whereas cohort 2 predominately reported wearing their EHMR for less than 1 hour and reported statistically significantly higher levels of discomfort for this category. These results suggest that users reported adverse experiences for the scenario in which they were more often experiencing—further supporting the need to improve aspects that contribute to physical discomfort.

Job roles and experience levels

This study was novel in that a variety of job roles were included in cohort 2 that had not been studied previously (eg, dental hygienists, dentists, fire-based EMS responders, and paramedics). This inclusion may have impacted some results. First, regarding the inclusion of different job roles in cohort 2, this may explain the results noted above—that users in cohort 2 were approximately 2 times more likely to experience excess moisture buildup and uncomfortable warmth. Specifically, users in cohort 2 also comprised fire-based EMS responders and paramedics, whose job tasks are different and likely demanded more cardiovascular exertion in comparison to HCP, who comprised all of cohort 1. Consequently, selecting certain EHMR models to cater to different job roles and demands may be useful to consider and further study.

Although user experiences varied between the 2 groups, it is important to note that the EHMR models used between the cohorts were physically the same in terms of fit, material, and manufacturer models distributed—the only difference was the configuration of the EV. So, even though users in cohort 2 (EHMR without an EV/with an EVF) reported interference with other PPE statistically significantly more often (36%) in comparison to 23% of users in cohort 1, experiences should not have practically or significantly differed. It is possible that the higher number of participants with less than 2 years of job experience in cohort 2 as well as the incorporation of new job tasks in cohort 2 elicited more adverse experiences among respondents or that there was something specific to their job task that required additional PPE, which elicited potential instances of interference. Consequently, future studies should explore job tenure and roles that may experience more cases of PPE interference to help determine tasks for which EHMRs may not be as practical when considering both worker and patient safety.

Similarly, organizations may determine that in some cases when source control is not a concern, certain job tasks can use EHMRs that have an EV to support user comfort, whereas when EHMRs are going to be used in a sterile environment, EHMRs without an EV or with an EVF be worn. In other words, advances in research and development are affording organizations additional flexibility to accommodate user preferences while ensuring patient safety. To this end, future work is needed with organizations that have varying levels of EHMR experience. In the current study, HCP in more experienced settings may have been more acclimated to wearing EHMRs and thus, might express different opinions. Possible confounders to individual and organizational experience should be proactively identified and if applicable, incorporated into RPPs as an element of emergency preparedness and employee efficacy in relation to the respirator(s) they are provided.

Limitations

Results must be considered within the current study's limitations and cannot be generalized to EHMR perceptions in general nor to other types of respiratory protection. First, all participating settings implemented EHMRs at their own pace and with numerous job roles. Because several SARS-CoV-2 variants emerged throughout the study period, distribution, adoption, and length of use likely varied based on when EHMRs were received and incorporated into RPPs. Similarly, cohort 1 had more experience with EHMRs than cohort 2, which could have affected the results.

Specific to cohort 2, those who wore EHMRs without an EV and with an EVF were combined into 1 group. Because it was more important to ensure participating organizations had access to respiratory protection when it was needed, 1 sample was retained for convenience throughout the demonstration project. Although there could have been differences in experiences between these 2 subgroups (eg, users wearing an EHMR without an EV may have experienced significantly warmer or more moisture buildup than those wearing an EHMR with an EVF), some organizations requested both models (without an EV and with an EVF) to compare, making it difficult to discern who may have worn one, or both types. However, a qualitative component of this study was also included[29] where managers of participating organizations completed a series of interviews throughout the study. These participants discussed employees' (perceived) experiences. No notable differences in user experiences regarding communication, comfort, and breathing emerged as a theme when discussing EHMRs without an EVF and with an EVF. However, future research may seek to intentionally explore these differences quantitatively, especially with additional models both without an EV and with an EVF entering the market. Also, given that participating health delivery settings represented different states and geographic regions, protocols might have varied and cannot be directly compared.

Further, employees who volunteered to complete the survey are subject to social desirability bias and self-selection bias, likely indicating these respondents had a priority toward health. It is possible that nonrespondents had varying views of EHMRs that may have swayed the results in some capacity. Also, some of the possible EHMR barriers are subject to inherent bias to the outcome being based on their job tasks (eg, communicating with residents vs patients vs coworkers) or physical characteristics (eg, wearing glasses or baldness). Although this study aimed to recruit and include a variety of locations and respondents with diverse job experiences to address previous limitations,[18] future research should be designed in a way to control for some of these physical characteristics.

CONCLUSIONS

This study compared user experiences across health delivery settings that used EHMRs during the COVID-19 pandemic. End-user experiences with FFRs were not assessed and therefore, the results should not be deduced to prioritize the routine use and stockpiling of FFRs or EHMRs. Rather, the findings, which demonstrated discomfort and challenges reported by users of EHMRs but more so among those using EHMRs without EVs or with EVFs, provide additional data to factor into the use and stockpiling of EHMRs for routine use and emergency preparedness and response.

Even though the results share themes with previous research for informing future models,[30] this also triggers the need for more research, development, and education around EHMRs without EVs or with EVFs. From a research and development standpoint, it is important to identify viable routes to improve EHMR comfort. New respirator designs have been recommended for decades to improve worker tolerability.[8,12,19,30] However, during the COVID-19 pandemic when HCP were wearing EHMRs for a longer period or donning and doffing more often, some employees reported making adjustments

to the respirator to minimize adverse effects such as skin irritation.[25] However, if users adjust their respirator to improve comfort, this has the potential to jeopardize the integrity of the respirator's protection and voids NIOSH approval.

Second, from an education standpoint, as EHMRs continue to advance, the likelihood for exploration and prevalence in their use may increase—whether for routine or emergency situations. More research is needed with specific job roles and tasks. For example, this study showed that discomfort is prevalent among end users and more often among those who wore EHMRs without an EV or with an EVF. However, future research would want to understand objectively whether it does get significantly hotter and more humid when a user wears EHMRs without an EV or with an EVF to validate these subjective responses. In the future, it is possible that organizations may not only need guidance about respirator selection but also model-specific selection to meet their needs.

HUMAN SUBJECTS REVIEW

IRB reviews occurred at the Allegheny Health Network Research Institute's IRB, which provided a certificate of exemption (2021-034 "Healthcare Worker Survey on Elastomeric Masks"), dated February 22, 2021, and the University of Maryland Baltimore's IRB, which provided a letter of exemption as well (HP-00094424), dated January 26, 2021, and the National Institute for Occupational Safety and Health, deeming the study exempt.

ATTRIBUTION STATEMENT

N95 and NIOSH Approved are certification marks of the US Department of Health and Human Services (HHS) registered in the United States and several international jurisdictions.

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