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EVIDENCE-BASED GUIDELINES FOR FATIGUE RISK MANAGEMENT IN EMERGENCY MEDICAL SERVICES

P. Daniel Patterson, PhD, NRP, J. Stephen Higgins, PhD, Hans P. A. Van Dongen, PhD, Daniel J. Buysse, MD, Ronald W. Thackery, JD, Douglas F. Kupas, MD, David S. Becker, MA, EMT-P, Bradley E. Dean, MA, NRP, George H. Lindbeck, MD, Francis X. Guyette, MD, MPH, Josef H. Penner, MBA, John M. Violanti, PhD, Eddy S. Lang, MDCM, CCFP (EM), Christian Martin-Gill, MD, MPH

Received July 14, 2017 from the Department of Emergency Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania (PDP, FXG, CMG); National Highway Traffic Safety Administration, Washington, District of Columbia (JSH); Sleep and Performance Research Center and Elson S. Floyd College of Medicine, Washington State University, Spokane, Washington (HPAV); Department of Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania (DJB); American Medical Response Inc., Greenwood Village, Colorado (RWT); Department of Emergency Medicine, Geisinger Health System, Danville, Pennsylvania (DFK); College of Safety & Emergency Services, Columbia Southern University, Orange Beach, Alabama (DSB); Rowan County Emergency Medical Services, Salisbury, North Carolina (BED); University of Virginia School of Medicine, Charlottesville, Virginia (GHL); Mecklenburg County EMS, Charlotte, North Carolina (JHP); Department of Epidemiology and Environmental Health, University at Buffalo - The State University of New York, Buffalo, New York (JMV); Department of Emergency Medicine, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada (ESL). Revision received August 31, 2017; accepted for publication September 1, 2017.

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All authors contributed to the conception of the design of this work. All authors contributed to acquisition of study data. PDP led the analysis, and all authors contributed to the interpretation of findings, drafting of the manuscript, and providing critically important intellectual content. All authors reviewed and approved the final version and agree to be accountable for all aspects of the work.

Supplemental data for this article can be accessed on the publisher's website.

Address correspondence to P. Daniel Patterson, PhD, University of Pittsburgh, Emergency Medicine, 3600 Forbes Avenue, Iroquois Bldg., Suite 400A, Pittsburgh, PA 15260, USA. E-mail: pattersonpd@upmc.edu

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ABSTRACT

Background: Administrators of Emergency Medical Services (EMS) operations lack guidance on how to mitigate workplace fatigue, which affects greater than half of all EMS personnel. The primary objective of the Fatigue in EMS Project was to create an evidence-based guideline for fatigue risk management tailored to EMS operations. Methods: Systematic searches were conducted from 1980 to September 2016 and guided by seven research questions framed in the Population, Intervention, Comparison, Outcome (PICO) framework. Teams of investigators applied inclusion criteria, which included limiting the retained literature to EMS personnel or similar shift worker groups. The expert panel reviewed summaries of the evidence based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology. The panel evaluated the quality of evidence for each PICO question separately, considered the balance between benefits and harms, considered the values and preferences of the targeted population, and evaluated the resource requirements/needs. The GRADE Evidence-to-Decision (EtD) Framework was used to prepare draft recommendations based on the evidence, and the Content Validity Index (CVI) was used to quantify the panel's agreement on the relevance and clarity of each recommendation. CVI scores for relevance and clarity were measured separately on a 1-4 scale to indicate consensus/agreement among panel members and conclusion of recommendation development. Results: The EtD framework was applied to all 7 PICO questions, and the panel created 5 recommendations. PICO1: The panel recommends using fatigue/sleepiness survey instruments to measure and monitor fatigue in EMS personnel. PICO2: The panel recommends that EMS personnel work shifts shorter than 24 hours in duration. PICO3: The panel recommends that EMS personnel have access to caffeine as a fatigue countermeasure. PICO4: The panel recommends that, EMS personnel have the opportunity to nap while on duty to mitigate fatigue. PICO5: The panel recommends that EMS personnel receive education and training to mitigate fatigue and fatigue-related risks. The panel referenced insufficient evidence as the reason for making no recommendation linked to 2 PICO questions. Conclusions: Based on a review of the evidence, the panel developed a guideline with 5 recommendations for fatigue risk management in EMS operations. Key words: recommendations; PICO framework; GRADE methodology

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BACKGROUND

Mental and physical fatigue in the Emergency Medical Services (EMS) workplace affect large numbers of EMS personnel (1) and have been linked to EMS personnel injury, patient care error, and adverse events (2). EMS personnel work in shifts, which has been shown in other shift worker groups to disrupt normal patterns of sleep and circadian rhythms, and contribute to fatigue (3). The problem of fatigued EMS personnel is widespread and not isolated to one type of EMS operation or category of EMS clinician (2, 4, 5). Administrators of EMS organizations are not sufficiently equipped to address fatigue in the workplace, in part because of the absence of guidelines for fatigue risk management in the EMS setting.

Fatigue risk management can be seen as one critical component of safety management systems and is defined as "a scientifically based, data-driven addition or alternative to prescriptive work hour limitations, which manages employee fatigue in a flexible manner appropriate to the level of risk exposure and nature of the operation" (6). Aviation, rail, nuclear power and other high-risk industries have aimed to directly address the dangers of fatigue by developing and applying advanced processes for fatigue detection and mitigation (7). Despite this progress, none of these industries has developed guidelines for fatigue risk management based on a systematic review of the best available evidence.

Evidence Based Guidelines (EBGs) help to normalize practice and policies, and to aid decision-making based on a review of the best available evidence. EBGs are widely supported by national EMS and other medical organizations (8, 9). Guideline development is a multi-step process that requires careful review of the evidence and consideration of factors that can affect adoption and implementation of recommendations. The National Model Process was created to aid EBG developers with developing, implementing, and evaluating Prehospital EBGs (10). This Model Process encourages the use of a rigorous methodology such as the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework to form recommendations based on a careful review of the evidence and other factors that may impact acceptance of an intervention by the target population (11).

This paper describes guideline development for the Fatigue in EMS project and reports the results of the panel's review of the evidence and recommendations. This project was supported by the National Highway Traffic Safety Administration (NHTSA) to address gaps in guidance for fatigue risk management through the Model Process and to aid the EMS industry with recommendations tailored to EMS operations and personnel. The primary targeted audience for this work includes individuals in positions of leadership, administration, and/or management of EMS personnel.

Table 1. Members of expert panel

		_
Name	Area of Expertise	Institution
Hans P. A. Van Dongen, PhD	Sleep and Fatigue Science	Washington State University
John M. Violanti, PhD	Fatigue in Public Safety	University at Buffalo
Daniel J. Buysse, MD	Sleep Medicine	University of Pittsburgh
Douglas F. Kupas, MD	Emergency Medicine & EMS	Geisinger Health System
Frank X. Guyette, MD, MPH	Emergency Medicine & EMS	University of Pittsburgh
Josef H. Penner, MBA	EMS Administration	Mecklenburg County NC EMS
Ronald W. Thackery, ID	EMS Risk Administration	American Medical Response
David S. Becker, MA, EMT-P	Fire / EMS	Columbia Southern University
Bradley E. Dean, MA, NRP	Field Personnel / Clinician	Rowan County NC EMS
George H. Lindbeck, MD	State EMS Medical Direction	Virginia State Office of EMS
Dennis Eisnach*	Consumer Representative	None / Retired

 $^{^{*}\}mathrm{Mr}$. Eisnach discontinued participation on the panel February 2017 due to illness

These recommendations should also guide the decision making of individuals in the position of educating, training, and influencing policies that impact the work environment, health, and safety of EMS personnel. Fatigue risk management is a shared responsibility between the employer and employee (6, 12). Therefore, these recommendations are also meant to inform EMS personnel, and to guide their decision-making toward actions that can mitigate fatigue in the workplace.

METHODS

Overview

The development of these guidelines followed recommendations of the 8-step Model Process for the creation of prehospital EBGs. The primary aim was to create EBGs for fatigue risk management that are tailored to the EMS workplace (10). External Input (Step 1) was solicited through public comment periods during project-related meetings in April 2016, and with an online solicitation for public comments on a designated project website. Guideline Initiation and Evidence Review (Step 2) was accomplished by forming a panel of experts with knowledge of and experience in sleep medicine, fatigue science, emergency medicine, EMS, risk management, administration, and consumerism (Table 1). The panel's configuration satisfied the Institute of Medicine's (IOM) recommendation of diversity in experience, expertise, and content knowledge (8). Panel member disclosures appear in Online Supplement Appendix A (13).

The panel produced seven research questions framed in the Population, Intervention, Comparison, and Outcomes (PICO) format. The development of each research question is described elsewhere (13). Each question informed the research team's Evidence Appraisal (Step 3), which included seven systematic reviews and where possible, meta-analyses (14-20). All systematic reviews were registered with PROS-PERO (21), the international database of prospectively registered systematic reviews (2016 registration numbers: CRD42016040097; CRD42016040099; CRD42016040101; CRD42016040107; CRD42016040110; CRD42016040112; CRD42016040114). Evidence profile tables were created as prescribed by the GRADE system (11). Guideline Development (Step 4) focused on evaluation of the evidence, panel discussions of the balance between benefits and harms, appraisal of the values and preferences of the target population, and deliberation regarding the resources needed to implement each intervention contained within the PICOs.

Steps 5–8 comprise translating recommendations into model protocols or policies, dissemination, implementation, and evaluation/testing (10). This paper does not address Steps 5–8. This paper provides a summary of recommendations and their development, so they may be disseminated, incorporated into policy, and field-tested. The panel supplemented recommendation statements with the panel's collective expert opinion on interpretation of recommendations.

Protocol

The Institutional Review Board of the University of Pittsburgh approved the protocol. In March and April of 2017, the panel gathered for a face-to-face meeting and a conference call/webinar to review the evidence profiles for each PICO. The principal investigator (PDP) and GRADE methodologist (ESL) led panel members through an orderly review of GRADE evidence profile tables for each research question. The panel evaluated the quality of evidence, reflected on the balance between benefits and harms of a particular intervention, considered the values and preferences of the targeted population, and evaluated the resource requirements/needs associated with a particular intervention. The discussions were documented with the GRADE Evidence-to-Decision (EtD) Framework (22). The EtD framework is a form developed by the GRADE working group that guides panel members through the process of evidence evaluation and consideration of important information and questions (e.g., values and preferences of targeted populations), and ensures transparency in decision-making toward development of recommendations (22).

Measures and Statistical Analyses

Following the evidence review, the Principal Investigator and GRADE methodologist offered the panel a draft recommendation for consideration and editing.

The panel was directed to debate the draft statement and then rate the relevance and clarity separately of draft recommendation statements. The question of relevance was presented to panel members as follows: "Is the statement connected/germane to [a] the findings of the systematic reviews; [b] the balance between benefits and harms; [c] the values and preferences of the EMS community of shift worker clinicians and administrators; [d] any concerns for resource use (costs); and [e] suitable in its current form for purposes of guiding the EMS community with regards to fatigue risk management?" The question of clarity was presented as follows: "Is the statement clear, intelligible, appropriately worded, sharp, and easy to understand by a diverse audience?" Panel members scored relevance and clarity on a 4-point ordinal scale: [1] = the statement is not relevant/clear; [2] = the statement needs major revisions to be relevant/clear; [3] = the statement needs minor revisions to be relevant/clear; and [4] = the statement is relevant/clear. The panel calculated a total score for relevance and clarity separately by following procedures for the Content Validity Index (CVI) measure (23). The CVI is the proportion of scores of 3 or 4 divided by the total number of individual scorers (23). The draft recommendations were revised and scoring procedure repeated until the total score for relevance and total score for clarity were greater than or equal to 0.78, a common benchmark for CVI measurement (23). The panel prohibited modifications or edits to the text or wording of recommendation statements once the panel's score exceeded the CVI benchmark.

RESULTS

Evidence-based recommendations are listed in the following sections. The CVI score for each of the seven recommendation statements was 1.0 (See Table 2). The panel required only a single round of scoring on relevance and clarity for each draft recommendation statement before reaching the maximum possible CVI score of 1.0. The completed EtD frameworks for each PICO are available in the Online Supplement Appendices B–H.

Recommendations by Expert Panel

Question 1: Are there reliable and valid instruments for measuring fatigue among EMS personnel?

Recommendation 1: Recommend using fatigue/sleepiness survey instruments to measure and monitor fatigue in EMS personnel.

Strength of Recommendation: Strong

Quality of the Evidence: Low

Panel Remarks and Opinion: In total, the panel considered evidence from 34 experimental and observational studies, which was interpreted as supportive of 14 different fatigue and sleepiness survey instruments (14). The greatest limitation of current survey instruments is that none has undergone comprehensive

Table 2. Evidence-based recommendations for fatigue risk management in EMS

PICO	Recommendation statement	Relevance CVI Clarity CVI	Total Round of Voting
1	Recommend using fatigue/sleepiness survey instruments to measure and monitor fatigue in EMS personnel.	1.0	1
	(strong recommendation, very low certainty in evidence)	1.0	
2	Recommend that EMS personnel work shifts shorter than 24 hours in duration.	1.0	1
	(weak recommendation in favor, very low certainty in effect)	1.0	
3	Recommend that EMS personnel have access to caffeine as a fatigue countermeasure.	1.0	1
	(weak recommendation in favor, low certainty in effect)	1.0	
4 Recommend that have the opport while on duty to fatigue. (weak recommend)	Recommend that EMS personnel have the opportunity to nap while on duty to mitigate fatigue.	1.0	1
	(weak recommendation in favor, very low certainty in effect)	1.0	
5	Recommend that EMS personnel receive education and training to mitigate fatigue and fatigue-related risks.	1.0	1
	(weak recommendation in favor, low certainty in evidence)	1.0	
6	No recommendation: The confidence in effect estimates is insufficient to make a recommendation at this time. (Reference to GRADE Handbook	_	1
7	6.1.4) No recommendation: The confidence in effect estimates is insufficient to make a recommendation at this time. (Reference to GRADE Handbook 6.1.4)	_	1

testing of reliability and validity (common indicators of an instrument's utility) with EMS personnel and other shift worker groups (14). Positive reliability and validity findings instill confidence, which is important when choosing an instrument for diagnostic/assessment purposes. Most studies reported internal consistency reliability, which refers to the internal correlations between items that are used to operationalize or define a construct of interest (24). Other tests of reliability, such as test-retest reliability, were not widely reported (14). Validity testing (i.e., criterion-related validity, sensitivity, and specificity) (25) are often more challenging to assess than reliability. The absence of a gold standard and consensus objective technique for assessment of occupational fatigue accounts for the lack of validity testing (26–29). A gold standard is needed to facilitate tests of sensitivity and specificity, which are two important outcomes for this evidence review (13).

The evidence profile of the 34 included studies reveals that the overall quality of evidence is low. The panel considered research design, risk of bias, and consistency of reported findings across studies; indirectness of the populations studied; imprecision; the potential for publication bias; and other considerations that may impact the certainty of findings (i.e., the evidence) (30). Many panel members raised concerns about the accuracy of fatigue and sleepiness survey instruments when used in EMS settings. The consequences of fatigue instrument implementation are difficult to predict. Inaccurate assessments could lead personnel to report high levels of fatigue in order to leverage fatigue mitigation policies that limit or eliminate work and invoke mandatory rest. Conversely, personnel may report low levels of fatigue to avoid lost opportunities for work or overtime.

Despite these concerns, the panel believes the benefits of using fatigue and sleepiness survey instruments outweigh both their limitations and the liabilities of not using such instruments at all. The survey instruments identified are easy to use, are supported by considerable evidence of reliability in shift worker populations, and show at least some evidence of validity (e.g., construct, content, and criterion-related with indirect outcome measures) (14). Furthermore, reliability and validity for many of the instruments reviewed have been demonstrated in studies of non-shift worker populations (26, 31).

Despite a judgment of low quality of evidence, the panel concluded that these instruments consistently measure fatigue in workers similar to EMS personnel and could feasibly be implemented with limited effort within the EMS environment. These survey instruments are potentially useful tools to EMS administrators for assessing the fatigue and sleepiness status of EMS personnel. Their use in a fatigue risk management program will do more good than harm. The panel issues a strong recommendation for their use for the specific purpose of assessing and monitoring fatigue and sleepiness in the EMS setting.

While the panel recommends their use, the panel suggests careful review and consideration of each instrument. They vary in length, number of scales (domains) measured, and time periods that are assessed or referenced. Six of the reviewed survey instruments solicit feelings of fatigue "in general," during the past month, or over the past 7 days (14). Others solicit perceptions of sustained fatigue over an unspecified timeframe. Four instruments assess fatigue either at the time of administration, in the past 24 hours, or at the end of a shift (14). In operational settings, the terms "fatigue" and "sleepiness" are often used interchangeably (32). Three survey instruments assess situational sleepiness (e.g., in real-time), while one instrument (the Epworth Sleepiness Scale [ESS]) measures sleepiness from a trait-level perspective.

Some instruments may require payment, licensing, or special permissions issued by the developer prior to use (33–35).

The panel considered the feasibility of distributing survey instruments and the potential burden placed on EMS personnel tasked with repeatedly reporting fatigue status. A random or targeted sample of shifts (rather than all shifts) may provide the optimal balance of utility and feasibility. Random sampling rather than complete sampling is less burdensome on respondents and may lead to improved rates of participation. Higher participation will contribute to a more representative picture of fatigue in the workforce. The panel also recommends targeted assessments of specific shifts such as extended duration shifts (e.g., \geq 12 hours), shifts that occur overnight, or shifts that occur in close proximity (i.e., rapid returns), including shifts worked across different agencies. A detailed description of performance measurement linked to this recommendation is published separately

Further development and testing of fatigue and sleepiness survey instruments should be a priority for future research. The panel recommends investigators fully test the utility of fatigue and sleepiness survey instruments with EMS personnel in the EMS operational environment. Investigators who seek to tailor instruments to fit the EMS environment should adhere to the common standards for development and testing of survey instruments as outlined by Norbeck (37): [1] clearly defining each construct measured; [2] reference to the literature linked to the construct of interest; [3] clear and transparent description of item-scale development; [4] analysis of content validity with established content validity measurement techniques (23, 38, 39); [5] tests of reliability (24); [6] tests of construct validity; [7] clear description of target population for the instrument's intended use; [8] description of sampled respondents; and [9] reporting of common statistics (e.g., measures of central tendency and dispersion) for each item and construct measured (37). Measurement development should also include use of qualitative techniques such as focus groups and indepth interviews involving the targeted population in order to solicit input on the constructs being measured and face validity of draft items. Whether using one of the 14 instruments identified in this evidence review or developing new instruments, it is essential that common indicators of reliability and validity be reported. These data will guide and help to improve the future of fatigue/sleepiness assessment of EMS personnel. See Online Supplement Appendix B for a summary of our deliberations germane to this recommendation.

Question 2: In EMS personnel, do shift-scheduling interventions mitigate fatigue, mitigate fatigue-related risks, and/or improve sleep?

Recommendation 2: Recommend that EMS personnel work shifts shorter than 24 hours in duration.

Strength of Recommendation: Weak **Quality of the Evidence**: Very low

Panel Remarks and Opinion: The panel examined the quality of evidence from 100 studies that compared critical and important outcomes for different durations of shift work (15). The panel documented their discussion and decision-making in the EtD framework appearing in Online Supplement Appendix C. In total, the panel grouped 24 different shift duration comparisons across 100 studies into three main comparisons: 1) shifts < 24 hours versus ≥ 24 hours, 2) 8-hour versus 12-hour shifts, and 3) a composite of other comparisons that present greater than two shift durations (multiple comparisons) (15). Given the large number of studies, the panel aggregated studies with favorable findings on critical or important outcomes and compared them to studies with unfavorable or mixed/inconclusive findings.

Regarding the 15 studies that compared shifts <24 hours to ≥24 hours in duration, the ratio of favorable findings on critical or important outcomes to unfavorable findings strongly favored shifts <24 hours in duration (15). Findings from nine studies were judged favorable toward shifts <24 hours for at least one outcome. Findings from one study were judged as unfavorable toward the shorter duration shift for the outcome of personnel performance. None of the studies reported unfavorable findings for shorter duration shifts (<24 hours) on critical outcomes of patient and personnel safety.

While the findings strongly favored shifts <24 hours vs. ≥24 hours in duration, shorter shifts were not similarly supported when comparing 8-hour versus 12-hour shifts or a composite of other combinations of shorter versus longer shifts (15). The panel determined that the existing evidence is mixed with respect to the 8-hour versus 12-hour shift comparison. Similarly, the panel identified no convincing pattern of evidence for or against shifts of other durations.

The panel acknowledges an ongoing debate regarding the safety and impact of longer versus shorter shifts in the EMS workplace (40). The desirable anticipated effects of EMS personnel working shifts shorter than 24 hours include reduced fatigue, improved alertness, better sleep and sleep quality, better health and wellbeing of personnel, and improved safety for patients and personnel (41). Undesirable anticipated effects might include potentially higher cost to the system (42, 43), reduced access to care for patients, and increased risks to personnel.

Numerous factors may impact the costs associated with shorter versus longer shift durations, and these costs will vary system-to-system (e.g., size of workforce, deployment model). Costs may be greater with shorter versus longer shift durations (e.g.,

predominantly 8-hour versus predominantly 12-hour shift schedules) (42–44). These data mostly come from studies of police departments, where shift schedules and rotations are fairly consistent (e.g., 8-hour shifts, 3 shifts per 24-hour period, with set days of rotation) and may be meaningful to a subset of EMS operations with similar shift schedules. Longer shifts lead to less frequent transitions of medical crews, which are particularly important in EMS settings where medical equipment needs to be signed out and/or checked at the beginning of each shift, creating lead time before being able to respond to medical incidents.

The panel recognized that many EMS personnel favor longer duration shifts. Recovery between shifts is potentially greater with longer duration of shifts (45). Longer duration shifts may allow for additional employment due to less time spent to travel and transition to and from work. This may be especially important for EMS agencies with bases located in remote locations (e.g., air medical providers or rural EMS agencies), and longer shifts may influence the ability to recruit individuals to work at these locations. Many EMS personnel (>80% in some locations) report multiple jobs (45, 46), and modifications in shift scheduling may impact the feasibility of employment with multiple organizations or recovery between shifts. To some stakeholders, a reduction in the number of personnel with multiple jobs would be viewed as a potentially positive step for safety, health, and wellbeing. Others may react differently. The panel accepts the validity of such concerns, and the challenge of finding viable solutions. However, such concerns and challenges should be addressed within the context of consistent findings from numerous empirical studies.

Some remote and low-volume EMS operations rely on extended duration shifts due to limited resources and personnel to staff ambulances. It may not be practical, or cost-effective, and potentially not safe to eliminate extended duration shifts in some EMS operations. The decision to implement specific shift durations should not be based solely on the evidence, which the panel believes favors a recommendation of shifts <24 hours in duration (refer to Online Supplement Appendix C). However, the panel encourages organizations to consider the evidence, the benefits versus potential dangers of shifts ≥24-hours in their systems and community, the values and preferences of their EMS personnel, and the costs unique to their EMS operation. If shifts ≥24 hours must be utilized to ensure adequate staffing, other fatigue risk mitigation strategies outlined in these guidelines should be implemented to optimally balance safety, performance, and retention of EMS personnel.

Future research should investigate: [1] if critical and important outcomes (e.g., patient safety) differ in EMS systems that operate longer versus shorter duration shifts; [2] if the costs and resource requirements of longer versus shorter duration shift schedules differ by

size of the EMS operation (e.g., small, medium, large organizations); and [3] if it is cost-effective for EMS operations to move from longer to shorter shifts.

Question 3: In EMS personnel, does the worker's use of fatigue countermeasures mitigate fatigue, mitigate fatigue-related risks, and/or improve sleep?

Recommendation 3: Recommend that EMS personnel have access to caffeine as a fatigue countermeasure.

Strength of Recommendation: Weak

Quality of the Evidence: Low

Panel Remarks and Opinion: The evidence review shows the positive effects of caffeine on psychomotor vigilance, which is important for performance, and on acute fatigue and sleepiness (16). However, the health and safety risks associated with excess caffeine consumption should also be addressed (47, 48). Excess caffeine may contribute to onset of, or difficulty managing, conditions such as anxiety and cardiac dysrhythmias (47, 48). The safety profile of longer-term caffeine consumption for mitigation of workplace fatigue is not well known (49). Individuals will often self-regulate consumption and caffeine is generally safe at low to moderate doses (e.g., 250 mg/day) (49). Sleep may be affected by caffeine and additional guidance on use in the workplace is needed (50, 51).

Caffeine is readily available in many EMS settings, but may not be considered proactively by EMS systems as a tool to mitigate fatigue, particularly for shifts of prolonged duration or taking place during overnight periods. There is a minimal amount of information to inform EMS administrators regarding the total costs (e.g., annual) of providing access to caffeine in the EMS setting. The costs of providing caffeinated beverages might exceed thousands of dollars annually for moderate to large EMS operations. Costs may differ depending on the type of EMS deployment model. For instance, EMS personnel deployed from fixed base sites may have easier access to caffeine than personnel deployed dynamically in the ambulance. Personnel deployed in ambulances for the duration of their shift may find access to caffeine challenging for a number of reasons (e.g., proximity to businesses that sell caffeinated beverages). The panel recommends EMS administrators provide access to caffeine regardless of system deployment and whether it is provided directly

Consumption of caffeine for the purposes of mitigating work-related fatigue in the EMS environment should be guided by education and training in a robust fatigue risk management program that recognizes caffeine use as only one component of a comprehensive fatigue management strategy. A formal program is recommended for monitoring utilization, safety, and the impact of caffeine on EMS personnel performance. The panel also calls for future research to explore the route, dosing, and timing of caffeine for diverse EMS shift schedules and operations (Online Supplement Appendix D).

Question 4: In EMS personnel, does the use of sleep or rest strategies and/or interventions mitigate fatigue, fatigue-related risks, and/or improve sleep?

Recommendation 4: Recommend that EMS personnel have the opportunity to nap while on duty to mitigate fatigue.

Strength of Recommendation: Weak **Quality of the Evidence**: Very low

Panel Remarks and Opinion: The panel reviewed the evidence for shift workers napping while on duty (17). The panel determined that current evidence supports the use of naps while on duty as an effective strategy to positively impact fatigue-related outcomes. Naps improve alertness, reduce sleepiness, and improve personnel performance (e.g., reaction time).

While the available evidence supports napping, several potential undesirable effects may occur. The most important of these is sleep inertia, a period of reduced alertness or impaired cognition immediately after waking (52, 53). Sleep inertia may inhibit EMS personnel response times, especially from the time of notification to the time when personnel are in the ambulance (apparatus) and en route. Standards followed by many EMS operations, such as the National Fire Protection Association's (NFPA) Standard 1710 of one-minute turnout time, may be impacted by personnel who engage in napping.

The review of the evidence did not address the optimal duration of the nap or the impact that nap duration has on sleep inertia (17). Naps ranging from 15 to 120 minutes during shift work have been associated with better performance and reduced levels of acute fatigue/sleepiness (17). Some evidence indicates that shorter duration naps (e.g., 10 minutes) lessen the risk of sleep inertia, while providing some rest and/or recovery (53). The use of naps as a fatigue countermeasure will likely take different forms in different EMS organizations. Some may decide to implement short duration naps, whereas other organizations may choose to utilize longer duration naps, or some combination of naps with deployment of additional personnel and resources as a possible temporary replacement for personnel engaged in napping. The panel believed that EMS organizations can develop innovative policies and protocols for napping, while at the same time accounting for the possibility of sleep inertia. The benefits of napping, as shown in the evidence review (17), outweigh the risks.

The general public may perceive EMS personnel napping on duty as unacceptable. The panel concluded that the benefits of improved alertness on duty, and ultimately improved patient and personnel safety, are a commonsense justification to this anticipated undesirable effect. Additionally, it is common knowledge that many EMS personnel and other first responders work long duration shifts requiring nighttime sleep when

not on a response. Policies and protocols that clearly describe the appropriate use, structure, and benefits of naps on duty may be useful toward educating the public and reducing potential negative opinion.

Many EMS organizations have existing facilities that enable napping. Some organizations may incur costs to modify or construct facilities that allow an individual to lie down and limit exposure to light and noise, which are important characteristics of workplace napping facilities (54, 55). The true costs associated with an intra-shift napping policy or program are unclear. Operations that use dynamic deployment will face unique challenges adopting and implementing a policy of napping. A nap in the front cab of the ambulance (apparatus) is likely better than no nap. Administrators may consider a requirement that personnel nap only when in the passenger seat (securely belted) or patient compartment (securely belted) to avoid the possible negative effects of sleep inertia on operating the ambulance immediately upon waking and while not fully alert.

None of the reviewed studies demonstrated an impact on the critical outcome for this evidence review (personnel safety). However, the expert panel concluded that napping during shifts can be an effective strategy to mitigate fatigue and fatigue-related risks, especially in extended duration shifts (e.g., ≥12 hours) and shifts during overnight periods. Napping during shifts may be beneficial for EMS personnel who work contiguous shifts (without breaks in between) or consecutive shifts with short rest periods (rapid returns), within or between agencies. Napping may be a useful tool to mitigate the effects of fatigue even in shifts <12 hours in duration or on shifts occurring during daylight hours. Permitting naps does not absolve EMS personnel of the responsibility to present to work well rested. The panel recommends that EMS agencies have a broad policy that allows napping at all hours, and that they work toward providing adequate nap facilities whenever possible.

The panel recommends a formal program of monitoring be established to determine utilization and impact of intra-shift naps on important and critical outcomes (Online Supplement Appendix E). Future research should involve EMS personnel to determine the optimal duration of an intra-shift nap, the optimal timing of naps during shifts, what constitutes an adequate location for a nap, and assesses the time interval immediately post nap.

Question 5: In EMS personnel, does fatigue training and education mitigate fatigue, fatigue-related risks, and/or improve sleep?

Recommendation 5: Recommend that EMS personnel receive education and training to mitigate fatigue and fatigue-related risks.

Strength of Recommendation: Weak Quality of the Evidence: Low

Panel Remarks and Opinion: The panel discovered a variety of programs to deliver fatigue/sleep education and training of shift workers, which use multiple formats (e.g., lectures and workshops), durations (e.g., one hour presentations and eight-week courses), instructors (e.g., fatigue experts, teammates and peers), and delivery methods (e.g., in person, online, or via email) (18). Our evidence review of 18 studies showed a favorable relationship between education and training in fatigue (and sleep health) and important outcomes of patient and personnel safety (18). A meta-analysis of five studies showed improvements in shift worker sleep quality four to eight weeks after fatigue education and training (18).

Education and training in fatigue and sleep health may have the anticipated and desirable effect of identifying undiagnosed sleep disorders such as obstructive sleep apnea (OSA) (56). Large numbers of EMS personnel are at risk of OSA and other sleep disorders that contribute to fatigue and poor sleep quality (1, 57). Being overweight or obese (a risk factor for OSA) affects three-quarters of EMS personnel and 75% of EMS personnel fail to meet recommendations for physical activity (1, 58). The panel believes that increased awareness of sleep disorders through education and training will contribute to increased awareness and subsequent diagnosis, ultimately reducing fatigue in the EMS workplace.

Costs of workplace health and wellness programs that address fatigue and sleep health are a concern. Costs will likely vary, and the total cost burden for the average EMS organization is unknown. Costs of general worksite health, wellness, and fitness programs range from 130 to 150 U.S. dollars per employee per year (59, 60). Adding fatigue or sleep health modules to an existing program may be cost-neutral or minimal in real dollars for some EMS organizations. The panel does not provide recommendations or suggestions for the depth, breadth, or source of content for fatigue or sleep health education. Multiple methods, and sources of content, may be needed to educate and train EMS personnel on these topics (61). Findings from the metaanalysis of five diverse programs were favorable for personnel sleep quality, regardless of which program was analyzed in the pooled analysis (18). The panel believes EMS organizations may choose to use a variety of sources for their content, develop education and training tailored to their organization's needs, and be able to introduce fatigue and sleep health education and training for minimal cost.

EMS personnel should receive fatigue education and training during new employee orientation/training, as well as every 2 years, in order to prevent decay in knowledge (62–67), skills (62–67), and proficiency in techniques that can help mitigate fatigue and fatigue-related risks. Recommended retraining at least every two years is consistent with existing recommenda-

tions for other required educational programs for EMS providers, including cardiopulmonary resuscitation and advanced cardiac life support. Education and training in fatigue and sleep health should be a key component of a comprehensive strategy to mitigate the effects of fatigue related to EMS shift work. Research priorities include investigating: [1] the content that has a meaningful impact on outcomes; [2] the effectiveness of diverse methods of educating and training personnel; [3] the costs of education and training; and [4] the impact of education and training on the behavior(s) of EMS personnel. See Online Supplement Appendix F for a summary of our deliberations germane to this recommendation.

Question 6: In EMS personnel, does implementation of model-based fatigue risk management mitigate fatigue, mitigate fatigue-related risks, and/or improve sleep?

Recommendation 6: No recommendation: The confidence in effect estimates is insufficient to make a recommendation at this time (Reference to GRADE Handbook 6.1.4).

Strength of Recommendation: Not applicable **Quality of the Evidence**: Very low

Panel Remarks and Opinion: The evidence review produced only one study that met criteria for inclusion (19). Findings from this one study were favorable for two important outcomes of interest. However, the panel determined that the body of evidence evaluated for this research question was insufficient for purposes of making a recommendation. The panel recognizes that biomathematical modeling is a novel approach for determining the role of sleep and circadian rhythms in relation to fatigue (68). A preponderance of the existing research reports on development and modification of models to improve fatigue estimation (69–74). The systematic review did not intend to examine this information; instead the review sought to identify the evidence that implementation of a biomathematical model impacts outcomes like safety. The panel discovered a minimal amount of evidence, yet the panel believes these models will one day be an instrumental component of fatigue risk mitigation for EMS organizations. Their widespread use in aviation, rail, and other highrisk industries suggests utility and promise for EMS fatigue risk management (68).

While biomathematical fatigue models may reduce fatigue and improve safety, undesirable effects may include improper reliance on such models to estimate individual "fitness for duty." Licensing biomathematical models from suppliers or service providers entails recognized, unpublished costs.

Priorities for future research in this area include determining the unique sleep and circadian patterns of EMS personnel, given that these data are key inputs for biomathematical models. Next, use of models calibrated with EMS inputs should be evaluated for impact on critical and important outcomes such as patient and personnel safety. The panel documented discussions and conclusions about this evidence review in the EtD framework (see Online Supplement Appendix G).

Question 7: In EMS personnel, do task load interventions mitigate fatigue, mitigate fatigue-related risks, and/or improve sleep?

Recommendation 7: No recommendation: The confidence in effect estimates is insufficient to make a recommendation at this time (Reference to GRADE Handbook 6.1.4).

Strength of Recommendation: Not applicable **Quality of the Evidence**: Very low

Panel Remarks and Opinion: The search produced five prospective observational studies (20), with wide variation in the description and definitions of task load and workload. One study investigated the relationships between workload, fatigue, and personnel performance. None of the evidence reviewed investigated the relationship between task load (or workload), fatigue, and personnel safety, patient safety, and cost to the system. The panel concluded that evidence quality was very low and determined that this body of evidence was insufficient for purposes of making a recommendation.

Task load and workload are of interest to many administrators of shift workers. While modifying task load or workload (e.g., reducing workload) may help to reduce fatigue and fatigue-related risks (75), potentially undesirable effects may also occur. A reduction in patient volume (one possible measure of EMS task load or workload) could contribute to loss of skill and proficiency with caring for acutely ill and injured patients (76). This may contribute to error, especially when dealing with patients that need time-sensitive intervention (76). Reducing workload without appropriate accommodations in staffing may increase response times or decrease patient access to care. It may also add cost to the system through decreased unit-hour utilization, a common metric used in the EMS industry to track workload.

Task load or workload interventions may take on many different forms. Possibilities include [a] deployment of additional personnel and ambulances to cover for others who may reach a threshold of workload; and [b] limiting the number of transports or patient encounters per crew per shift. Interventions of this type would increase costs for the system. While the panel believes these interventions are possible, it is unclear how different stakeholders view these and other similar options for modifying EMS crew task load or workload.

If an EMS organization chooses to modify task load or workload, the panel recommends a formal program to monitor and evaluate the intervention. The panel advocates the following research priorities: [1] identify common tasks in EMS that contribute to fatigue and/or fatigue-related risks; [2] determine which tasks contribute the least or most to fatigue; [3] investigate the impact of a task load or workload intervention on fatigue, safety, and other important/critical outcomes; and [4] test the reliability and validity of measures designed to quantify task load/workload specifically for the EMS setting. The panel's discussions and conclusions relevant to this evidence review are recorded in the GRADE EtD framework (see Online Supplement Appendix H).

DISCUSSION

Fatigue risk management is a shared responsibility between EMS organizations and personnel (6, 77). All EMS personnel have a responsibility to report for duty well-rested, and EMS employers have a responsibility to proactively identify fatigue (6), determine when fatigue is a threat, and mitigate fatigue with strategies informed by evidence-based recommendations. Successful implementation will require a comprehensive strategy tailored to local needs, given the diversity of EMS organizations and personnel. Regardless of organization type or classification of personnel, EMS administrators should strive to fully integrate fatigue risk management into daily operations and make fatigue mitigation a core component of the organization's safety culture.

Implementing an effective fatigue risk management program requires multiple strategies (multiple layers of defense) (78). For example, one of the panel's recommendations endorses shift durations <24 hours in duration. Hours-of-service restrictions should be a fundamental part of a comprehensive fatigue risk management program, but they should not be the program's sole focus or feature. Limiting the hoursof-service for shift workers was a common twentieth century tactic for fatigue management in numerous high-risk industries (79, 80). Modern approaches combine hours-of-service policies with fatigue mitigation strategies (77–79). The panel believes that EMS administrators jeopardize the success of fatigue risk management if the sole focus is on hours-of-service. Limiting work hours to <24 hours may be harmful to some EMS personnel and their patients in rural, frontier, or otherwise remote locations. In these locations, personnel may need to travel great distances for many hours to and from work. The opportunity to rest and recover may be extensive given limited workload and low patient volume. In such settings, shorter shift durations may elevate risk rather than reduce it, and fatigue risk management programs focused primarily on hours-of-service may be counterproductive. Thus, the panel advised EMS administrators to implement a program that incorporates multiple strategies supported by evidence.

Administrators should communicate with personnel to understand the potential impact of recommendations on daily operations, personnel health, and work-life balance. Such communication may reveal informal strategies that are tightly aligned with recommendations in these guidelines and that might easily be transformed into formal strategies (81). A change in shift duration, for example, might impact staffing and frequency of crew substitutions and rotations. Personnel may reveal an informal process of shift swaps or substitutions between personnel that could inform a formal plan if shift duration becomes a focus for fatigue risk management. Implementing a nap period during shifts could similarly impact operations. In some locations, EMS administrators may consider staggering naps between partners so that at least one crewmember is alert to initiate driving toward a response. Personnel may reveal an alternative approach that is equally attentive to safety, yet more feasible. While implementation of other recommendations (e.g., providing access to caffeine) potentially has less impact on daily EMS operations, administrators should consider the impact prior to implementation and engage personnel in the development and tailoring of program components.

Administrators will face challenges and potential barriers to implementation of recommendations that can be overcome with awareness and planning. Altruism, the belief in one's own invulnerability to fatigue, and poor organizational safety culture are some of the many potential barriers or threats to successful fatigue risk management in the EMS setting. Persons entering the EMS occupation report sensation seeking, altruism, and commitment to community (82, 83). Many of these individuals may be willing to work extended work periods, and administrators may be willing to approve large amounts of overtime or extended work periods when faced with deficits in personnel and coverage. Some EMS personnel, as reason for choosing the EMS occupation, may judge themselves as invulnerable to fatigue and discount or reject common signs of fatigue as nothing more than part of the job, a sign of weakness, or not in keeping with the occupational identity of an EMS professional (84). Other personnel may lack a personal commitment to fatigue mitigation based on a poor perception of their organization's safety culture and commitment to personnel safety (85). Many may be unaware of the dangers associated with fatigue, sleep deprivation, and shift work. Mistrust between administrators and EMS personnel is a barrier to successful implementation of fatigue risk management and a safety culture (80). Faced with these and other barriers or threats, EMS administrators should clearly communicate their support for the evidence-based recommendations adopted. Increasing the awareness of fatigue as a threat should be a top priority, as limited awareness of the problem and solutions supported by evidence are commonly cited barriers to successful implementation of evidence-based guidelines (86).

Sample protocols and policies are a means of improving the feasibility and timeliness of implementing guidelines. The approaches to fatigue risk management will differ across EMS organizations. The panel recommends administrators use a checklist to facilitate the implementation of a successful and comprehensive fatigue risk management program. An example checklist appears as Table 2 in a separate publication (36). Administrators should use this checklist in concert with the performance measures and instructions for incorporating performance measurement and evaluation described in a separate publication (36).

LIMITATIONS

The panel, which was formed based on the IOM's recommendations for panel composition (8), included representatives from a variety of disciplines (i.e., sleep medicine, fatigue science, emergency medicine). A different panel with a different set of PICO questions may have created recommendations unlike those produced in this study.

The GRADE framework is an emerging standard for development of EBGs that inform clinical practice and occupational health (11, 87). The panel utilized the Model Process for EBG development germane to the prehospital environment, and adhered to the GRADE framework for evaluating the certainty in evidence and formulating recommendations (10, 11). Other methodological processes for guideline development exist and could yield different evaluations of the evidence and recommendations.

Similar efforts to produce EBGs report using a "majority vote" to determine agreement on recommendation statements (88). The panel felt it important to objectively measure agreement of the panel on the wording of recommendations. The panel used the CVI and established CVI benchmarks to quantify relevance and clarity, which the panel feels improved the objectivity of the protocol and findings (23).

CONCLUSIONS

Fatigue is an important issue that impacts all EMS personnel. The panel completed a rigorous process for the creation of evidence-based guidelines for fatigue risk management in the EMS setting. The panel recommends using fatigue and sleepiness survey instruments for assessing and monitoring fatigue. The panel recommends scheduling shifts <24 hours whenever possible, providing access to caffeine throughout shifts, incorporating on-duty naps, and providing education and training in fatigue risk management. The evidence on which the panel based these recommendations is substantial, although generally of low quality. Implementation of these evidence-based recommendations has the potential to improve multiple fatigue-related

outcomes including patient and personnel safety, and advancing the field of Emergency Medical Services.

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