Final Progress Report: Impacts of Alcohol and Fatigue on Paramedic ALS Skills

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1. ABSTRACT

Purpose. The goal of this study is to assess the effects of alcohol use and fatigue on paramedic judgment and performance associated with providing advanced life support (ALS) and to validate a manikin simulator system as a tool for assessing provider performance.

Scope. Emergency Medical Technician-Paramedics (EMT-Ps) are prehospital providers of sophisticated, invasive emergency medical care including manual defibrillation, medication administration, and advanced airway management. EMT-Ps work long shifts in stressful environments. Neither their hours of service nor their use of alcohol prior to duty are federally regulated.

Methods. Using a counterbalanced within-subjects experimental design, subjects were recruited from regional jurisdictions and asked to (1) complete a battery of tests, including cognitive/psychomotor performance assessments and mood assessments; (2) provide their sleep history for the preceding 48 hours and complete a standard questionnaire on sleepiness and/or hangover symptoms; and (3) serve as a rescue team leader using an instrumented manikin simulator system on three separate occasions. The EMT-P under evaluation is either (a) naturally fatigued coming off of a 24-hour shift; (b) experiencing some degree of alcohol hangover consequent to controlled experimental dosing with high-congener beverage alcohol; or (c) fully rested and unimpaired by alcohol.

Results. Preliminary findings suggest that the manikin simulator is adequately sensitive to detect deficits in paramedic performance. Further data collection and analysis are necessary before conclusions can be reached on the potential impacts and relative impacts of shiftwork- and hangover-induced fatigue.

Key Words: Fatigue, Hangover, Emergency Medical Services, EMT-Ps, EMS, Paramedics.

2. PURPOSE

Among employees in safety-sensitive occupations, the two most prevalent forms of performance deficits are fatigue and alcohol-related impairments—whether intoxication or hangover. The research seeks to determine whether routine levels of fatigue and alcohol hangover among certified practicing EMT-Ps can be found to impair judgment and/or performance in such a way that patients who are reliant on the medical resuscitation and stabilization skills of EMT-Ps are consequently placed at unacceptable risk. Currently, there are no national standards for regulating these types of impairments for EMT-Ps, nor have the consequences of such impairments ever been systematically studied.

The study is important because EMT-Ps are society's front-line, prehospital providers of emergency medical care, bringing Advanced Cardiac Life Support (ACLS) into America's homes and businesses. This study seeks to validate a methodology and provide pilot information about specific areas of performance deficit among EMT-Ps as well as assess whether an instrumented manikin simulator integrated with personal computer-based ACLS software can serve as a sensitive indicator of performance impairment among licensed EMT-Ps. Depending on the ultimate findings, the results will serve to temper concerns that typical levels of fatigue and alcohol hangover raise patient risk and warrant mounting a more comprehensive evaluation of these relationships, and/or initiate policy action that will lower risks if risks are identified.

The three specific aims of this study follow:

Specific Aim 1: Assess EMT-P performance deficits on standard cognitive and psychomotor tasks known to be sensitive to fatigue from partial sleep deprivation as well as low blood alcohol concentration (BAC), or alcohol hangover.

Specific Aim 2: Validate the sensitivity of a rescue skill-specific programmable instrumented manikin simulator with assessment protocols known to be sensitive to fatigue and hangover, and determine the extent to which the simulation can detect areas of task-relevant impairment among EMT-Ps when they are fatigued toward the end of typically long work shifts of 24 hours and when they are coming onto a shift following moderate alcohol use that produces hangover symptoms 6 or more hours later.

Specific Aim 3: Communicate preliminary findings to the emergency medical research community and to the state and national licensing boards authorized to set policy for EMT-Ps, emergency nurses, and emergency physicians.

3. SCOPE

Emergency Medical Technicians

The scope of practice of Emergency Medical Technicians (EMTs) is defined by federal guidelines (NHTSA, 1998). As practice levels progress from *Basic* through *Intermediate* to *Paramedic*, the scope and intricacy of skills and responsibilities increase. EMT-Basic skills are limited to non-invasive tasks such as bandaging and administration of oxygen. EMT-Intermediate practice adds some invasive skills and cardiac monitoring. EMT-Ps perform a wide range of invasive tasks including intravenous therapy, airway management by orotracheal and nasotracheal intubation and cricothyroidotomy, and invasive procedures for trauma management including needle thoracotomy (chest decompression), monitoring cardiac dysrhythmias and treating them through medication administration, defibrillation and application of external cardiac pacemakers. EMT-Ps also treat a range of emergency medical conditions by administering medications. As part of their training and biannual license renewal, EMT-Ps must complete the American Heart Association-sponsored Advanced Cardiac Life Support (ACLS) Course (American Heart Association, 1997). Completion of the ACLS program is required by many employers for emergency department and intensive/specialty care physicians, physician assistants, nurses, and other hospital-based health care professionals. There is only one ‘version’ of the ACLS course; the ACLS course that EMT-Ps are required to complete is identical in scope to the course completed by hospital-based personnel. Last, treatment protocols for cardiac emergencies in most jurisdictions are closely modeled after ACLS guidelines, which serve as a de facto standard of care. In this report, the term *prehospital care* describes emergency medical care provided by EMT-Ps in homes and businesses, on roadways, and in other nontraditional care environments.

Busy EMT-Ps Serving the Public

Though comprehensive industry-wide statistics are not maintained, available information suggests that EMT-Ps work long shifts in busy fatigue-inducing environments. In a 1997 survey, paramedics in 41 states and Canada, 22% reported duty tour durations of 24 hours, and 26% reported duty tours of 12 hours (Mayfield, 1998). There is reason to believe that the 22% figure from the 1997 survey is an under-report. Two years later, a similar survey found that 50% of fire-department-based EMT-Ps responding reported 56-hour average work weeks (Mayfield, 2000), which is associated with 24-hour shift work.

In consideration of the career preparation necessary and the importance of their work, it is surprising that the EMT-P is not classified as working in a "safety-sensitive" occupation. Unlike truck drivers, which are considered safety sensitive, EMT-Ps are not prohibited from working long fatigue-inducing work shifts. The 24-hour shift is a traditional characteristic of the fire department. Large career fire departments are providing EMT-P service to densely populated urban and suburban areas with high call volumes; many of the areas with the highest demands for Emergency Medical Service (EMS) are served by EMT-Ps working 24-hour shifts. The impact of the long work shifts upon the life-saving care they provide to the public is unknown.

Though the long shifts of EMT-P work nearly guarantee that fatigue is regularly present, there is no evidence that significant alcohol impairment is prevalent among EMT-Ps. However, concern is warranted that even a low BAC (less than 0.04%) and/or the performance impairment of hangover resulting from a night of drinking (at zero BAC) can and does significantly affect performance in many job-related tasks. Some sensitive occupations, such as airline pilots, are required to avoid alcohol before work shifts. Furthermore, alcohol can contribute to sleep difficulty; alcohol-related and sleep-related impairments can be additive. The age group of working EMT-Ps spans the same range (early 20s to mid-40s) of typical alcohol treatment populations and DWI populations.

Alcohol, Fatigue, and Safety Sensitive Occupations

Howland, Rohsenow, and Cote et al. (2000) have noted that alcohol's burden on workplace productivity and safety may be underestimated, because usually workplace alcohol policies do not extend to low BAC levels (0.04%). Human factors performance research by Moskowitz and others (Moskowitz, Burns, & Williams, 1985; Liguori, D'Agostino & Dworkin, 1999; Grant, Millar, & Kenny, 2000) demonstrate important cognitive and physiological consequences that can lead to poor driving-related performance at low BAC. Recent studies suggest that alcohol consumption and duration-induced fatigue may impair performance to a similar degree (Dawson & Reid, 1997). In recognition of the hazards of lower BAC in some occupational settings, aircraft pilots, railroad engineers, merchant mariners, and nuclear power workers are prohibited from functioning at BAC $\geq$ 0.04%, which is half the limit for operating a passenger car in the United States.

Many drivers who do drink are unaware that their BAC level remains elevated the morning after drinking. Drivers with restricted licenses who are required to use an alcohol interlock to prevent drinking and driving nonetheless have the highest rate of failed in-vehicle BAC tests between 7 and 8 a.m. (Marques, Voas, Tippetts et al., 1999). This occurs despite the driver abstaining from alcoholic beverages since the previous evening and usually having no ill intent (confirmed by interviews and the self-interest of needing to get to work). Simply stated, after a night of drinking, BAC levels often do not return to zero by the next morning. At an average metabolic clearance of 0.017% per hour, a drinker who was well under the average BAC level of arrested of drunk drivers (e.g., 0.16%) at bedtime would still have an elevated BAC above 0.04% when reporting for work in the morning. An average size male drinking 10 or 12 beers would find himself in this situation the morning after. Even this post-intoxication level BAC would be prohibited in some nations and some occupations.

In most European Union nations, the legal driving limit for cars ranges from 0.02% to 0.05%. For US truck drivers, the legal limit is 0.02% (CFR, 1988).

Alcohol and Performance

Moskowitz, Burns, and Williams (1985) demonstrated that performance on a divided attention task and a visual search task was significantly impaired by alcohol ingestion, even at a very low BAC of 15 mg/dL (e.g., 0.015%).

Operators of vehicles (Laurell, 1977; Tornos & Laurell, 1991; Liguori, D'Agostino, & Dworkin, 1999), aircrafts (Billings, Wicks, Gerke et al., 1973; Morrow, Leirer, & Yesavage, 1990; Morrow, Leirer, Yesavage et al., 1991; Yesavage, Dolhert, & Taylor, 1994; Yesavage, Dolhert, & Taylor, 1994), and—most recently—marine vessels (Howland, Rohsenow, Cote et al., 2000) display operational impairment that begins at low BACs. For example, impairment for motor vehicle operators performing emergency braking and evasive maneuvers can begin at BACs as low as 0.042% (Laurell, 1977); for pilots, it can be as low as 0.02%. Some impairments in Laurell's (1977) study began to emerge at BACs as low as 0.024%. As a consequence, the American Medical Association and the National Safety Council's Committee on Tests for Intoxication concluded that, at 0.03% BAC, cognitive and motor performance began to decline to unsafe levels (Council on Scientific Affairs, 1986), and the Transportation Research Board (TRB) of the National Research Council (NRC) recommended that US Department of Transportation set 0.0% as the BAC standard for operators of all modes of transportation (TRB, 1987).

The impacts of alcohol are not limited to the intoxicated individual per se or even to someone with a measurable BAC. There is growing consensus on a common definition of hangover or veisalgia (Wiese, Shlipak, & Browner, 2000). The complex of symptoms associated with hangover may include headache, a poor sense of overall well-being, diarrhea, anorexia, tremulousness, fatigue, and nausea. Wiese, Shlipak, and Browner (2000) note that the patient with hangover is at risk for increased injury and decreased job performance. Hangover impairment has been demonstrated in pilots (Yesavage & Leirer, 1986; Yesavage, Dolhert, & Taylor, 1994), drivers (Seppala, Leino, Linnoila et al., 1976; Tornros & Laurell, 1991), and recreational skiers (Cherpitel, Meyers & Perrine, 1998) and has also been found to affect managerial skills (Lemon, Chesher, & Fox, 1993; Strerufert, Pogash, Braig et al., 1995). Importantly, evidence suggests that hangover is "much more common" in light to moderate drinkers than in heavier drinkers (Wiese, Shlipak, & Browner, 2000; Crofton, 1987).

Sleep Deprivation

A survey of house staff at a large urban medical school found that respondents averaged 3 hours of sleep during 33-hour on-call shifts, much of which was fragmented by frequent interruptions (Marcus & Loughlin, 1996).

Drummond, Brown, Gillin et al. (2000) note that sleep deprivation for as little as one night impairs performance on many cognitive tasks (Horne, 1988; Dinges & Kribbs, 1991; Pilcher & Huffcutt, 1996; Harrison & Horne, 1997;1998), especially verbal learning (Williams, Gieseking, & Lubin, 1966; Polzella, 1975; Lubin, Hord, & Tracy, 1976), but the impacts of sleep deprivation on cognitive performance may depend in part on task-specific demands.

The Impacts of Shift Work

Paley and Tepas (1994) studied the impacts of rotating shift work on firefighters' mood and sleepiness ratings. Negative mood scores were higher and sleepiness ratings greater on the night shift. Tepas, Walsh, Moss et al. (1981a) reported that approximately 50% of shift workers typically spend at least 24 hours awake on the first night shift in a tour of duty.

The Night Shift and Sleepiness

Traditional examples of night shift-related performance deficits include reduced reaction time or diminished abilities in mental arithmetic (Tepas, Walsh, Moss et al., 1981b; Tilley, Wilkinson, Warren et al., 1982). It is not uncommon for night shift workers to struggle to stay awake (Leger, 1994) and to nap (Akerstedt & Gillberg, 1981; Peacock, Globe, Miller et al., 1983; Mills, Arnold & Wood, 1983).

Motor vehicle crashes (Harris, 1977; Hamelin, 1981) and military (Ribak, Ashkenzai, & Klepfish, 1983) and civil (Price & Holly, 1981) air crashes have been linked to fatigue due to scheduling. Finally, the Committee on Catastrophes, Sleep and Public Policy of the Association of Professional Sleep Societies (APSS, 1988) released a consensus report indicating that the Three Mile Island reactor meltdown, the near misses at Rancho Seco and the David Beese reactor, and the NASA Challenger space shuttle disaster stemmed from errors in judgment made in the early morning hours by insufficiently rested personnel. Furthermore, the Chernobyl nuclear disaster, officially attributed to human error, began at 1:23 AM (APSS, 1988). Perhaps less observable errors are a regular feature of fatigued EMT-Ps treating critically ill patients in the early morning hours of a shift that began the previous day.

In some occupations, personnel are allowed to sleep on the night shift, as is the case for physicians and for paramedics on 24-hour shifts. Akerstedt (1988) noted that, if a greater part of the night is spent working, considerable fatigue will result. The "on-call" system of shift work may be one of the most taxing, because the duty period begins immediately after a normal day of work has ended and the on-call period may be immediately followed by another normal day of work (Akerstedt, 1988).

Shift Work, Night Work, Extended Hours, and Performance

In many ways, the care provided by EMT-Ps draws upon components of the traditional skill sets of nurses and physicians. Because of task similarity and because this area is virtually unstudied for paramedic performance, we review studies of fatigue in physicians.

Medicine

A 1989 editorial in the *Lancet* decried the "Dangers of Not Going to Bed" for junior doctors. The editorial also reviewed nine cognitive task studies, eight of which showed impairment due to sleep deprivation. Durnford (1988) concluded by proposing that consideration be given to applying the same shift-duration rules to physicians that currently apply to pilots.

Asken and Raham (1983) concluded in their review that, though studies were sparse, the information available at the time led to the conclusion that "sleep-deprived physicians are likely to show deficits." Samkoff and Jacques (1991) reviewed existing literature in this area back to 1970. They concluded that sleep-deprived physicians compensate for sleep loss when faced with crises or novel situations but that performance suffered on tasks that were routine, were repetitive, or required sustained vigilance. Most recently, Kuhn (2001) has reviewed the literature on physician performance, emphasizing the impact of desynchronosis and observing that a few studies explore that component of shift-work-related impairments. Frequently cited studies on the impacts of sleep deprivation in hospital-house officers are those of Denisco, Drummond, and Gravenstein (1987), in which anesthesia residents scored significantly worse on vigilance tests when fatigued, and Robbins and Gottlieb (1990), in which internal medicine residents showed statistically significant declines in performance on cognitive tests after night call and pediatric residents showed declines in selected fine motor skills (Storer, Floyd, Gill et al., 1989). Deary and Tait (1987) reported mood changes and deficits in short-term recall after a night shift in an emergency department. Jacques (1990) was able to relate lowered Family Practice 'Board Scores' to the amount of self-reported sleep on the night before the exam. Smith-Coggins, Rosekind, Hurd et al. (1994) compared the performance of emergency department physicians working day and night shifts. Physicians working nights both were significantly slower at intubating a manikin and neglected procedural details.

Harrison and Horne (2000) have recently emphasized deficits in divergent or creative thinking that might be more sensitive to sleep deprivation than convergent rule-based thinking. Several studies support this view. Goldman, McDonough, and Rosemond (1972) reported that sleep-deprived junior physicians were more hesitant and showed less focused planning during a surgical procedure. Nelson, Dell'Angela, and Jellish (1995) examined the impacts of sleep deprivation (due to 'on-call' status) on innovative thinking as measured by the Torrance Test of Creative Thinking (TTCT). These investigators sought to determine how divergent thinking, as is commonly used in critical situations (Jerison & Pickett, 1963), would be affected by sleep deprivation and found marked deterioration in scores. Anesthesia residents who slept no more than 30 minutes per night displayed impaired innovative thinking and verbal fluency, whereas complex convergent task performance was unaffected. The implication of this type of sleep-deprivation effect for EMS problem solving is clear.

Finally, Taffinder, McManus, Russell et al. (1998) examined the effects of sleep deprivation on surgeons' dexterity on a laparoscopy simulator. Using a within-subjects design, they determined that sleep-deprived surgeons made significantly more errors and took longer to complete tasks.

Equilibrating Cognitive and Performance Deficits of Alcohol Use and Sleep Deprivation

In an effort to translate the performance impacts of fatigue into a metric more easily understood outside the sleep research community, a few studies have compared the performance-impairing effects of fatigue to those from alcohol. As early as 1970, it was demonstrated that night-shift performance on a flight simulator falls to levels typically associated with a 0.05% BAC (Klein, Bruner, & Holtman, 1970).

Dawson and Reid (1997) and Lamond and Dawson (1999) evaluated healthy subjects aged 19-26 with a battery of standard performance tests during and after a period of sustained wakefulness of 30 hours after being dosed with alcohol to a BAC of 0.10% and after being dosed with a placebo beverage. Equating the performance impairment, 17 hours of wakefulness produced performance decrements equivalent to a BAC of 0.05% (Dawson & Reid, 1997). Furthermore, 20-25 hours of wakefulness produced impairment performance decrements equivalent to those observed at a BAC of 0.10%. The relationship of these findings to deficits in real-life task performance is unknown; for practical and ethical reasons, the only pragmatic option left to investigators is, as we propose, to study a simulation.

It is clear that a physician or paramedic intoxicated to a BAC of 0.10% would pose a patient-care hazard. It is also evident that regulations in a variety of non-health sectors stipulate that safety-sensitive workers may not have even a 0.04% BAC. The fatigue of double-nursing shifts, physician-on-call practices, and EMT-P 24-hour shifts easily matches or exceeds the equilibrated fatigue/BAC performance decrements.

In a recent driving-simulator study (Fairclough & Graham, 1999), the performance of subjects who had not slept the night before testing matched the safety-critical deficits of the group of subjects who had been dosed with alcohol. A partially sleep-deprived group (only 4 hours of sleep the night before testing) showed performance decrements but not to safety-critical levels. Interestingly, the fully sleep-deprived group displayed a significantly higher frequency of lane crossing than did the alcohol group, but the partially sleep-deprived group displayed a significantly higher frequency of near-lane crossing than did the two intervention groups or a placebo control group. Williamson and Feyer (2000) tested a group of sleep-deprived and alcohol-dosed subjects on a range of performance tests, including cognitive and motor speed, accuracy, coordination, and attention. By the 17th hour of sleep deprivation, levels of performance on all tests had declined to be equivalent to a BAC of 0.05%. After 19 hours, performance had declined to levels associated with a 0.10% BAC. The 17th hour corresponded to 2230 h, well within a duration and time of day consistent with a 24-hour shift beginning in the early morning and nearly identical to that for the subjects who were recruited for the study.

Sleepiness and Decision Making

Harrison and Horne (2000) reviewed two decades of literature on the impacts of sleep deprivation (SD) on decision making. The following divergent thinking skill areas have been shown to be sensitive to SD: (1) appreciating a complex situation while avoiding distractions; (2) keeping track of events and developing and updating strategies; (3) thinking laterally and being innovative; (4) assessing risk and anticipating a range of consequences; (5) maintaining interest in outcome; (6) showing insight into own performance; (7) remembering “when” rather than “what”; and (8) communicating effectively. Each area listed above is arguably central to the provision of emergency medical care, especially in the chaotic prehospital environment, where EMT-Ps practice their trade.

Research Methods

The approach to this investigation involves use of trained EMT-Ps in a within-subjects design. Test subjects perform several standard cognitive and psychomotor tasks and mood evaluations, and they serve as a rescue team leader using the instrumented manikin on three separate occasions. In each of the rescue situations, the EMT-P under evaluation is naturally fatigued coming off of a 24-hour shift, experiencing some degree of alcohol hangover consequent to controlled experimental dosing with high-congener beverage alcohol, or fully rested and unimpaired by alcohol.

The effect of the experimental manipulations to induce measurable performance deficits in cognitive and motor skills performance is assessed first with standard assessment protocols known to be sensitive to fatigue and impairment. Then, the subject is tested in his or her ability to perform critical rescue skill routines on the instrumented manikin. In order to control for positional or learning effects, experimental subjects are exposed to each of the conditions in a counterbalanced design so that no test condition across subjects will have had a greater or lesser amount of prior exposure to the testing situation.

EMT-Ps in Maryland

EMT-Ps in Maryland are certified by the Maryland Board of Physician Quality Assurance. The Maryland Institute for Emergency Medical Services Systems (MIEMSS) administers Maryland's statewide EMS program. Treatment protocols and the skills sets of Maryland EMT-Ps are standardized across the state. The resuscitation sections of the Maryland Protocol for EMT-Ps are adapted from the ACLS guidelines referred to earlier in this report. The implication to the research is that Maryland's ACLS-based protocol for EMT-Ps is appropriate as a performance measure for EMT-Ps in Maryland and potential findings are generalizable to EMT-Ps outside of Maryland.

Subjects, Recruitment, and Sample Size

Pacific Institute for Research and Evaluation's (PIRE) Calverton, MD, office, the site of the study is located in MIEMSS EMS Region 5. There are well over 500 career EMT-Ps in Region 5 as well as at least that number in neighboring EMS regions. Staffing of paramedic transport units falls into two primary schemes: (1) two EMT-Ps assigned to a paramedic transport unit, supported by first-responding firefighters, who are certified to the level of Emergency Medical Technician-Basic (EMT-Basic), assisting EMT-Ps in the treatment of critically ill patients; or (2) one EMT-P with an EMT-Basic driver, supported by other first responders on the scene of emergency medical incidents. Typically, a three- or four-member crew is involved in a resuscitation scenario: two EMT-Ps and one or two assisting EMT-Bs, or a crew of two EMT-Ps and one or two assisting EMT-Bs. Even amongst paramedics in jurisdictions accustomed to working with a second EMT-P, situations are not uncommon in which a paramedic provides care solely supported by EMT-Bs.

These crew structures are familiar and comfortable for the EMT-Ps recruited for this study. Furthermore, completion of the ACLS course is required every 2 years for recertification as an EMT-P. Thus, the subjects have prior general experience with ACLS testing scenarios. The evaluation procedures described below simulate practice situations with the typical complement of team leader and support that the EMT-Ps are familiar with. There is no team-level evaluation planned, and all evaluations are targeted on the index EMT-P serving in the role of team leader in the rescue situations. Support functions are provided by two PIRE staff consultants instructed to role-play as EMT-Bs; one acts as a practicing EMT-P, and the other acts as a former nurse. The field experience and familiarity of these individuals with resuscitation scenarios reinforce the fidelity of the testing scenarios.

Study subjects were recruited with the assistance of Consultant Dr. Terry Jodrie, MIEMSS Region 5 EMS Medical Director, through personal contacts managed by the Principal Investigator and through flyers and word of mouth. Ultimately, flyers were distributed to Nurse Managers and Emergency Department Directors in hospitals in and around Region 5.

Minimal prescreening occurred at the point of initial contact—usually telephone—to screen out teetotalers or those who otherwise state they do not drink and to ensure that potential applicants met the shift-work criteria. After agreeing to the general idea of the evaluation, prospective subjects complete the SMAST (Short form of the Michigan Alcoholism Screening Test). Scores >5 on the SMAST constituted an exclusion criterion, to avoid accepting subjects who show past or current evidence of a drinking problem. In addition, anyone who had been in substance abuse treatment, mothers who were nursing, or women who were pregnant were excluded. Prior to any session involving ingestion of alcohol, womens self-tested for pregnancy with an e.p.t.®

early pregnancy test. Due to the nature of the repeated testing protocol, including the need for subjects to agree to report after a long work shift and their needed voluntary compliance with an alcohol-dosing regimen, the nature of the evaluation was fully disclosed. The recruitment flyer and the informed consent form noted that the purpose of this study was to evaluate a combination of performance skills relevant to EMT-P work. It might be argued that, by knowing that their performance is under evaluation, for example in an alcohol hangover protocol, the demand characteristics of the test situation might set up an expectation of poor performance that is validated by the findings. Expectation has not been found to be an important source of variation when evaluated in other employment performance simulations (Howland, Rohsenow, Cote, et al., 2000). More importantly, a hangover in the real world will not be something that can be inadvertently slipped into the experience of a subject. Even ignoring informed consent issues (which we do not), on these bases we believe there is no reason to misrepresent the study's purpose.

Each subject received $400 if they were willing to comply with all three of the evaluation scenarios. All potential subjects received $25 for participating in the pre-screening process. Due to the importance of having all subjects serve in all three conditions, the payment schedule was set up so that completing part or all of the first testing scenario yielded an additional $75 ($100 total including the pre-screening incentive); any or all of the second scenario, another $100; and any of the third, $200. Subjects who completed all three would receive a total of $400.

Independent Variables

The two deficit conditions to be evaluated are fatigue/partial sleep deprivation and hangover/post alcohol intoxication. These are contrasted with assessments when the subject is fully rested and unaffected by unusual stimulus or arousal conditions. Consequently, there are three experimental variables. Because this study was set up as a model test situation to evaluate the deficit conditions in a way that has real-world relevance, the experimental manipulations were normative deficits, not extreme or uncommon deficits. To minimize subject error, all subjects were exposed to all conditions. To eliminate sequence effects or positional effects of exposure to the independent variable, the subjects were randomly assigned to a fully counterbalanced design. The design is more fully described in a later section.

Fatigue – Partial Sleep Deprivation

The fatigue scenario is scheduled when EMT-Ps have completed a full 24-hour duty shift. There is always some possibility of sleep during a 24-hour shift. Subjects are asked to report their sleep history for the 7 days preceding each session. Twenty-four-hour shift periods in this region typically end at 7 a.m. or earlier. Subjects report promptly to PIRE's Calverton location as soon as possible after work. To minimize the possibility that lighting and social arousal cues animate the subjects in a way that interferes with the partial sleep deprivation, subjects are maintained in low light and are required to participate in the somewhat monotonous cognitive tasks prior to testing in the manikin simulation. At this hour of the day, the PIRE office is still very quiet, as the working day for most staffers begins around 9 a.m.

Hangover

The general approach to induction of hangover will follow methods similar to those used previously by the applicant for alcohol dosing of experimental subjects (McKnight, Marques, Langston et al., 1997; McKnight and Marques, 1990). All procedures are in accord with the

National Institute of Health dosing guidelines for use of alcohol in experimental subjects; subject exclusions, such as those noted previously, were observed. The Principal Investigator, a licensed EMT-P, was present during the full duration of dosing and testing and ready to intervene in the unlikely event of an adverse reaction to alcohol. Subjects who passed the screening and signed informed consent documents were scheduled to arrive at PIRE in the morning after a light (low-fat) breakfast of cereal, fruit, and a beverage. Additional snacks were available at PIRE.

All subjects were weighed, and their BrAC (breath alcohol content) tested with a fuel-cell SD-2 preliminary breath tester (Lion Alcometer) was measured at baseline. PIRE already owns these devices, and they were available to the study at no added cost. The subject's height and weight information was used to estimate lean body mass (e.g., body water content), which was used as an early predictor of how much alcohol would be required to achieve the maximum target BAC of 0.10%. BrAC tests were conducted only after a mouth rinse with clear water and 5 minutes elapsed with no additional drinking. This was done to preclude mouth alcohol affecting measurements. During the dosing period, BAC was tested every 20 minutes. The PIRE staff prepared the drinks so that consumption could be logged, and the subject was permitted to choose from three different beverage types (bourbon, tequila, rum). These beverages were selected to enhance the possibility of hangover due to their relatively higher levels of congeners. Subjects were allowed to choose from a small number of mixers. Body mass and gender gave a preliminary indication of how many drinks would be needed to bring the BAC to near 0.10% without exceeding that level. Low-fat snacks were available for munching while the dosing was in progress. As drinking progressed, the BrAC test data was used to adjust a predicted BAC curve built on expected number of drinks required. This was done to avoid overshooting the target 0.09-0.10 g%. The typical number of drinks for men and women of normal body mass index is 5-6 for an 80-kg man and 4-5 for a 65-kg women, when consumed within 2.5-3 hours. Once this level was confirmed, subjects were asked to rest in a mock bedroom (a converted conference room) that was equipped with a cot, video player, tapes, TV, and various magazines. After the target BAC was reached or when the BAC rose at a rate that can be predicted to reach 0.10%, the subject was asked to stop drinking. At this point, he or she was engaged in conversation and watched for approximately 1 hour, and the BAC was tested to confirm the rate of rise has stopped. During the resting interval, a nursery-type audio monitor allowed the EMT-P researcher to confirm subject safety and comfort. The subject was told that the monitor will also serve as a convenience if he or she wanted to talk with the investigators. The subject was told to rest approximately 5 to 6 hours, watch videos, read, have lunch, or whatever seems of interest. BAC is tested periodically to predict when testing can proceed. The testing conditions are satisfied when BAC reaches 0.02% or lower. If drinking is completed by noon, this means testing can commence by 5 PM.

Design

A within-subjects design, wherein all subjects serve in all three conditions over a total of three testing sessions, provides a maximal amount of statistical power and keeps subject error to a minimum. In order to preclude introduction of positional effects, all test conditions and combinations of sequences are represented so that error due to position can be controlled in a counterbalanced design. With three independent variables to be manipulated, this requires [3x1x1] or six sequences of administration. By representing all possible combination sequences, this is more complete than a standard three-treatment Latin square design. Table 1 summarizes the design. In total, five subjects were randomly assigned without replacement to each of the six sequences in Table 1, for a total of 30 subjects.

Table 1. Testing Sequences

Sequence Number	1st Testing Session	2nd Testing Session	3rd Testing Session
1	Alcohol hangover protocol	Fatigue protocol	Rested/normal protocol
2	Alcohol hangover protocol	Rested/normal protocol	Fatigue protocol
3	Fatigue protocol	Alcohol hangover protocol	Rested/normal protocol
4	Fatigue protocol	Rested/normal protocol	Alcohol hangover protocol
5	Rested/normal protocol	Alcohol hangover protocol	Fatigue protocol
6	Rested/normal protocol	Fatigue protocol	Alcohol hangover protocol

Within each testing session, there are four people present: the investigator, the index subject who is evaluated, and two support players who are PIRE staff. The index subject is the team leader. The two support players participate in the roles that would ordinarily be played by additional members of a rescue team.

Dependent Measures

The dependent measures can be divided into cognitive/psychomotor performance assessments, mood assessments, and complex skill assessments on the manikin. In each assessment procedure, tasks are scored on criteria that relate to time, accuracy, and/or dichotomous detection of an event. PIRE's subsidiary, National Public Services Research Institute (NPSRI), produced a comprehensive, computer-driven battery, the Automated Psychophysical Test (APT), built upon standard assessments of the kind in the Pilcher and Huffcut (1996) studies. The APT includes divided attention, memory, reaction time, perceptual speed, motion detection, acuity, form detection, and other tests (McKnight & McKnight, 1994; McKnight & McKnight, 1999). This battery has been used with hundreds of drivers in an effort to screen out debilities in performance information processing in a pre-licensing evaluation of elderly drivers. The relationship between real on-road performance deficits correlated highly with the APT tasks.

Mood

The Nowlis Mood Adjective Checklist (Nowlis, 1965) contains 46 mood-related words. The subject reacts to these words on a 4-point scale, expressing the degree to which the mood describes their mental state.

Automated Psychophysical Test

The APT battery is customizable for the needs of the research question. Fourteen of the tasks were selected as germane to the skills we expect to be impaired by fatigue or hangover. The subject sits in front of a computer screen with a joystick in hand and listens to an introduction to the battery. The joystick is used for five different response possibilities: four directions of stick movement and one button press.

Complex Rescue Skills

The original equipment identified for the study, the Gaumard Scientific's Code Blue® III Interactive System for ACLS, seemed promising as a simulation engine for the study, but it became clear over time and even after considerable customization that Code Blue® III did not allow rapid and precise recording of subject's performance and so was not suitable for this study.

The new HAL® manikin simulator (Figures 1 and 2) features respiratory movements, palpable pulses, heart, breath, and Koratkoff sounds and generates electrocardiographic signals that can be detected by cardiac monitors. Internal circuitry can detect and measure defibrillatory and cardioversion shocks as well as pacemaker impulses through a realistically appearing conductive chest skin. The manikin and its feature set, suitable medical instruments, and supplies and role-playing actors, combine to create a high-fidelity simulation environment for measurement of subject performance. Working with Gaumard Scientific, a software feature set suitable for scientific applications was combined with a manikin simulator under development to create an appropriate test bed for this study. The software system is run on a tablet computer (Figure 3), connects via proprietary radio link with the manikin, and provides for automatic and pen input recording of subjects' interventions. The software system allows the investigator to rapidly and precisely record subject performance.

Figure 1. The HAL™ torso accommodates off-the-shelf medical equipment

Figure 2. A view of the HAL™ head and upper torso

Covariates

Development and Refinement of Assessment Instruments. Several instruments were created for subject pre-screening and/or experimental data collection: (1) The Alcohol Use Disorders Inventory (AUDIT; Saunders, Aasland, Babor et al., 1993) was modified for screening subjects to avoid accepting subjects who have shown or show evidence of a drinking problem. (2) A brief medical screening form was developed to avoid accepting subjects medically unable to drink alcohol, mothers who are nursing, or women who are pregnant. (3) The WITS Sleepiness Scale (Maldonado, Bentley, & Mitchell, 2004) was adapted and used with the permission of the authors. (4) The Nowlis Mood Adjective Checklist (Green & Nowlis, 1957) was recreated in its original form. (5) The Hangover Symptoms Scale (Slutske, Piasecki, & Hunt-Carter, 2003) was adapted and used with the permissions of the authors. Finally, the APT—which includes divided attention, memory, reaction time, perceptual speed, motion detection, acuity, form detection, and other tests (McKnight & McKnight, 1994; McKnight & McKnight, 1999)—was configured for use in this study.

BAC/Drinks

We record information on maximal BAC, testing BAC and the number of drinks consumed.

Procedural Sequence

As described in the original application, a system of resuscitation scenarios was developed in consultation with the study medical advisers (Table 2). Three sets of testing scenarios were developed in consultation with the study's medical advisors. Within each set, the difficulty of the intervention increases from Testing Session 1 through to Sessions 2 and 3. These scenarios have been programmed into the HAL® software.

Figure 3. A view of the HAL™ tablet-run software with proprietary wireless link

A given subject is assigned to Set 1, 2, or 3 to be tested in any of six treatment condition sequences (Table 1). All procedures and forms were pilot tested, and subjects consented at their first visit. Baseline BAC was collected on all subjects in all conditions. If BAC at baseline was zero and the evaluation for that day was not for alcohol dosing, further BAC testing was omitted and a test result of zero was assumed. When a subject is ready to be tested, he or she is asked to complete the instruments described above and the APT before entering the testing scenario. Dr. Becker served in the typical 'Instructor' role of an ACLS testing scenario. He was responsible for ensuring that the equipment is operational and ready for use. The sequence moves through the easy code, then the medium code, then onto the most difficult code.

Table 2. Scenario sets developed for the EMS Fatigue Study

DIFFICULTY	SET 1	SET 2	SET 3
LOW 1st Testing Session	ASYS	ASYS	SB
	5-7 Minutes	5-7 Minutes	5-7 Minutes
	VFIB	VTACH W/O PULSE	VFIB
	5-7 Minutes	5-7 Minutes	5-7 Minutes
	RSR	RSR	ASYS
	2 - 4 Minutes	2 - 4 Minutes	2 - 4 Minutes
MEDIUM 2nd Testing Session	SR W/PVCs	SR W/PSVT/LOW BP	SR W/PSVT/LOW BP
	5-7 Minutes	5-7 Minutes	5-7 Minutes
	VTACH W/PULSE	AFIB W/RVR	VTACH W/PULSE
	5-7 Minutes	5-7 Minutes	5-7 Minutes
	VTACH W/O PULSE	IDIO/PEA	VTACH W/O PULSE
	2 - 4 Minutes	2 - 4 Minutes	2 - 4 Minutes
HIGH 3rd Testing Session	SB W/VENT ESCAPE	2° AVB II W/LOW BP	2° AVB II W/LOW BP
	5-7 Minutes	5-7 Minutes	5-7 Minutes
	3° AVB	JUNCTIONAL BRADY	3° AVB
	5-7 Minutes	5-7 Minutes	5-7 Minutes
	SB/PEA	ASYS	VFIB
	2-4 Minutes	2 - 4 Minutes	2 - 4 Minutes

4. RESULTS

Aim 1

Paramedic Psychomotor Tasks. Progress toward achieving this goal is in the early stages. Three subjects have been tested through each treatment condition for a total of nine sessions. Utilizing PIRE institutional funds, additional subjects will be enrolled in the study to raise enrollment to levels necessary to achieve the aims of this study.

Aim 2

Important parameters of any medical simulation system are its sensitivity and realism with respect to subject performance. Stated simply, a medical simulator system must realistically represent the body systems being modeled and appear realistic with respect to shape, form, and response to intervention. It also must be designed in such a way that capable providers can intervene successfully using levels of effort commonly associated with successful intervention in real patients, neither substantially more nor less.

Formal assessment of sensitivity will be deferred until all subjects are run and data analysis is complete. In Tables 3, 4, and 5, we present findings from the first three trials (3 subjects x 1 testing session).

Table 3 suggests that the manikin realistically presents basic life support functions (i.e., responsiveness, pulse, and respiration) and that providers have performed well on fundamental basic life support interventions to date.

Table 4 indicates that the manikin simulator system provides realistic opportunities for performance and non-performance of ALS skill. In opportunities to date, intubation of the manikin has proven difficult. Further trials are required to determine if this is a function of manikin design, provider skill level, treatment condition, or some combination of these variables. Other skills, such as obtaining intravenous access, appear more readily accomplishable to date.

Table 3. Basic life support performance opportunities and interventions

Pilot Results: Basic Life Support (BLS) Skill Performance (Based on three trials)			
Skill	**Opportunities for Invention**	**Successful Intervention**	**Percent Successful Intervention**
Assess Responsiveness	3	3	100
Assess Airway Patency	3	3	100
Assess Breathing Sufficiency	3	3	100
Assess Circulation Sufficiency	3	3	100
BLS Skill Total	12	12	100

The findings in Table 5 provide an early glimpse into the difficulty of choosing appropriate medications for given scenarios and determining appropriate doses. Thus far, subjects have experienced little difficulty in determining the appropriate medication for a given situation and have experienced only slightly more difficulty in determining appropriate dosages.

Table 4. Advanced Life Support Opportunities and Interventions

Pilot Results: Advanced Life Support (ALS) Skill Performance (based on three trials)			
Skill	**Opportunities for Invention**	**Successful Intervention**	**Percent Successful Intervention**
Dysrhythmia recognition	10	8	80
Endotracheal intubation	7	1	14.4
Defibrillation	11	9	81.8
Transthoracic pacing	1	0	0
Obtaining intravenous access	5	3	60
ALS skill totals	34	21	35

Aim 3

This final report describes an iterative process of refinement, working with simulation equipment manufacturers, to develop software and a manikin simulator incorporating adequate fidelity. Software and hardware limitations are only two elements of simulation fidelity. Though preliminary findings are not yet available, the process of refining the comprehensive simulation environment has yielded a wealth of information. These findings will be presented at 5th Annual International Meeting on Medical Simulation, January 14-16, 2005, in Miami, Florida (Becker and Marques, 2005).

Discussion

Preliminary findings support the feasibility of assessing paramedic performance via an instrumented manikin linked to automated logging software. Experience with the initial software system chosen for the project led to the search for a responsive logging system that would allow real-time coding of subjects' actions. The system chosen for use facilitates rapid, accurate logging of provider interventions—key for minimization of measurement error.

Table 5. Medication Administration Opportunities and Performance

Pilot Results: Medication Administration (Based on three trials)			
Medication	**Opportunities for Administration**	**Correct Medication Identified**	**Correct Dose Administered?**
Epinephrine 1:10,000	8	8/8	8/8
Atropine Sulfate	7	7/4	6/7
2% Lidocaine	2	2/2	2/2
Sodium Bicarbonate 1 mEq/mL	1	1/1	1/1
Medication Administration Totals	18	18/18	17/18 (94.4%)

Our early pilot data indicate that the difficulty levels of some treatment tasks are sufficient to demonstrate performance deficits. To the extent that the current research is a pilot study, success has been achieved by establishing that a suitable manikin simulator system can be used to challenge paramedic performance. As more subjects are enrolled into the study, it will be possible to assess the impacts of the treatment conditions and develop recommendations regarding paramedic hours of service and consumption of alcohol prior to duty tours.

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