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FIELD-TRIAL VALIDATION OF THE JWGD MILPERF-NAMRL MULTIDISCIPLINARY PERFORMANCE TEST BATTERY (NMPTB)



E.A. Molina







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¹ This Final Report was prepared by Mr. E. A. Molina. Captain O. G. Blackwell underwent open Heart Surgery and since then, retired.

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FOREWORD

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In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45CFR46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institute of Health.

A. Moline 24 Investigator's Signature 24 April 10

JWGD³ MILPERF R&A OCTOBER 1991

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1. INTRODUCTION

In FY84, concern over the use of chemical weapons by Soviet Forces and by client states resulted in reanalyses of the U.S. forces chemical warfare (CW) defense. In particular, the DOD Joint Service Review Group had indicated (FY83) that the adversarial use of chemical agents is a serious possibility. As a result, the Chief of Naval Operations issued Operational Requirement S-0140-SL in which research on agent antidotes and chemical casualty treatment became high-priority Navy requirements. This multiphase research project addressed that Operational Requirement.

On 6 July 1983, a tri-service committee met at Headquarters, U.S. Army Medical Research and Development Command. The purpose of that meeting was to discuss human testing that could predict decrements in military performance as a result of treatment with medical chemical defense drugs. The committee agreed to establish a working group to address, in the short term, problems associated with operational use of pyridostigmine as a CW antidote and, over the long term, to identify and develop a test battery that would evaluate the performance effects of other possible antidotes and pretreatment drugs. Dr. Frederich W. Hegge was chairman of this group, which was officially designated the Joint Working Group to Determine Drug-Produced Decrements in Military Performance (JWGD MILPERF).

On 22 August, the Naval Medical Research and Development Command (NMRDC) requested the Naval Aerospace Medical Research Laboratory (NAMRL) to assess its capability to evaluate the effects of chemical defense antidotes on personnel performance in military operations. At that time, NAMRL was well along developing a performance test to be used in another research program. The objective of that program was the development of performance-based biomedical standards for the selection, retention, and classification of Navy and Marine Corps aircrews. On 31 August 1983, a description of these test batteries was presented to the Committee with the suggestion that these tests could be readily adapted for evaluating the effects of chemical defense antidotes on personnel performance in a variety of military operational situations.

On 15 September FY84, NMRDC directed that NAMRL develop a formal research program with three technical objectives:

1. Develop and validate a tri-service performance test battery for assessing the effects of CW antidotes on the performance of military personnel with and without protective clothing. 2. Develop guidelines for the use of commonly used medications and CW antidotes by naval aircrews under operational conditions.

3. Develop medical CW doctrine for Navy operations.

In response to the NMRDC directive, NAMRL developed the research program titled "Biomedical effects of chemical threat agent antidote and pretreatment drugs on military performance" with Dr. J. D. Grissett as principal investigator for the period FY84 through FY85. Captain O. G. Blackwell was assigned as principal investigator of the research project for the period of FY86 through FY89. In FY88, the research program was retitled "Validation of the JWGD' MILPERF-NAMRL Multidisciplinary Performance Test Battery (NMPTB)." At the end of FY89, the program was then continued as two separate research programs under the following titles: "Refinement and Implementation of the JWGD' MILPERF-NAMRL Multidisciplinary Performance Test Battery (NMPTB)" with Mr. E. A. Molina as the principal investigator, and "Modeling Human Performance Assessment" with Dr. R. R. Stanny as principal investigator.

This work unit and the existing NAMRL work unit that constituted the Biomedical Standards research program were organized and managed such that they were complementary and not duplicative.

This Final Report covers work performed for work unit 3M463764B995.AB.082 at the Naval Aerospace Medical Research Laboratory for the period covering Fiscal Years 1984 through 1989 inclusive.

Out of the three objectives, objective (1) has been completed. Completion of objectives (2) and (3) will require considerable amount of data collection and analyses from different operating communities. Budget funding limitations made it impossible to complete objectives (2) and (3).

Scientists at NAMRL developed the NAMRL Multidisciplinary Performance Test Battery (NMPTB) that allows a rapid and broadspectrum assessment of drug effects on human performance. The battery is comprised of tests from five different disciplines: vision, cognition, physiology, vestibular, and acoustical sciences.

2. METHODS

RESEARCH DESIGN AND METHODS

The overall research program was designed to have four phases.

Phase 1.

The first phase was to be conducted in the laboratory using a comprehensive range of tests to evaluate performance of riomedical functions that are relevant to naval and Marine Corps aviation tasks. These tests provided data to assess the possible effects of CW antidotes on these military relevant tasks. Subjects were tested before and after treatment with antidotes.

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Phase 1.

In the second phase, those tests that were shown to be affected by the antidotes were to be incorporated into mobile facilities for transport to the field for further testing on personnel who were engaged in military training activities that simulate critical tasks in the operational environment. Correlation between performance on the various aspects of the training activities were to be used to validate the operational relevance of the biomedical tests. Changes in biomedical performance caused by the antidotes would provide the bases for predicting changes in operational performance. Some of the training may be such that personnel could also be under the influence of the antidote without incurring an unacceptable risk. In such cases, the predictive value of performance decrements as shown on the biomedical test could be directly validated.

<u>Mobile Field Laboratories</u>. The mobile field laboratories would be used to perform the following tasks:

1. The mobile field laboratories could be transported to the Navy's Tactical Air Combat Training System for evaluating aviators and naval flight officer's performance under conditions of acceleration stress, high information-processing workload, high visual acuity and tracking demands, and auditory communications requirements. Performance in air combat maneuvering could be correlated with performance on the biomedical test battery.

The risk is probably too high for tactical jet crews to fly while under the influence of antidotes, therefore it would be necessary to transport the field laboratories to a centrifuge to evaluate the effects of the antidote on G-loading and thus validate the ability of the cardiopulmonary test battery to predict changes in G-loading tolerance. 2. The field laboratories could be transported to various flight simulators to evaluate cognitive, visual, and auditory performance. The simulators would allow the subjects to take the antidotes without incurring a risk; therefore, these facilities would provide good data on the performance effects of the antidotes and the predictive value of the test batteries.

3. The field laboratories could be transported to Marine Air Wing units to evaluate the performance of ground support units and aviators in air-to-ground combat and in aircraft designed for vertical takeoff with fixed wings.

4. The field laboratories could be transported to antisubmarine warfare patrol squadrons to evaluate the cognitive performance of aircrews and evaluate the effects of the antidotes on fatigue and endurance associated with sustained flight operations.

5. The field laboratories could be transported to altitude chambers to evaluate the synergistic effects of altitude and antidotes on cognitive performance, tolerance to hypoxia, cardiopulmonary performance, and auditory communications.

Phase 3.

The third phase would evaluate the synergistic effects of antidotes and CW protective clothing on performance. These tests would be run primarily at field units where the availability of protective gear and subjects are sufficient.

Phase 4.

The fourth and final phase would evaluate the synergistic effects of antidotes and commonly used drugs such as salicylates and antihistamines and also those prescription drugs that are approved for treating patients while they remain on normal duty status.

Human performance decrements would be evaluated on the test batteries, designed to measure a wide variety of biomedical parameters. Subjects would be run on these tests before and after treatment with a specific drug.

3. RESULTS AND DISCUSSION

RESULTS

Phase 1.

a. A review of the Navy and Marine Corps CW doctrine was performed, identifying occupations that are most critical to combat mission and that must be performed without the benefit of collective CW protection systems. Existing task analyses were compiled, and a summary of that effort is reflected in references 1 and 5.

b. Nine NAMRL investigators attended the Army Research and Development Command Fourth Annual Chemical Defense Bioscience Review held at Aberdeen Proving Grounds, MD, 30 May to 1 June 1984.

c. Two field exercises were conducted with the Army National Guard and Marine Corps to identify criterion variables for analysis of operational performance.

d. Thirty-two subjects participating in a drug test were administered 2.0 mg of atropine (i.m.), a chemical agent antidote drug. They were tested on batteries spanning five major disciplines: (1) sensory response to motion, balance, and spatial orientation; (2) speech perception and fine-motor control associated with speech production; (3) vision and eye tracking capabilities; (4) cardiopulmonary, metabolic, and musculoskeletal function; and (5) cognitive information processing capabilities. Performance measures were also recorded while these subjects were under the effects of a placebo (1 ml saline).

Analysis of the data indicated the following:

(1) Dynamic equilibrium of the subjects was significantly degraded by atropine. Some difficulty in ambulatory equilibrium was also reported on a questionnaire administered to the subjects.

(2) Atropine produced a significant elevation (80%) of heart rate, 1 hour after administration. The rate returned to near baseline after 4 hours. Blood pressure changes were minimal and not significant.

(3) Suppression of nystagmus was significantly reduced by atropine.

(4) Questionnaire results suggested that coordinated fine-motor movements may be affected by atropine.

(5) Near point of visual accommodation, the closest distance an object can be brought into focus, was extended outward for subjects under the influence of atropine.

(6) Accommodative flexibility, the time required to shift focus from a distant target to a near target, was extended for subjects under the influence of atropine. (7) Analysis suggested that subjects wearing contact lenses performed significantly worse on a battery of vision and tracking tests than subjects not wearing contact lenses.

(8) The ability of subjects to perceive noise-degraded speech decreased by 1.5% to 4.5% (+4 dB and 0 dB signal-to-noise ratios, respectively), and the capability of subjects to produce intelligible speech was reduced by 1.0% to 3.0%.

(9) The overall vocal outputs of the subjects during atropine condition decreased in amplitude by 1 to 5 dB. This reduction in level was corrected to preserve the +4 dB and 0 dB signal-to-noise ratios. Without this correction, it is highly probable that speaker intelligibility would have been significantly reduced.

(10) Atropine produced no significant effects on pulmonary function, muscular strength, or the work output of subjects. However, in some subjects, atropine appeared to affect orthostatic tolerance.

The complete reports of data analyses for the 2-mg atropine study are provided in references 3 and 10.

Phase 2.

(a) Contracts were awarded for the A & E design and construction of three mobile field laboratory trailers. The design was completed in February 1986. Construction was completed in August 1986. Installation of the scientific test equipment was completed in December 1987. Detailed descriptions of the three mobile field laboratory trailers are given in reference 9.

(b) A NAMRL and WRAIR initial effort resulted in the design and development of the Unified Tri-Service Cognitive Performance Assessment Battery [4,7].

(c) The design, development, and testing of the NAMRL Multidisciplinary Performance Test Battery (NMPTB) consisted of the UTC-PAB tests (Cognitive discipline) and additional tests derived from the four major scientific disciplines: (a) auditory, (b) physiological, (c) vestibular and (d) vision. Initially five scientific disciplines comprised the following tests:

Auditory:

Tone audiometry (500-8000 Hz) Speech perception in noise (tri-word modified rhyme test Speaker intelligibility

Cognitive:

Moodscale IMoodscale IIMast-2Mast-6Digital recallSleep scaleMatrix-1Matrix-2Time wall

Encode/Decode Logical Serial add/subtract Wilkinson

Physiological:

Dynamic muscular strength and endurance Peak Torque of right knee extension Peak Torque acceleration energy (TAE) Pulmonary function tests:

- Vital Capacity (VC)
- Forced Vital Capacity (FVC)
- Forced expiratory flow at 50 % total lung capacity
- Maximal voluntary ventilation (MVM)
- Peak respiratory flow

Orthostatic tolerance (measured using the tilt table) Changes in blood pressure and heart rate during the following scenario:

- Supine position for 5 min
- 20 deg off vertical for 15 min
- Supine position for 5 min

Percentage of body fat

<u>Vestibular</u>:

Static postural equilibrium Vestibulo-Ocular-Reflex performance test (VORPET) Ambulatory balance (Walk on Floor Eyes Closed procedure) Vestibular suppression Tracking task

Vision:

Visual acuity far Visual acuity near Horizontal phoria at near Vertical phoria at near Near point accommodation Pupil diameter Dynamic visual acuity (at 50 deg/s) Far to near accommodative flexibility threshold, and associated reaction time Additional information is described in references 6 and 12.

(d) The UTC-PAB/AGARD STRESS Battery described in reference 16 was implemented. The Battery consisted of the following programs that correspond to the specifications defined by AGARD AMP WG-12 [17]:

- Reaction time
- Mathematical processing
- Memory search
- Spatial processing
- Unstable tracking
- Grammacical reasoning
- Dual task (unstable tracking with concurrent memory search.

(e) Through a cooperative effort of NAMRL and USAARL, the performance effects of 4.0 mg atropine were studied using the NMPTB. Fourteen Army helicopter pilots were used in this study. Results confirmed those obtained from the 2.0-mg atropine study done in FY86. Data analyses revealed a wide variance in the atropine effects, indicating the need for atropine screening of individuals who perform critical tasks. The effects of atropine on visual acuity and reaction time affected the measurements of cognitive ability and gaze control so changes in test procedures and statistical analysis were implemented to make such tests independent measures. Detailed results of these atropine studies are reported in references 3, 6, and 12.

(f) In a cooperative effort of 4 Tri-Service laboratories NAMRL, WRAIR, NMRI and USAFSAM evaluated the effects of 100 mg of diphenhydramine (Benadryl®) and 60 mg of terfenadine (Seluane®) on 12 naval aviation students. This study involved a comparison of drug effects on the ability to execute a specific flight profile in an A-4 simulator and performance on the NMPTB. Detailed results are reported in reference 12.

Funds were not available to accomplish the other three field studies: drug effects on ground support crews at a Marine Air Wing; syrergistic effects of drugs and fatigue at an ASW patrol squadron; and synergistic effects of drugs, altitude, and hypoxia at a low-pressure chamber.

Phase 3.

Funds were not available to study the synergistic effects of CW drugs and protective clothing.

Phase 4.

Although funds were not available to conduct the

experimental work to study the synergistic effects of CW drugs and commonly used therapeutic drugs we identified the following theoretical and clinical issues that should be considered for this phase of the program and for the ultimate development of medical doctrine for CW drugs.

Multidrug interaction typically falls into one or more categories such as: (a) simple additive effects, (b) potentiating synergistic effects, (c) counteractive of blocking effects, or (d) confounding, anomalous or complicating effects.

Two basic principles of therapeutics are to choose a drug with the greatest benefit to risk ratio and always use the smallest effective dose. A basic principle of pharmacodynamics is that as dosage is incrementally increased, the rate of improvement in the benefit to risk ratio begins to decline and then reverses. This ratio decline and reverse can occur rapidly, unpredictably in certain circumstances, and occasionally catastrophically.

Therapeutic experience, dictates that for almost any safe purpose, when the lower doses are insufficient or only partially effective, then a second or third drug should be considered as a substitute for, or an addition to, the first drug rather than increasing the dose of the first drug to hazardous levels. The decision whether to add or substitute depends on several factors: (a) How badly does the patient need the less than optimum benefit of drug one, (b) how certain is the second drug to give a beneficial effect, (c) are there any intolerable adverse interactions to be expected, (d) are the potential benefits of the second drug derived by competitive (blocking), additive, or synergistic mechanisms, (e) are the adverse side effects of both drugs additive, synergistic, or blocking.

An example of the above concept that relates to CW drug effects is the possibility that drugs from the atropine group (ACh blockers) combined with drugs from the pyridostigmine group (AChE blockers) could offer a significant probability of additive or synergistic beneficial effects while canceling each others adverse effects. Specifically, the adverse performance effects of pyridostigmine or even physostigmine may be cancelled or at least reduced by the concurrent administration of atropine or scopolamine. A protocol for performance testing of this concept could be developed for consideration using a scopolamine patch concurrently with a pyridostigmine patch after testing each in single application.

Development of medical doctrine for pretreatment drugs must consider the dynamics of drug tolerance because the individual may be given the drug for days in response to threats that may occur at intervals for weeks or months. Tolerance may develop rapidly, altering the physiological effects of pharmacological compounds including nerve agent.

Another complicating factor is that altered tolerance to pretreatment drugs also changes the effect of postexposure treatment. For example, pretreatment with any ACh antagonist stimulates compensatory increases in central and systemic ACh levels and receptor density. Both effects almost certainly increase the lethality of nerve agents while reducing the treatment effectiveness of atropine as a postexposure drug. Conversely, pretreatment with AChE blockers would tend to stimulate protective increases in levels of AChE, which would enhance the postexposure effects of treatment with an ACh antagonist.

These dynamic effects of multidrug interaction and tolerance are better understood in terms of clinical response than for their impact on human performance. Development of military medical doctrine must also consider these effects on human performance and the consequent impact on mission accomplishment. Defining these relationships and developing optimal doctrine for CW drugs can be a very tedious and slow process that will require a large sample of the selected military population.

DISCUSSION

The ultimate goal of this tri-service program was to develop tools for assessing the effects of CW drugs on human performance. Implied in that objective was the expectation that these tools would be used to establish the military medical doctrine for using the CW drugs. Obviously, this doctrine would have to balance the risks to individuals, risks to combat mission, benefit to individuals, and benefit to mission. Members of the JWGD' recognized from the beginning that the issues were so complex that statements of medical doctrine could not anticipate all contingencies. The program objectives therefore included the development of a data base and interactive computer models that would allow military line commanders to access data that may predict drug-induced performance decrements on tasks applicable to specific mission profiles. We expected the data base to be dynamic with frequent additions of new research data and reports of actual field experience.

If funds had been available for completion of phases 3 and 4, data for the nucleus of the data base would have been established. The mobile field laboratories were designed for researchers to take their expertise to the field and accumulate data that line commanders could reasonably extrapolate to combat situations. Without this type of field data, the line commanders will have greater need for medical and human performance specialists to access a data base containing esoteric research data. These specialists will then make an "educated" extrapolation from laboratory results to combat situations. The $JWGD^3$ developed modeling software called Micro SAINT that may ultimately allow users to apply laboratory data to predict performance on military tasks. In FY88, NAMRL began using this software to model some of the tests on the NMPTB. These results are reported in references 8, 11, 13, 14, and 15.

In 1986, the Advisory Board Group for Aerospace Research and Development (AGARD), an element of the North Atlantic Treaty Organization (NATO), formed a Working Group to assess the current literature and recommended a battery of tests for human performance assessment. Dr. J. D. Grissett was appointed to that Working Group, and because he was also a member of the JWGD, he kept the two groups informed of the other's activities. The AGARD group selected and recommended to all NATO countries a battery of tests that was compatible with those under development by the JWGD'. The final report [17] of the AGARD published in 1989 provided detailed specifications for the tests but left the problem of computer software to the users. Under sponsorship of OMPAT, the NAMRL developed the software [16] thus making it possible for this battery of tests to be implemented and for OMPAT to be the international center for software distribution and data base development.

4. CONCLUSIONS

In coordination and collaboration with other JWGD³ MILPERF laboratories, and utilizing many of the performance assessment metrics already developed at NAMRL, a system has evolved that can evaluate human performance in five separate research disciplines: (1) cognitive, (2) physiology, (3) speech/hearing,(4) vestibular, and (5) vision.

The system was designed to test subjects under a variety of stressors, primarily chemical defense pretreatment and therapeutic drugs, but also environmental or physiological stressors, such as heat stress in chemical defense apparel and fatigue. Selected parts of this system will evaluate human error in sustained operations where mental and physical fatigue are common. Adaptations can be made for evaluation of error during difficult multitask stress, with the objective of reducing accidents and/or enhancing group coordination.

The existing system, with efficient movement of subjects between test stations, has demonstrated the capability to produce significant and relevant broad-spectrum performance data on a subject in approximately 5 hours following administration of a drug. In only 1 day, 7 subjects have been tested on all these tests. The purpose of this system is to provide field and fleet commanders and their medical staffs with an appraisal of the combat performance capabilities of their personnel in order to facilitate appropriate planning, training, and scheduling, or to identify special equipment necessary for mission accomplishment. Initial progress on this effort has been reported in references 2, 3, and 12.

Micro SAINT modeling has a great potential to make predictions of drug effects on related military operations. Once a particular operational task has been modeled, drug effects on task performance can the studied by programming various levels of skill decrements that a given drug level may cause (using literature reports of that particular drug effect) without actually exposing a human subject to the effects of the drug.

The continuous advance and wide use of lap-top computers will make possible the use of information collected in the field under actual training conditions (field-data bases) for predicting new or modified operations or field tasks.

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