U.S. Army
Research, Development, And Engineering Command (RDECOM), Independent Test And Evaluation Of The Stand Alone Patient Simulator (SAPS), Under The DoD Challenge Program.

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Medical Modeling and Simulation represents a relatively new venue for the Modeling and Simulation (M&S) community. While several studies have been conducted for training efficacy as a measure of effectiveness, no consensus has been reached as to the appropriate methodologies to provide test and evaluation strategies for verification, validation, and accreditation. The United States Army Research, Development and Engineering Command (RDECOM) developed a new technology for medical simulation called the Stand Alone Patient Simulator (SAPS). This development represents disruptive technology that, once fielded, will significantly increase combat medical readiness .The SAPS has qualified for accelerated fielding under the DoD Challenge Program. Consequently, RDECOM has contracted to conduct an independent test and evaluation at joint selected military locations under that program. The effort will be a precedent setting event for the world of medical modeling and simulation. This test will represent the first time a mannequin based patient simulator has gone through the Verification, Validation, and Accreditation (V,V&A) process. It will also represent the full application of the system engineering process to a test and evaluation construct.

Key words: Medical Simulation, Test and Evaluation, Verification, Validation, Accreditation, Mannequin Based Simulation, Stand Alone Patient Simulator, System Engineering.

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The Defense Science Board (DSB) established a task force on developmental testing in 2007. This study completed in 2008 made some significant observations. *"The DSB's findings concluded that systemic changes to acquisition processes and a lack of a disciplined systems engineering process have resulted in the high failure rates in suitability"* (DiPetto, 2008). To often, research and development efforts do not lead to viable production and fielding programs due to transitional documentation deficiencies and their associated corrective action strategies. A maturing technology requires complete documentation and corrective action management from concept through prototype and first article development into acquisition for production and fielding. As part of the research and development effort, these transition packages must be completed in order to facilitate the movement necessary to bridge the research and development phase into acquisition and fielding in a controlled process environment. In addition, acquisition and fielding funding cannot be readily obtained without these transition packages. In the worst case, life cycle funding can exceed developmental funding for reliability failures. All these issues are factored against tremendous pressure to get systems into war fighter's hands. Given the current OPTEMPO in asymmetric warfare, deploying forces need solutions now and cannot wait for traditional waterfall developmental processes. This dilemma can be resolved by using effective and efficient system engineering processes for requirements traceability to educational tasks, and detailed functional, component, and data flow descriptions within the conduct of developmental testing.

Medical Simulation
Medical Modeling and Simulation represents a relatively new venue for the Modeling and Simulation community, particularly for test and evaluation. Currently, the issue of effective test and evaluation matrixes for medical simulation has generated much discussion within the medical community (van Meurs, et al, 1997, DeVita, et al, 2004, Bradley, 2006). While several studies have been conducted for training efficacy as a measure of effectiveness, no consensus has been reached as to the appropriate methodologies to provide test and evaluation strategies for verification, validation, and accreditation (Gordon, et al, 2003,Gallagher, et al, 2004, Meier, et al, 2005). In addition, the suitability of one particular simulation (CD ROM) over another (patient simulator) is just now being considered. (Johnson, et al, 2008) However, there is a general consensus that medical simulation is a viable educational tool and will continue to proliferate (Wayne, et al, 2005). Thus research into a standard test and evaluation methodology is highly desired.

Figure 1. The Stand Alone Patient Simulator

Stand Alone Patient Simulation (SAPS)
A revolutionary technology has been developed in the research and development phase for medical simulation, the Stand Alone Patient Simulator (Figure 1). This development represents disruptive technology that once fielded will significantly increase combat medical readiness. The SAPS is the first physiologically based, ruggedized, wireless, feature rich, full patient simulator. It was developed under the Advanced Medic Training Technologies – Army Technology Objective (AMTT-ATO), to address specific Army training requirements, and to demonstrate the application of advanced technologies. The SAPS is the first full-bodied patient simulator designed from the start to be used in simulated combat environments. It is based on a reinforced skeletal structure with electronic, hydraulic, and pneumatic systems integrated under a foam flesh layer covered with realistic skin. The SAPS introduces the capability to train critical medical skills in rugged terrain, without the need for cumbersome logistic support. The SAPS is designed to train care under fire, and tactical field care while providing the capability to move and treat patients through all levels of battlefield medical care. It is also capable of training a majority of 68W (Combat Medic) and Combat Life Saver (CLS) critical tasks for initial entry, refresher, transition, and sustainment training, thus contributing to the Army's Simulation, Training, and Instrumentation mission and Army Medical Command's high priority interests. In addition, because of its high fidelity, it can be used for advanced skill training to include nurses and physicians, as well as, critical thinking and team interaction. It provides medical educators and instructors with a capability to objectively evaluate student performance through the implementation of valid, accurate, and repeatable medical conditions and procedures that eliminate subjective influences on

simulation outcomes or assessment of student behavior. This allows it to be used both for proficiency and mastery-based training. While SAPS is partially documented in a test-model-test approach, additional effort must be dedicated to independent test and evaluation before it can be fully fielded to ensure that the government maximizes all technological inserts available and establishes the suitability of use for each level of technology demonstrated. In addition, the future specifications and requirements for the formalized acquisition process must be independently established and completely described by the government to facilitate the suitability and reliability of the procurement, production, fielding, and life cycle support effort. This project will execute an expeditious best value solution to the documentation requirement for the research and development effort, and will furnish the necessary requirements data packages to transition the SAPS program to full productization and acquisition.
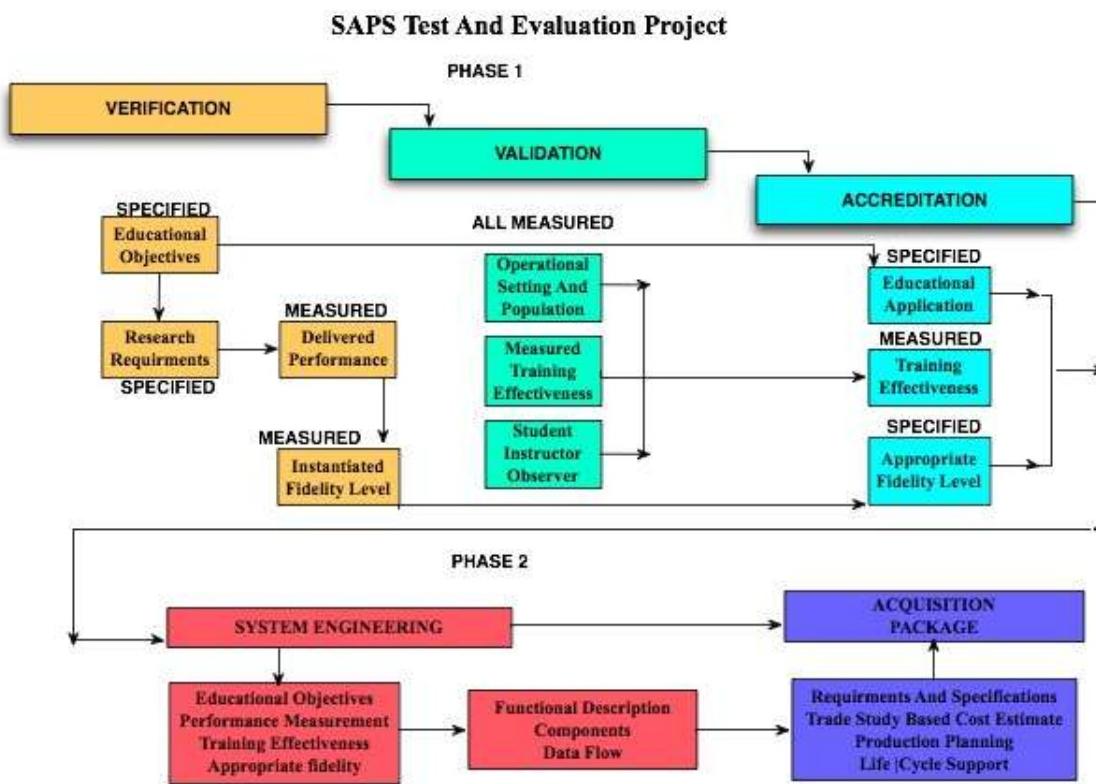

Figure 2. SAPS Test Design

Design Of The Effort And The Test And Evaluation Master Plan
The SAPS has been selected under the DoD Challenge Program to be accelerated for production and fielding. This program is procuring eight SAPS systems for both developer design improvement and independent testing. As part of that effort, RDECOM has instituted an Independent Test and Evaluation project to provide complete documentation to move the SAPS research concept into the acquisition, production, fielding, and life cycle support arena. The efficacy of this project has been reinforced by DoD Test and Evaluation changes in a December 22, 2007 memorandum that describes the necessity of early identification of technical, operational, and system deficiencies, so

that appropriate and timely corrective actions can be taken prior to fielding. The Test and Evaluation Master Plan (TEMP) has been constructed using DoD Directive 5000.1 with a modified Naval Air Warfare Center Training Support Division Trainer Test and Evaluation Master Plan format. Based on these elements, the project design was constructed with two integrated phases. Phase One is to establish Critical Operational Issues and Criteria (COIC) and Measures Of Performance (MOP) and Effectiveness (MOE) for the SAPS system, create a Test and Evaluation Master Plan, execute verification assessment of the research effort, conduct independent validation test and evaluation of the SAPS system at three selected joint operational medical training sites, and fuse and analyze the data collected. The processed data will be used to fully document user requirements, to verify the SAPS delivery to the government, to validate the SAPS concept as a viable instructional tool, and to prepare accreditation packages for the appropriate agencies for specific utilization approval. The data will also be available for full peer review. Cost will be considered as an independent variable and project progress and quality of effort will be measured. Consequently the project will produce inspectable test and evaluation and assessment data and system engineering functional, component, and data flow traceability to be used for requirements definition (Figure 2). Independently testing and evaluating the SAPS in actual use environments will determine its true effectiveness for these environments, identify weaknesses in the design, as well as in training and help provide a better product for incorporation into the DoD medical training centers.

Test Methodology
The first phase of the project is the independent test and evaluation. The test methodology for verification will be to use a prototype simulator with a go/no go evaluation of thirty designated performance items. These performance items will then be ratio scale graded as to the fidelity of their implementation, i.e. low fidelity is scaled as a 2, mid fidelity is scaled as a 4, and high fidelity is scaled as a 6. Thus an item rated as a low fidelity item will receive a composite score of between -2 to +2 or a range of five. Low or high fidelity is not "good" or "bad" in of itself, but only as it applies to educational effectiveness. Some medical tasks require more fidelity than others.
The test methodology for assessment of performance will be by training manager and instructor questionnaire, observer/controller grading, and by instructor evaluation and student pre and post-test. No control group will be used since each of the test locations all use patient simulation, and patient simulation effectiveness itself is not test item. The efficacy of the simulator is not the question. It is the appropriate application of the developed technology to the right Programs Of Instruction (POI). Instrument validity will be conducted prior to test conduct using standard validation methods. The test data will also be verified using standard statistical correlation methods.
The first fielding effort will most likely be for the United States Army Medical Simulation Training Centers (MSTC). The MSTCs are currently developing an automated training effectiveness measurement system for medical technical, applied, and tactical skills. Since these facilities have seen the most use of patient simulation in the military, their program efforts for measurement will be leveraged within this effort, particularly the use of an automated measurement tool called SIMILE^{TM} (Figure 3). SIMILE^{TM} is a government development co-jointly sponsored by the United States Navy

and the Advanced Distributed Learning (ADL) Co-lab. The primary objective was to develop a middleware application to integrate simulations and games into a SCORM compliant Learning Management System (LMS).
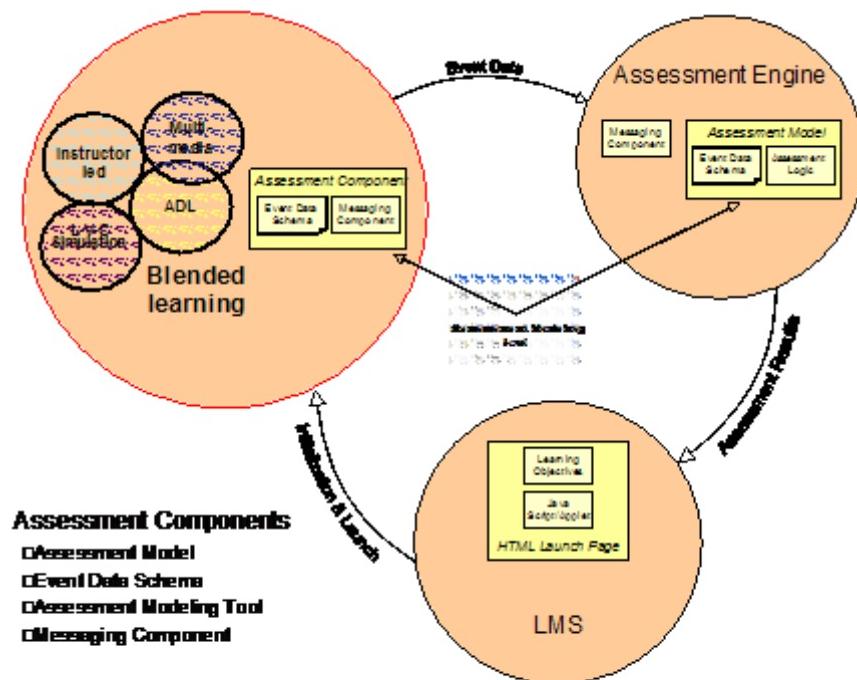

Figure 3. SIMILE^{TM}

The SIMILE^{TM} system consists of a user-friendly graphical interface for instructional designers and training managers, which minimizes pre-requisite technical knowledge for simulation or game data schemas. It has automated after-action review organizational capabilities hereafter referred to as performance assessment routines, and a feedback engine that provides evaluation of student performance and instructional methodology. This makes it an ideal candidate for test and evaluation data management.

The entire effort will furnish independent test and evaluation data to establish the verification, validation, and potential accreditation for the SAPS. In addition, the application of system engineering processes for requirements traceability will ensure that the test data is formatted for use in the acquisition cycle.

System Engineering
The second phase of the project is to conduct detailed system engineering processes to create the requirements and specifications for a production level product. This will include a detailed task analysis, a fully documented functional, component, and data flow design, and a productization process schedule. This effort will be based directly on the independent test and evaluation data gathered in the first phase with full traceability to the entire SAPS research and development effort. The resulting package will be

formatted in an acquisition, production, and fielding template to facilitate the procurement process for the next generation of military patient simulators.

For SAPS, government sponsored user tests have demonstrated three distinct needs; break away extremities, increased durability, and lowered cost. The three critical needs identified above will be independently evaluated. Also, the development Program Manager wants an independent assessment of fidelity to educational application to ensure requirement suitability.

Critical Operational Issues And Criteria

A detailed analysis of the current educational literature with particular attention on a variety of military occupational specialty educational requirements was conducted. In essence, those tasks all fell within specific domains for patient assessment, trauma management, treatment, and evacuation. In addition, these tasks were executed in four specific environments; care under fire, tactical field care, casualty evacuation, and high level care facilities. These tasks were correlated to the SAPS BAA requirements. In addition, user test deficiencies as well as Program Manager concerns were combined to create seven COIC.

The first issue was the simulator's stand alone capability. This issue was at the core of the research and development effort. Previously, patient simulators had been limited in their mobility because they were tethered to numerous devices; gas containers to make them breathe, electric power sources, fluid reservoirs for bleeding, and computer control units. These tethers made field use and realistic casualty evacuation almost impossible.

The second issue was the simulator's robustness for field training (particularly joints and skin). During user tests conducted during the development phase there was a high degree of unreliability, particularly with the joints and the skin, both of which were new developments. Previously, patient simulators had insufficient movement capability to be realistically evacuated or moved. In addition, skin was highly unrealistic both in appearance and behavior.

The next three items were the simulator's anatomical reality, the simulator's clinical accuracy, and the simulator's quick reconfigureability for lane training.

Finally, the last two items were particular concerns of the Program Manager, the simulators cost, and the applicable fidelity to the appropriate POI.

Site Selection And Population

Four sites were chosen to conduct the test, one for verification and three for validation. The verification test will be conducted at RDECOM in Orlando, Florida using simulation and military clinical subject matter experts. Because it is to verify traceability of instantiated requirements, no test population is necessary. The validation sites were chosen for their ability to support the test, the necessity for joint service evaluation, the experience of their instructors, and the diversity of their students. The sites include a DoD Medical Training facility, a U.S. Army MSTC, and a U.S. Marines Corps facility, which trains Navy corpsmen.

The DoD facility is the Defense Medical Readiness Training Institute (DMRTI) located in San Antonio, Texas and was chosen because of its mission, instructors, and student base. DMRTI is responsible for training all levels of students from physician to medic in tactical combat casualty care. Its instructors are some of the most experienced in DoD

and most are combat veterans. They have a tactically realistic simulation center with full observational control and data recording abilities, and have SAPS on site. Their command willingly supports research and test and evaluation. They are a joint facility that trains all services.

The U.S. Army's MSTC located at Ft. Bragg, North Carolina, supports the XVIII Airborne Corps, whose units have extensive deployments to both Iraq and Afghanistan. It is supported by both military and contract instructors. The students range from Combat Life Savers (CLS), who are non-medical personnel, and 68W Soldier Medics. They conduct skills, lane and validation (test) training.

The training facilities for U.S. Navy corpsmen supporting the U.S. Marine Corps are located in San Diego, California, and Camp LeJune, North Carolina. Their instructors are strong advocates for patient simulation. Their students are corpsmen who have completed initial entry training who upon completion of training deploy to forward U.S. Marine Corps units. Their training is combat skills based, and they have observational control and data recording capabilities.

In each case, on site training managers are totally involved in test planning and conduct to ensure validity of results. Site command receives entrance and exit briefings. Confidentiality and control of data is ensured, and neither test personnel nor procedures will interfere with their on-going training mission.

Measures Of Performance (MOP) And Measures Of Effectiveness (MOE)
MOPs will be used in the verification portion of the test. MOEs will be used in the validation portion of the test. Both will support the accreditation package preparation. All of the above data will support the system engineering process to prepare the acquisition package.

There are thirty measures of performance identified. They are divided into four categories; operating requirements, feature requirements, system requirements, and educational requirements (Figure 4). The measurement criteria are four rated categories with comment. The MOP either fails to meet the requirement, partially meets the requirement, meets the requirement, or exceeds the requirement.

There are sixty-five MOEs which are based on Training Circular, TC 8-800, United States Army, Medical Education And Demonstration Of Individual Competence, dated January 2008, primarily Table VIII which is the hands-on skills testing. These tasks are the primary source for 68W training and are grouped into six categories; trauma assessment and treatment, airway management, intravenous access, medications and management, medical assessment and treatment to include Chemical, Biological, Radiological, and Nuclear (CBRN), triage and evacuation, and cardiopulmonary resuscitation management. Table VII, obstetric, gynecology, and pediatric treatment was excluded, as was full decontamination for CBRN. The measurement of effectiveness will be determined by student cognitive skills pre and post-test, coupled with patient outcome as determined by recorded physiological state, both correlated to the instructor's rating of task performance. The test will be controlled by subject matter expert observational checklist.

MEASURES OF PERFORMANCE

FEATURE REQUIREMENTS

1. Physiologically correct reactions
2. Simulator weight should replicate soldier
3. Simulator should bend as a human
4. Airway anatomically correct
5. Pulses reactive to physiological change
6. Realistic pulse rate and quality
7. Bleeding and fluid loss
8. Blinking eyes and reactive pupils
9. Realistic heart sounds/breath sounds
10. Basic psychomotor skills for trauma treatment
11. Simulate orthopedic injuries
12. Flail chest
13. C-spine immobilization
14. Tremors
15. Multiple drugs
16. Surrogate drug injection devices
17. Specific drugs
18. Anatomical reality

OPERATING REQUIREMENTS

1. Free of all external connections
2. Internally powered w/external charge
3. External power source 110v with options
4. No scenario interruption w/power change
5. Wirless central control
6. Capability to introduce complications
7. Field ruggedized

SYSTEM REQUIREMENTS

1. Documented network interface
2. Multiple simulators centrally controlled
3. Networkability and interoperability
4. Cost of $30K

EDUCATIONAL REQUIREMENTS

1. Support all 68w tasks with two exceptions

Figure 4. Measures Of Performance

Test Conduct And Test Data Management

The verification test will be conducted using a relational matrix, which is a yes/no (go/no go) test. The research prototype either does the function or does not. There will be a correlated column data item to rate the fidelity of the tested function by the Subject Matter Expert (SME), with three categories; high degree fidelity, medium degree fidelity, low degree fidelity. The fidelity rating will be scale graded based on the functional performance requirements. In addition, the specified requirements will be directly traced to the educational tasks. Retesting of any identified discrepancies will be determined by the government.

The validation tests will be conducted at the above identified training locations. Questionnaires will be distributed to training managers, instructors, and students to determine the efficacy of each instantiated function. Selected scenario events will be

observed and recorded to reinforce the questionnaire data. Student performance will be observed for clinical accuracy and rated based on patient outcome. Learning will be evaluated by pre and post-test of task cognitive skills. Trainer downtime limitations during testing will be identified. Testing will not be terminated due to identified deficiency reports or inoperative trainer systems and subsystems.

The accreditation packages will be based on validation testing results and instructor input for selected Programs Of Instruction at each location. Training efficacy assessment will be done by a computer based program, SIMILE^{TM}, to ensure objectivity.

The Application Of The Results To V,V&A

In the conduct of this test, the following definitions were used to describe V,V&A (Elele, 2008). Verification is the process of determining that a model implementation and its associated data accurately represent the developer's conceptual description and specifications. The practical question answered by verification is "Is the model relatively error free, and does it do what the originator intended?"

Validation is the process of determining the degree to which a model and its associated data are an accurate representation of the real world from the perspective of the intended uses of the model. Note that M&S validation is not the same as software validation. The practical question answered by validation is "Do model results match real world data well enough for the user's needs?"

Accreditation is the official determination and certification that a model, simulation, or a federation of models and simulations and its associated data are acceptable for use for a specific purpose. The practical questions answered by accreditation are "Does the accreditation authority have adequate documented evidence to be confident that a model and its input data are credible for a particular use; and is that enough documented information to show that this M&S is fit for this purpose?"

These definitions are composites that fit the joint nature of the test.

The verification test was conducted in January 2009. The preliminary results are reported below as well as the lessons learned. The verification test was conducted in Orlando, Florida independently of any student or instructor presence. It was different than standard verification in that in addition to rating requirement delivery, it also assessed requirement traceability to educational standards. Past verification tests in most cases assumed valid requirements.

The validation tests will be conducted in the spring of 2009. For medical simulation, validation must be based ultimately on patient outcome. Thus physiological states must be known and accurate. Also for medical simulation, the reflection of procedural or algorim accuracy is a key measurement to ensure that the physiological state achieved is directly related to the clinical intervention. Additionally for medical education cognitive task expression is a measure of confidence level, a critical performance determinant as well as a measure of educational retention.

The accreditation packages will be completed and submitted to the various agencies in the summer of 2009. In essence, these will indicate by test data analysis what particular instructional items have been fully validated with an accreditation recommendation. This does not constitute a product endorsement.

Test Results

To date the only reported results are preliminary for the verification test conducted in January 2009. Of the MOP, the SAPS fully met six of the seven operating system requirements and partially met the seventh, field ruggedness. The issue was the strength of the simulated skeletal joints.

The SAPS fully met thirteen of the feature requirements, partially met three, and exceeded one. There was only one feature that was not met, replication of orthopedic injuries.

Of the system requirements three were fully met and one was not. The one not met was the cost.

Of the education task requirements, sixty of the sixty-five TC8-800 tasks could be performed on the SAPS.

The level of fidelity is still being evaluated, as well as, the educational needs to requirements traceability.

Lessons Learned

Though the test results are preliminary, four initial lessons learned have emerged.

The first is that any education or training simulation research development must be firmly grounded in educational requirements and that these requirements must be specified. Three of the five educational requirements not met were not specified. The other two not met were based on the failure to meet one feature requirement.

The second lesson learned is that effective developmental testing is essential to eliminate failure and to provide risk mitigation in assuring accurate delivery. The above failure was not identified in the initial user test conducted, indicating a developmental test failure.

The third lesson learned is that high fidelity should not be included for its own sake. Missing the system objective of cost has significant implications for the acquisition package. The suspected cause of this failure was an over aggressive application of unnecessary fidelity and technology. This will be verified when the fidelity data and validation data is compiled. Again, the focus has to be on meeting the specific educational requirements with precisely specified performance parameters. The fourth lesson learned is that in program requirements ruggedization must be expressed in reliability, availability, and maintainability measurements. Field ruggedness presented significant problems during the development. While field ruggedness was specified in the initial requirements, it was never fully defined.

Conclusion

The independent test and evaluation process, when applied with V,V&A principles and directly tied to system engineering processes, serves as an important risk mitigator to ensure program success. In addition, appropriate application of this process has the potential to produce significant cost savings for acquisition and life cycle costs.

Mr. John J. Anton is the principal investigator on this project. He has been responsible for developing the test methodology and the verification, validation, and accreditation applications. He also has been responsible for leading the system engineering effort. Mr. Anton is the former Chief Technology Officer for Medical Education Technologies Inc. and a Senior Systems Engineer for Loral Aerospace. He has a Masters Degree in educational psychology and has published several articles on verification, validation, and accreditation, performance modeling and medical simulation. He is currently employed by Information Visualization And Innovative Research Inc. He is a retired from the United States Army.

Ms. Emily Burns is the test engineer for the project. She is responsible for test execution and data collection. Ms. Burns is a former associate of Eagle Simulation, a medical patient simulation company, and a system and test engineer for GE Aerospace. She has a BS degree from Embry Riddle. She is currently employed as a Project Manager and Test Engineer for Information Visualization And Innovative Research Inc.

Mr. Jack Norfleet is the Lead Science And Technology Manager For The United States Army Research, Development and Engineering Command for Medical Simulation. Mr. Norfleet is the project Program Manager and Test Director. He also supervised the SAPS Development Program. He has been responsible for over ten medical simulation programs. He is currently enrolled in the University of Central Florida's PhD program in modeling and simulation.

LTC Dave Thompson is the Assistant Project Manager for Medical Simulation for PM CATT, for the United States Army's Program Executive Office for Simulation, Training, and Instrumentation. He directly supervises the Military Simulation Training Centers. He is the program's user advocate.

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