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U.S. ARMY

MEDICAL MATERIEL DEVELOPMENT ACTIVITY

1990 ANNUAL REPORT

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U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY
FORT DETRICK
FREDERICK, MARYLAND 21702-5009

31 JANUARY 1991

ANNUAL REPORT FOR PERIOD 1 JANUARY 1990 - 31 DECEMBER 1990

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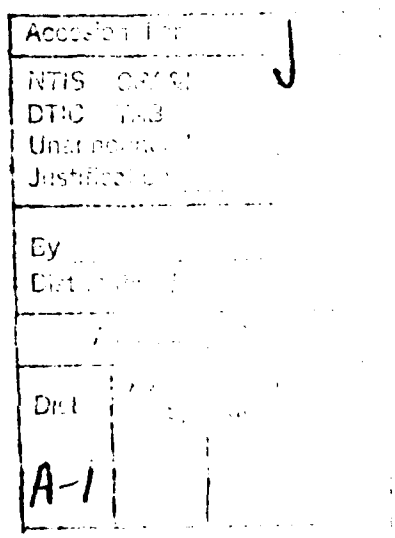
U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
FORT DETRICK
FREDERICK, MARYLAND 21702-5012



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The Annual Report, Calendar Year 1990, summarizes development projects monitored by the U.S. Army Medical Materiel Development Activity in projects authorized by the Surgeon General, the Army, and the Commander, U.S. Army Medical Research and Development Command, and supported by RDTE funds from the U.S. Army Medical Research and Development Command.

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U.S. ARMY
MEDICAL MATERIEL DEVELOPMENT ACTIVITY

1990 ANNUAL REPOPT

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INTRODUCTION

Once again, the year was filled with challenges as the staff of the U.S. Army Medical Materiel Development Activity kept pace with world changes and the very immediate threat of war in the Middle East. Many products were accelerated through the final steps of acquisition and FDA approval, funding allocations changed daily, and interspersed in all this turmoil were the concerns associated with reorganization. Shepherding progress in each product development by the three project management offices required intense innovative management.

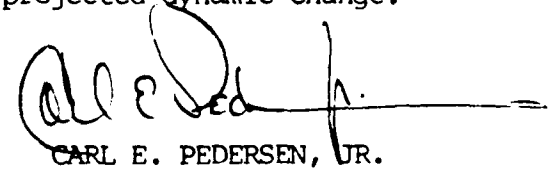
Accountability and proactive management remain the primary themes for the organization; reviews and analyses, data base updates, prioritization and concomitant funding alignments, MAMP and MSRC deliberations, IPRs, and high-level briefings to the senior AMEDD leadership and the DA/DOD staffs all reinforced the credibility of our efforts as well as acknowledging the fact that we actively serve the best interests of the user community. Witnessing the threat develop to near reality placed more emphasis on the organization to quickly and effectively field products.

Primarily due to events in the Middle East, high visibility products that were on track for the early 1990's were expeditiously fielded. Notably, the Rapid Identification Kit, diazepam autoinjector, decontaminable litter, and topical skin protectant were expedited through the FDA approval, contracting and fielding processes. The NDI program began in earnest as the Computerized Tomography (CAT) Scanner which was undergoing intensive testing was expeditiously prepared for deployment overseas. We still have no shortage of requirements to substantiate our development program.

The evaluation of the AMEDD acquisition system came to its conclusion with a series of recommendations for reorganization that are currently being reviewed by the AMEDD leadership for implementation prior to October 1991. When implemented, they will have profound implications on how the AMEDD acquisition process is conducted and managed.

In 1991, we intend to continue to scrub our major support contracts which serve as the underpinnings for our products. As funding becomes more difficult to justify, management must strictly control cost growth in the development program, and as the resources are allocated, they become targets for keenest outside scrutiny. Competition among product priorities will become even more intense, and product managers will be forced to use decisive trade-offs which impact on cost drivers, vis-a-vis, need for product enhancements.

The future will clearly be challenging, and we stand ready to fully support the AMEDD community during an era of projected dynamic change.



CARL E. PEDERSEN, JR.
Colonel, MS
Commanding

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PROGRAM MANAGEMENT

INTRODUCTION

The Project Management Support Division (PMSD) provides centralized program-wide administrative, financial, contracting, regulatory affairs and logistical support. Throughout 1990, the PMSD emphasis was directed to enhancing the support provided to the Project Management Divisions, and improving accountability for resources throughout the AMEDD materiel development spectrum.

MAJOR ACCOMPLISHMENTS

RESOURCES MANAGEMENT BRANCH

- Automated Data Processing Support: A 3Com local area network (LAN) was installed, providing new capabilities for laser quality printing for all Macintoshes and Zeniths; data exchange within USAMMDA and other USAMRDC facilities on post; and networkable software. Additional Macintosh IIs were procured to meet the expanding presentation graphics needs of the staff. To allow greater ease and flexibility in preparation of Gantt charts for the R&A briefings, FastTrack was purchased to replace the Gantt charting presentation module of the Project Management Control System (PMCS). The project management schedule functions of PMCS are now done with the PC-based software package, Timeline, for nonstandard developments or LOGPARS, the Army Standard System, for standard development projects. Work is continually progressing on upgrading the LAN to meet changing technology in the computer field.

- General Analysis/Priority System (GAPS): Development was completed on an enhanced version of GAPS, an automated resource management tool designed to assist in planning and programming for the cost of product development. GAPS contains vital product identification and funding data concerning all products managed by USAMMDA. GAPS provides easy on-line access to all product data ("Z Sheets") and a wide array of management reports which serve as invaluable tools in allocating limited dollar resources. GAPS also includes an on-line Help Module, a Query Module to provide "what if" capability, and a ZPrint Program resident on the LAN to provide individual Z Sheets to all users. GAPS was designed to operate in conjunction with MAMP database and software, thus maintaining data integrity and providing a stable environment for software and data maintenance needed to support the MAMP conference.

- Major Support Contracts: The PMSD is the Contracting Officer's Representative (COR) for a major support contract with Sherikon, Incorporated, to provide approximately 25 technical manyears annually to accomplish the Project Managers' documentation requirements. The contract objective of facilitating the timely and efficient execution of medical materiel development was met by providing preparation and assembly of support documentation required for coordinating development, production, procurement and fielding of developmental medical products. USAMMDA awarded 82 tasks during the year to provide In-Progress Review (IPR) participant packages, either a System Concept and a Decision Coordinating Paper; 20 life cycle cost estimates; 18 various logistical support plans and documents, 18 acquisition strategy plans; a logistics demonstration plan for contractor evaluation; a depot maintenance support plan; 4 market investigations; 7 draft Requirements documents for staffing; several other incidental product-specific analyses and papers; as well as support for program-wide data collection and analysis efforts such as the General Analysis/Priority System and the Mission Area Materiel Plan.

- Medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP): The FY90 Medical RDA MAMP Conference (July 1990) performed product assessments for evaluating the USAMRDC RDA Program with respect to medical-related combat requirements. Representatives from USAMRDC, USAMMDA, USAMMA, OTSG, Air Force, Navy, AHS, and TRADOC schools evaluated 91 development products and formally assessed 67 products against 27 Medical Area capability issues (CI). The 67 assessed products were then matched to 14 medical related Battlefield Development Plan (BDP) capability issues and three Army Capability Packages. Regional applicability and level of care appropriate for each product was also determined by conference participants. Additionally, the key issue of product affordability was formally evaluated. The affordability of each product was rated relative to both itself and other products competing for the same procurement dollars. Affordability has been a consideration in previous MAMP conferences; however, this was the first formal attempt to measure the impact of affordability on product ranking by adding an affordability index to the MAMP formula. The index illustrated that affordability measurement may significantly alter MAMP rank. The increased level of automation accelerated data analysis and presentation, and simplified AMEDD's development of Solution Sets into the Concept Based Requirements System (CBRS). The FY90 AMEDD prioritization was developed and was approved by the Commander, USAMRDC and the Commandant, AHS and the MAMP Report was issued in September 1990.

Significant changes were made to the data processing support for the conference. Previously, data was loaded to a database in the weeks immediately prior to the conference, processed during the conference and the report preparation period, then archived until needed to assist in next year's data load. Now, the MAMP database is fully operational at all times, allowing continuous access to the vital information, while providing a stable environment for development of software to support the future MAMP conferences. Multiple versions of the database, such as both the "frozen" FY90 database and the permanently operational database, or "transitional" database (in preparation for FY91 MAMP), can be in use at any point. In addition, MAMP has been designed to operate in conjunction with the GAPS database and software. Thus, it is now possible to obtain many of the GAPS reports using the MAMP database.

- Program Development: USAMRDC experienced broad-based support for medical developments in outyear program guidance during the 1990 Field Long Range Army Materiel Plan formulation process during the summer and fall based on prioritization schemes formulated at the MAMP. USAMMDA, as the agent for preparation and defense of the development portion of the USAMRDC program, was heavily committed to preparing impact statements and program analysis to support the AMEDD participants. Program reductions imposed in the FY89 cycle were restored in the Combat Casualty Care program and no further reductions were imposed.

The Human Immunodeficiency Virus (HIV) and Soldier Protection 6.3b and 6.4 DA projects were presented to the FY92/93 Department of Defense Budget Hearings for the first fiscal review of these new development program lines. The programs were briefed and accepted as presented for commencement in FY92. The HIV program was a realignment from previous budget program 6.3a. The Soldier Protection program was a restructuring from existing DA projects in the Combat Casualty Care program.

HUMAN RESOURCES

Through novel and intensive recruiting efforts, three hard-to-fill civilian specialties were brought on board: a Regulatory Affairs Specialist, a Pharmacologist, and a Toxicologist. Actions continue to resolve problems with recruiting and retaining civilian Logistics Management Specialists and military Logisticians.

- **USAMMDA Key Personnel:**

Position	Name	Date
Commander	COL C.E. Pedersen, Jr.	1 Jan 90 to 31 Dec 90
PM/AMSPMD	COL B.A. Schiefer	1 Jan 90 to 31 Dec 90
PM/BSPMD	Dr. W.E. Brandt	1 Jan 90 to 31 Dec 90
PM/PSPMD	COL R.O. Pick	1 Jan 90 to 23 Jul 90
	COL D.G. Harrington	24 Jul 90 to 31 Dec 90
Dir/PMSD	MAJ W.F. Heinemann	1 Jan 90 to 31 Dec 90

- **USAMMDA Strength:** As of 31 December 1990:

	Military	Civilian	Total
Required	25	51	76
Authorized	19	34	53
Actual	13	32	45

FISCAL PERFORMANCE

• In-House: USAMMDA in-house fiscal execution exceeded the established disbursement target for FY90. The shortfall in obligations was only 0.7% below target. Disbursements for FY90 exceeded FY89 performance by 20%, indicating a much more closely managed program. The improvement in disbursements was attributable mainly to increased use of support contractor resources.

	Allotment	Obligations	Disbursements
FY90 Dollars ($000)	3,574	3,549	2,772
Target (%)		100	51
Actual (%)		99.3	77.6

• Program Wide: Performance in the command-wide development program was not as successful as USAMMDA in-house, but much more successful than FY89. Both laboratory and extramural program performance met the obligation target and exceeded the more critical disbursement target. Total program performance in disbursements increased 29% over FY89. The increase was attributable to closer monitoring of contractor and government administrative processes in recording earned value and disbursements, as well as tighter scheduling of contract funding releases.

		PERCENT					
	Allotment	Laboratory		Extramural		Total	
Project	($000)	OBL	DISB	OBL	DISB	OBL	DISB
836	6,690	100	80	100	81	100	80
808	6,407	100	79	100	26	100	54
809	4,579	100	90	100	44	100	58
993	5,912	99	86	100	43	100	58
Total 6 3B	23,588	100	83	100	52	100	63
832	3,729	100	76	100	65	100	66
847	7,321	100	86	100	50	100	54
848	4,694	99	70	100	71	100	71
849	2,960	100	52	100	78	100	68
Total 6.4	18,704	100	69	100	62	100	63
Total Program	42,292	100	79	100	57	100	63

LOGISTICS MANAGEMENT BRANCH

- Integrated Logistics Support and MANPRINT: All necessary logistical plans and documents for the support of Milestone In-Process Reviews for the following USAMMDA products have been prepared by the Logistics Management Branch.

MONTH	TYPE	PRODUCT
March	I/II	Medical Aerosolized Nerve Agent Antidote
March	I/II	X-ray System, Dental, Miniature
April	II/III	Hypertonic Saline/Dextran
July	III	Insect/Arthropod Clothing Impregnant
August	II	Inactivated Hepatitis A Vaccine
August	I/II	Schistosome Topical Antipenetrant
August	II	Vital Signs Monitor
August	II	Resuscitation Device, Individual, Chem.
October	III	Ethylene Oxide Sterilizer
October	III	Steam Vacuum Pulse Sterilizer System
October	I/II	Klebsiella/Pseudomonas IVIG
October	I/IIIa	Japanese Encephalitis Vaccine
October	III	Convulsant Antidote, Nerve Agent
November	Special	Resuscitative Fluids Production System
December	Ib	Nerve Agent Pretreatment, Pyridostigmine
December	III	Ribavirin, Therapeutic
December	IIIa	Halofantrine
December	I	WR238605
December	IIIa	Pentostam

The documents prepared for the listed IPRs included ILS plans, System MANPRINT Management Plans, Transition Plans, System Support Packages, Basis of Issue Plan Feeder Data, Qualitative/quantitative personnel requirements information feeder data, Configuration Management Plans, etc. All the required documentation to support the development programs was prepared within the mandated milestone and DOD guidelines of cost, performance and schedule as it relates to each product.

A comprehensive data base was established for all active USAMMDA products that provides up-to-date status reporting for program documentation to include logistics requirements and cost information.

- Project Management Support: The Logistics Management Branch is providing the contracting officer's representative for the Field Medical Oxygen Generating and Distribution System. During the past year, the Logistics Management Branch arranged and participated in the technical test readiness review and the

training review conferences for FMOGDS. These meetings were followed by delivery of test prototype systems to the U.S. Army Test and Evaluation Command at Dugway Proving Grounds, UT. The COR conducted an Army acceptance inspection at Dugway on the prototype systems. Changes to the statement of work that have resulted from the management meetings and testing have been drafted and coordinated by this office. Other related meetings have included a project status briefing to the Academy of Health Sciences and two site visits to the contractor's facility.

- Production Contract Preparation: This year, the contract statement of work and other supporting documentation for the initial production contract for the FMOGDS have been initiated. The X-ray System, Dental, Miniature full scale development and initial production Request For Proposal (RFP) package, consisting of the statement of work, acquisition plan, Commerce Business Daily announcement, Source Selection Board nominations, suggested source list, etc., was prepared and completed by the logistics branch staff. The production effort for the Military Field Radiographic and Fluoroscopic System that had been managed by this office was cancelled because of a decision by the Assistant Secretary of Defense for Health Affairs not to procure.

- Configuration Management Support: Liaison with the Belvoir Research, Development and Engineering Center at Fort Belvoir, VA has continued during this year for management of technical data for USAMMDA developed products and systems. This year, support was provided for the Field Medical Oxygen Generating and Distribution System, and an investigative effort was initiated for establishing a repository for the extensive toxicology study report files for pyridostigmine and other products.

REGULATORY AFFAIRS

- Protocol Review and Monitoring - Reviewed clinical protocols prior to implementation and monitored OTSG-sponsored clinical studies conducted by DOD facilities and contractors. Participated in meetings to initiate the multicenter VA/DOD cooperative clinical study for hyperimmune globulin. Coordinated with DOD investigators participating in the multicenter study to determine the status of their ability to begin the clinical study. Developed procedures for contractors and investigators to more efficiently capture data to facilitate statistical analyses.

- 510k (Premarket Notification) - Coordinated a successful request through the FDA to market the decontaminable litter. Obtained an expedited review of the 510k for the FMOGDs and permission to market, albeit for battlefield use only.

- Regulatory Affairs Contract - The Project Management Support Division is the COR for the EER Regulatory Affairs contract and has overseen the administration of 15 task orders. Three of those task orders are support, administration, archiving and preparation of annual reports. The remaining 12 task orders include IND preparation, investigational brochures and responding to FDA inquiries for the aerosolized atropine NDA. Eleven of the task orders have come from the Biologial Systems Project Management Division. Two of those 11 task orders are complete.

- Chairperson for the Quality Assurance Committee - Implemented SOPs that standardize the monitoring procedures for USAMMDA. Organized a Good Clinical Practices Course to be hosted at Fort Detrick in January 1991. Attendance has been opened up to the Command.

APPLIED MEDICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Applied Medical Systems Project Management Division is a multidisciplinary team with broad mission responsibilities to centrally manage the development and initial production of applied medical products, related diagnostic equipment, eyewear products, and pesticide delivery systems.

MILITARY RELEVANCE

Applied Medical Systems is committed to developing compact, lightweight, durable medical equipment to achieve both the Army's demanding Service-unique and multi-Service mission requirements. Diverse, multi-discipline technologies are integrated to create a wide range of state-of-the-art systems. Equipment initiatives are directed toward addressing medical defense against chemical warfare agents, medical protection against military hazards, and the ability to provide care to the combat casualty.

OBJECTIVES

Army readiness is predicated upon the timely and successful execution of programs by the Materiel Developer. To achieve this, Applied Medical Systems capitalizes on emerging Tech Base efforts and aggressively manages the development component of the AMEDD Research, Development and Acquisition process to meet DA and Joint Services performance and supportability requirements for field-survivable medical equipment.

PRODUCT DESCRIPTIONS

- The Field Medical Oxygen Generation and Distribution System (FMOGDS) is an on-site, lightweight medical oxygen generating and distribution system which provides both bedside and cylinder-refill oxygen capabilities within TOE hospitals and medical logistics organizations. The system is designed to provide greater mobility, greater operational flexibility, and reduce logistics dependence on medical grade oxygen resupply.

- The Resuscitative Fluids Production and Reconstitution System (REFLUPS) is a device which produces sterile Water for Injection from a potable water source, combines that water with concentrated electrolytes to formulate parenteral solutions, and packages the solutions in sterile plastic IV bags.

- Ballistic-Laser Protective Spectacles (B-LPS) afford ballistic protection against small mass (5.8 grain) low velocity (640-660 feet per second) fragments and directed energy protection against two wavelengths (ruby and neodymium) low energy (0.1-1.0 joule per pulse) lasers. Two versions are available, one clear and one tinted. An optional prescription lens carrier provides vision correction for the ametropic wearer.

- Laser Protective Eyewear (Materiel Change) is a family of polycarbonate eyewear which consists of the spectacle frontsert, helmet visor, spectacle lenses, mask outserts, and eyewrap. These eyewear products are designed to attenuate laser threats (three or more wavelengths) emitted from range finders, target designators, and low energy laser weapons.

- The Steam Vacuum Pulse Sterilizer System (SVPSS) is a microcomputer-controlled automatic steam sterilizer which employs a pressure/vacuum pulse-conditioning principle for air removal and is designed to sterilize instruments, linens, and solutions for field hospitals.

- The Ethylene Oxide Sterilizer System (EOSS) is a stand-alone device for sterilizing non-heat sensitive devices as well as those sensitive to moisture or heat or those damaged by steam or liquid chemical sterilization. Products that fall into the latter categories include any plastic or rubber products such as catheters, resuscitation bags, anesthesia masks, surgical gloves, and most fiber optic instruments.

- The Special Operations Forces Sterilizer (SOF) is a rugged, compact, lightweight, easy-to-use steam sterilizer for the Special Operations Forces medical personnel operating in mobile or unconventional warfare modes. This sterilizer can use electricity, wood fires, or gasoline/kerosene stoves as a heat source.

- The Field Computed Tomography Scanner (CT) is a compact x-ray scanning system which weighs about 1,600 pounds, requires less than ten kilowatts of power, can be deployed in a 1:1 ISO Shelter, produces diagnostic quality CT information, and because of the thermal management design, can be operated continuously.

- The Combat Digital Radiographic System (CDRS) is the combat casualty care incarnation of a battlefield filmless medical imaging network. The focus is on image acquisition, networking, display, and archiving for the echelon III and IV theater hospital environment. Peacetime variations of this technology are also being developed along with two other basic thrusts; teleradiology and intra-hospital digital imaging networks.

- The Miniature Dental X-Ray System (XRSDM) is a small, lightweight, hand-held dental x-ray system for field use. The system consists of a hand-held x-ray generator subsystem (suitable for use with self-developing film or digital imager) and a digital imaging and storage subsystem for displaying images without the use of film.

- The Lightweight Medical X-Ray System (XRSLM) is a battery operated radiographic system which weighs less than one hundred pounds and will produce diagnostic quality 14 x 17 inch images. The primary user will be the Special Forces.

- The Powered Ventilator (PV) is a lightweight portable device which uses an oxygen source or filtered ambient air to resuscitate and ventilate apneic casualties that are being medically evacuated. Ventilation can be administered through either an oropharyngeal mask or a cricothyroid cannula.

- The Vital Signs Monitor (VSM) is a noninvasive electronic device which will determine the heart rate and blood pressure of a casualty in chemical protective clothing while in a battlefield environment.

- The Life Detector (LD) is a hand-held device which provides a noninvasive method for detecting heart beat, respiration, or some other indicator of the presence of life, through chemical protective clothing without compromise to the protective ensemble or individual. It also determines the adequacy of prior antidotal treatment.

- M-40 CB Protective Mask Vision Correction (Materiel Change) is a vision correction device which uses the Ballistic Laser Protective Spectacle prescription lens carrier and is internally mounted on the M-40 CB protective mask. Prescription lenses are mounted in the frame component of this eyewear.

- M-17 and M-40 CB Protective Mask Laser Protective Outserts are made of polycarbonate with applied absorptive dyes which afford laser eye protection from ruby and neodymium wavelengths. Additionally, the polycarbonate substrate serves to provide ballistic eye protection against small mass and low velocity fragments.

- The Environmental Health Monitoring Equipment (EHME) consists of an Electronic Wet Bulb Globe Temperature (WBGT) Monitor to measure dry bulb temperature, wet bulb temperature, and globe temperature, and a Hand-held, Heat-stress Calculator which contains a prediction algorithm capable of computing work and rest cycles and associated water requirements for the individual soldier under a variety of environmental conditions.

- The Computer Assisted Post-Mortem Identification System (CAPMI) consists of computer hardware and a software routine that compares antemortem and postmortem dental records to yield a list of most probable matches for facilitating the process of identifying human remains.

- The Externally Mounted Rescue Hoist (EMRH) will be mounted on UH-60A (Black Hawk) Medical Evacuation (MEDEVAC) helicopters. It will allow 25 to 33 percent more space inside the aircraft compared to the current design with internally mounted rescue hoist. The additional cabin space can be used for patient care, medical equipment, and the MEDEVAC litter kit. Use of the EMRH will decrease mission time required for extraction of casualties or personnel and decrease aircraft weight.

- The Field Dental Operating and Treatment Unit (OTUDF) is a small, lightweight, mobile dental unit which will be used to provide emergency, limited preventive, and sustaining dental care in the field. It consists of a light source, suction apparatus, water reservoir, and high and low speed drills.

- The Decontaminable Folding Litter (Litter) is capable of being decontaminated and providing a surface on which patients can be Chemical Warfare Agent decontaminated. It consists of aluminum poles and spreader bars, polypropylene mesh, retractable nylon handles, and ethylene-propylene-diene-monomer securing straps.

- The Chemical Warfare Agent Resistant Field Dressing Cover (Cover) consists of a strip of cotton gauze sandwiched between two laminates of polyethylene/nylon/polyethylene. The cover is used over the field battle dressing to protect open wounds and prevent penetration by chemical warfare agents.

- The Chemical Warfare Agent Protective Patient Wrap (Wrap) is a disposable fabric container to protect decontaminated or uncontaminated patients from chemical agents during evacuation in a field environment.

- The new Field Medical Refrigerator will replace the current refrigerator, used to store blood and biologics, which has become logistically unsupportable.

- The Individual Chemical Resuscitation Device (RDIC) provides manually operated positive pressure respiratory resuscitation to assist in the restoration of normal breathing of a battlefield casualty. The RDIC filters chemical warfare agents from ambient air and is usable with an oropharyngeal mask or cricothyroid canula.

- The Molecular Sieve Oxygen Generating System (MSOGS) will provide medical grade oxygen on Medical Evacuation (MEDEVAC) aircraft for trauma and chemical agent patient resuscitation.

- The High Capacity X-Ray (Materiel Change) is a flywheel system which stores kinetic energy and produces short high power bursts of electrical energy to enable a high capacity x-ray to operate from a wide variety of power sources.

MAJOR ACCOMPLISHMENTS

- A User Test was completed in 1Q90 for the **Field Medical Oxygen Generation and Distribution System (FMOGDS)** project on the MEPECC M1-C with unfavorable results. These test results were briefed to the Army Medical Department Technical Committee during June 1990 at which time a decision was made not to continue testing the MI-C's. Two Guild developmental items were delivered in April 1990 to Dugway Proving Grounds where they began Technical Testing in June 1990. Technical Testing continued through 4Q90 with High Altitude Electromagnetic Pulse and Electromagnetic Interference testing being conducted at White Sands Missile Range.

- Finalizing design, coding software, and building the Engineering Development Models (EDM) were the major thrusts of effort for the **Resuscitative Fluids Production and Reconstitution System (REFLUPS)** project this year. Two EDM prototypes and eight EDMs have been constructed and released for hardware/software integration and Systems Engineering Testing to verify performance requirements.

- The product improvement program for **Ballistic-Laser Protective Spectacles (B-LPS)** was initiated. Major improvements include a three wavelength laser protective eyewrap and a darker sun protective eyewrap. Production to support Operation Desert Shield requirements was initiated September 1990.

- The Request for Proposal for Emerging Laser Threat Eye Protection to develop **Laser Protective Eyewear (Materiel Change)** was issued 8 June 1990. The Source Selection Evaluation Board met in September and December 1990 to evaluate the initial proposals and their revisions. Procurement of two and three wavelength Laser Protective Visors and Laser Protective Aviator Spectacles was initiated in September to support Operation Desert Shield. The first shipment of spectacles arrived in Saudi Arabia in November.

- The **Steam Vacuum Pulse Sterilizer System (SVPSS)** had a successful Milestone III In-Process Review in October 1990 moving it into the Production and Initial Deployment Phase.

- The **Ethylene Oxide Sterilizer System (EOSS)** development was completed this year. A Milestone III In-Process Review (IPR) in October 1990 decided not to field the system at this time. All IPR members concluded the development effort is complete, and the technical data package will remain under the U.S. Army Medical Materiel Development Activity's configuration management until a fielding requirement is re-established.

- The U.S. Army Biomedical Research and Development Laboratory-designed **Special Operations Forces Sterilizer (SOF)** essential characteristics were finalized and a Request for Bids for a production contract issued. A contract was awarded September 1990.

- The contract with Imatron for the development of a **Field Computed Tomography Scanner (CT)** expired without proceeding into phase two development. Loan agreements were signed with Picker International and General Electric Company for clinical and technical evaluations of their CT systems. Clinical evaluations of the units at Fitzsimons Army Medical Center and Brooke Army Medical Center were interrupted by an OTSG decision to ship them to Saudi Arabia.

- A proposal to develop the **Combat Digital Radiographic System (CDRS)** was not funded. Four potential sources were identified for competitive procurement. A draft Joint Service Operational Requirement incorporating essential characteristics was developed.

- Final testing was completed and test reports were available to support a Milestone I/II In-Process Review (IPR) in March 1990 for the **Miniature Dental X-Ray System (XRSDM)**. A favorable program decision was made to transition into an expedited Full Scale Development and structure the contract with a limited production option. The Request for Proposal package was developed following the IPR and passed to the U.S. Army Medical Research Acquisition Activity in October.

- The development of the **Lightweight Medical X-Ray System (XRSLM)** is a joint effort with the mechanical work and drawings being done by the U.S. Army Biomedical Research and Development Laboratory (USABRDL) and the electrical design and assembly by the University of Wisconsin. The design of the electronic controls, the high voltage power supply, and x-ray source were completed and fabrication begun. The USABRDL has started the fabrication of the mechanical components and assembly of the technical drawing package.

- The deficiencies indicated in the Concept Evaluation Program test and Independent Evaluation Reports for the **Powered Ventilator (PV)** were corrected this year. The PVs are currently being technically tested at the Uniformed Services University of the Health Sciences/USABRDL to verify requirements are met.

- **A Milestone II In-Process Review (IPR) was held in 4Q90 for the Vital Signs Monitor (VSM).** The decision was made to test the Protocol Propaq 104 VSM on simulated human casualties aboard U.S. Air Force Medical Evacuation aircraft. The results of this test will indicate its suitability for Echelon III/IV use. The IPR also transitioned the VSM program back to Tech Base.

- Pulse Oximeter and Microwave Reflectance prototypes were delivered in 2Q90 for the upcoming **Life Detector (LD)** Concept Evaluation Program test. The pulse oximeter devices did not work reliably. A decision was made by the U.S. Army Medical Materiel Development Activity/U.S. Army Biomedical Research and Development Laboratory not to pursue further development of pulse oximeter technology to satisfy the life detector requirements. Instead, a technology that measures chest wall (heart) motion will be pursued via a developmental effort.

- Technical and operational testing for the **M40 CB Protective Mask Vision Correction (Materiel Change)** commenced August 1990. An early result from User Testing indicates weapon-compatibility superiority of the new product over the existing insert.

- Fabrication and polishing of optical quality molds for the **M-17 and M-40 CB Protective Mask Laser Protective Outserts** were successfully completed during November and December, respectively.

- An OTSG chaired Tri-Service heat stress symposium was held in 3Q90 at the U.S. Army Research Institute of Environmental Medicine. The need for a Wet Bulb Globe Temperature device with Heat Stress Calculator capability was determined to meet the requirements for the **Environmental Health Monitoring Equipment (EHME)** program.

- **The Computer-Assisted Postmortem Identification System (CAPMI) Mission Element Needs Statement was approved by HQDA.** The Defense Eligibility Enrollment Reporting System (DEERS) Support Office began a Pilot Study in 3Q90 to verify the feasibility of incorporating the CAPMI antemortem dental data base into DEERS.

- A Joint Working Group was held at the U.S. Army Aeromedical Research Laboratory in 2Q90 to discuss the results of the **Externally Mounted Rescue Hoist (EMRH)** Technical Tests. A Non-development Item acquisition strategy appears to be feasible. An In-Process Review (IPR) package was constructed for the EMRH Milestone I IPR scheduled in 2Q91.

- **The Field Dental Operating and Treatment Unit (OTUDF)** transitioned to the Defense Personnel Support Center where the system is in final contract negotiations.

- A modification was made to the **Decontaminable Folding Litter (Litter)** to make it more compatible with the litter stantion support arms on board Medical Evacuation aircraft. A Low Rate Initial Production of 720 litters was conducted at the Arizona Industries for the Blind to validate the Technical Data Package and provide Litters for user evaluation. A contract was awarded to procure Litters in support of Operation Desert Shield.

- The requirement for the **Chemical Warfare Agent Resistant Field Dressing Cover (Cover)** was determined to be nonexistent, actions on this product have been terminated, and the Joint Service Operational Requirement has been placed in inactive status.

- The Defense Personnel Support Center has not yet assigned a directorate to manage **Chemical Warfare Agent Protective Patient Wrap (Wrap)**. As a result, OTSG provided funds for a special purchase of Wraps in support of Operation Desert Shield.

- A contract was awarded to purchase **Field Medical Refrigerators** in support of Operation Desert Shield.

- A Milestone II/III In-Process Review was held in 4Q90 for the **Individual Chemical Resuscitation Device (RDIC)**. The decision was made to transition the project to Production and Deployment. A materiel evaluation test was conducted at the U.S. Army Medical Department Board in 1Q91 on both the Ambu and Army developed resuscitation devices. Both devices tested successfully and are currently being procured to support Operation Desert Shield medical requirements.

- A Market Investigation was completed on the **Molecular Sieve Oxygen Generating System (MSOGS)** which identified five potential manufacturers of MSOGS: Xorbox, Clifton Precision (Litton), Essex Cryogenics, Mepecc, and Draegerwerk. One Xorbox unit was purchased and one Essex unit was obtained on loan agreement for technical testing. The Operational and Organizational Plan was approved.

- The **High Capacity X-ray (Materiel Change)** project was terminated for lack of validated requirement.

PROJECTIONS

- **All testing for the Field Medical Oxygen Generation and Distribution System (FMOGDS)** will be completed with test results available for a Milestone III In-Process Review during the 3Q91.

- **The Resuscitative Fluids Production and Reconstitution System (REFLUPS)** Joint Service Operational Requirement will be approved by the U.S. Army Training Doctrine Command 3Q91. Army IOT&E will be conducted on three REFLUPS Engineering Development Models (EDMs) in April 1992.

- Planned improvements will be added to new contracts for **Ballistic-Laser Protective Spectacles (B-LPS)** to support Operation Desert Shield. Testing of the improvements to the B-LPS will begin 4Q91.

- The Source Selection Board will continue evaluation of Emerging Laser Threat Eye Protection proposals. Contracts for development of **Laser Protective Eyewear (Materiel Change)** will be awarded 3Q91. Requests for additional procurement of two and three wavelength Laser Protective Aviator Spectacles are expected January 1990 to support Operation Desert Shield.

- Food and Drug Administration approval of **Steam Vacuum Pulse Sterilizer System (SVPSS)** 510(k) is expected in 2Q91. The essential characteristics will be finalized in anticipation of a Request for Bids in a production contract in 4Q91. The SVPSS contract will end in March 1991.

- **The Ethylene Oxide Sterilizer System (EOSS)** Technical Data Package will remain under configuration management until a fielding requirement is re-issued by the Academy of Health Sciences. The Army will reassess the use of disposables in the field which will reveal a need for chemical sterilizers. A generic Operational and Organizational Plan for chemical sterilizers will be established in 4Q91.

- **The Special Operations Forces Sterilizer (SOF)** production contract's option for extra units from the prime contractor, Atlantic Industries of Hardyville, South Carolina will be exercised by 3Q91 if the requirement is verified and funding is allocated.

- User Testing of the two commercial **Field Computed Tomography Scanner (CT)** systems in Saudi Arabia will provide data to support development of a purchase specification and modified Non-development Item procurement.

- Specifications for a **Combat Digital Radiographic System (CDRS)** will be developed to support a Request for Proposal.

- The **Miniature Dental X-Ray System (XRSDM)** Full Scale Development/Production contract will be awarded 3Q91. It will be officially evaluated and tested for application in a medical setting rather than limiting its application to dental purposes.

- System integration, technical evaluation, and documentation to support Concept Evaluation Program testing of the **Lightweight Medical X-Ray System (XRSLM)** will be completed in FY91.

- The **Powered Ventilator (PV)** Early User Test and evaluation will be completed in August 1991.

- The Air Force will complete the Technical Testing of the Protocol Propaq 104 **Vital Signs Monitor (VSM)**, and a decision will be made on the pursuit of a Non-development Item acquisition strategy.

- A contract will be awarded in 2Q91 to initiate the development of a **Life Detector (LD)** capable of measuring heart rate and perhaps other vital signs noninvasively/nonintrusively on a battlefield casualty.

- Engineering development prototypes of the **M40 CB Protective Mask Vision Correction (Materiel Change)** will continue to undergo Technical and Operational Tests into 2Q91. Selection of the final version will be made early 3Q91. User Testing for the vision correction will commence 4Q91.

- Advanced development prototypes for the **M40 and M17 CB Protective Mask Laser Protective Outserts** will undergo limited User Testing in 2Q91. Requests for substantial quantities of outserts are expected early in the year to support Operation Desert Shield.

- An Operational and Organizational Plan for the **Environmental Health Monitoring Equipment (EHME)** program will be staffed for formal review and approval in 3Q91. A developmental effort will be initiated to build and test prototypes reflecting the characteristics in the requirements documents.

- The Pilot Study for determining the feasibility of incorporating the **Computer-Assisted Postmortem Identification (CAPMI)** dental data base into the Defense Eligibility Enrollment Reporting System will be completed in March 1991, and a Milestone I/III In-Process Review will be held late 2Q91 to transition the product to the Quartermaster School.

- A Milestone I In-Process Review will be held for the **Externally Mounted Rescue Hoist (EMRH)** in 2Q91, and decisions will be made regarding a Non-development Item or a developmental effort strategy.

- The **Field Dental Operating and Treatment Unit (OTUDF)** production contract will be awarded 1Q91 with fielding during 4Q91.

- The Arizona Industries for the Blind will complete the assembly and delivery of all **Decontaminable Folding Litters (Litter)** in support of Operation Desert Shield by 1Q92.

- The Defense Personnel Support Center will assign a directorate in 1Q91 to manage the **Chemical Warfare Agent Protective Patient Wrap (Wrap)**. A National Stock Number will be assigned 2Q91.

- The Defense Personnel Support Center will award a contract in 2Q91 to purchase 1,523 **Field Medical Refrigerators** with two renewal options.

- A Litton **Molecular Sieve Oxygen Generating System (MSOGS)** will be provided by the U.S. Naval Air Development Center for Technical Testing which will commence in 2Q91. Air worthiness approval procedures will begin in 3Q91.

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BIOLOGICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Biological Systems Project Management Division manages the development and acquisition of biological products to prevent casualties or loss of soldier effectiveness due to disease. These diseases may be naturally acquired (close contact, unsanitary conditions, contaminated environment, biting insects), or acquired by deliberate exposure to aerosols. Product Managers exploit domestic and foreign medical technology to remedy deficiencies identified by the Combat Developer and monitor research projects for their application to disease protective measures.

MILITARY RELEVANCE

Casualties from disease have been a major cause of hospital admissions and ineffectiveness on the battlefield. Figures for admission for soldiers during a year in Vietnam were as follows: disease - 70.6 percent; battle casualty - 15.6 percent; nonbattle injury - 13.8 percent. Efforts to reduce the impact of disease on operations will make a significant contribution to soldier effectiveness.

OBJECTIVES

This Division's directive is to develop effective preventive measures against diarrheal diseases; malaria; acute respiratory diseases; hepatitis; insect-transmitted diseases such as dengue and Japanese encephalitis; hemorrhagic fevers and other diseases spread by aerosol (and rapid methods to identify the cause of illness); schistosomiasis; meningococcal disease; and opportunistic wound infections. Methods to address these deficiencies (some of which include treatment) are vaccines, immune enhancers, adjuvants, immune globulins, antiviral drugs, insect repellents, and rapid identification kits for clinical specimens.

PRODUCT DESCRIPTIONS

- Salk Vaccine Production Facility is a manufacturing facility dedicated exclusively to the production of vaccines and diagnostic reagents under Federal regulatory guidelines. The facility is managed by a task order contract for scheduling production of vaccines and reagents.

- Vaccinia Immune Globulin (VIG) meets the Department of Defense operational requirement for safe and effective treatment for potential vaccinia complications resulting from experimental vaccinia vectored vaccines or use of standard vaccinia. The VIG manufacturer requires plasma from hyperimmunized volunteers to ensure a product that exhibits potency criteria required by the Food and Drug Administration.

- University of Maryland Vaccine Testing Facility is used for evaluating vaccines in human safety and efficacy trials. The trials are done either in the 32-bed isolation ward or on an outpatient basis. Each trial is performed under a specific task order, with detailed protocols.

- Rapid Identification System for Biological Agents is a portable, rugged, easily-operated system designed to identify biological agents in clinical materials. In the test, drops of serum from soldiers exhibiting symptoms of disease are placed on credit card sized blotters in plastic holders. After the reagents are added and absorbed, positive or negative results are visible to the unaided eye in less than 30 minutes.

- Ribavirin is an antiviral drug that has been tested for efficacy against Hemorrhagic and Sandfly Fevers. The Army is evaluating the clinical studies that will be a part of a New Drug Application (NDA). The intravenous formulation could be used by military physicians to treat Hemorrhagic Fever with Renal Syndrome.

- J-5 Human Monoclonal Antibody reacts with the highly conserved lipid A region of the lipopolysaccharide, binds to a wide variety of endotoxins and to gram negative bacteria of many genera. The manufacturer, CENTOCOR, allows the U.S. Army to purchase and use this product to treat military members with septic shock and septicemia. It is an Investigational New Drug.

- Klebsiella/Pseudomonas Human Immune Globulins should prevent opportunistic infections in burn and wound patients. The immune globulins, obtained from the plasma of volunteers, immunized with Klebsiella and Pseudomonas vaccines, and tested as an investigational new drug in patients in Veterans and military hospitals. This is a collaborative effort between WRAIR, Department of Veterans Affairs and the Swiss Serum and Vaccine Institute.

- Lassa Fever Immune Plasma is an immune globulin isolated from Lassa Fever convalescent patients, and prepared under FDA guidelines.

- Hepatitis A Vaccine was produced at WRAIR by growing the virus first in cultured monkey kidney cells and then in human lung cells until antigen concentrations reached a stationary level. The virus was inactivated with formalin, safety tested according to regulatory guidelines, and tested in volunteers. Inactivated vaccines produced by Smith Kline and Beecham, Merck, Sharp and Dome, and Swiss Serum Vaccine Institute will be tested in order to determine the most immunogenic product.

- Adenovirus Vectored Hepatitis B Vaccine was developed by Wyeth Laboratories by using recombinant DNA technology to incorporate the Hepatitis B surface antigen gene into Adenovirus Type 7. This bioengineered adenovirus produces both Hepatitis B and Adenovirus 7 antigens in infected cell culture and has passed regulatory safety tests. The Army will test the vaccine in volunteers and use it in recruits if it can be licensed.

- Multivalent Dengue Vaccine consists of different serotypes of virus which have been attenuated by passage in primary dog kidney cells. The master and production seeds and the vaccine are produced in fetal rhesus monkey lung cells. Different passage levels of several isolates of the four serotypes will be evaluated in Phase I studies. Passage levels which are the most immunogenic with the least amount of reactagenicity for the four isolates will be combined for the multivalent vaccine.

- Vaccinia-Vectored Korean Hemorrhagic Fever (KHF) Vaccine is a live vaccine for military personnel being deployed to endemic or potential threat areas for this agent. The vaccine was developed by inserting the KHF gene that controls the production of immunogenic KHF antigens into a live vaccinia virus carrier (smallpox vaccine). The resulting recombinant vaccine was shown to elicit antibodies against both smallpox and KHF in animals. This vaccine, currently in production, was developed in a collaborative effort between USAMRIID and the Salk Institute.

- Smallpox Live Vaccine is a new cell culture produced animal pox virus (vaccinia) that will be free of bacteria presently found in the calf lymph vaccine. This should allow intramuscular rather than percutaneous administration.

- Argentine Hemorrhagic Fever Live Vaccine (AHF) is a live, attenuated vaccine for military personnel being deployed to endemic or potential threat areas with this agent. The vaccine was prepared by growing the virus in fetal rhesus monkey lung cells in a collaborative effort between USAMRIID and the Salk Institute. Following successful efficacy studies in Argentina, a license application will be prepared.

- Japanese Encephalitis Vaccine is extracted and purified from infected mouse tissue by a Japanese company (Biken) and has been shown to reduce the incidence of disease in endemic regions of the world. It is currently being administered as an investigational vaccine since it is not licensed in this country.

- Chikungunya Live Vaccine is a live attenuated virus vaccine obtained by growing the virus in cultured human lung cells at USAMRIID. The Salk Institute produced the experimental lots under regulatory guidelines for testing in humans and, following additional human testing, it will be stored in a lyophilized form as a contingency vaccine.

- Falciparum Malaria Sporozoite Vaccine is a product of recombinant DNA technology and consists of the circumsporozoite protein of Plasmodium falciparum. The vaccine is produced under a no-cost agreement with Smith, Kline and French Laboratories. The vaccine is being tested in combination with different types of adjuvants in order to increase the antibody titers in volunteers.

- Vivax Malaria Sporozoite Vaccine is a product of recombinant DNA technology and consists of the circumsporozoite protein of Plasmodium vivax. The vaccine is following the development of the falciparum malaria vaccine by collaboration between WRAIR and Smith, Kline and French Laboratories; the most effective adjuvant for the falciparum vaccine will be given priority for the vivax vaccine.

- Q Fever CMR Extract Vaccine is a formalin inactivated vaccine prepared at the Salk Institute from rickettsia that are grown in embryonated eggs. The extraction with chloroform-methanol was devised at the USAMRIID and was shown to eliminate severe skin reactions seen in animals inoculated with earlier vaccine. The vaccine is for biological defense.

- Tularemia Live Vaccine is a live, attenuated vaccine for military personnel being deployed to an area where there is a potential threat use of Francisella tularensis. New lots of vaccine, prepared at the Salk Institute under slightly modified production protocols, are currently being tested for safety in volunteers at USAMRIID. There may be sufficient efficacy data for licensure.

- Botulinal Toxoids, Types F & G, will be used in a polyvalent product for military personnel being deployed to an area where there is a potential threat use of Clostridium, botulinum toxin. The toxins will be purified from cultures of the bacteria that produce either Types F or G toxin, inactivated with formalin to produce the toxoid, and tested separately and then together for their ability to produce toxin neutralizing antibodies in humans.

- Shigella Vaccines are oral products containing live bacteria with specific antigens to protect against diarrheal diseases. These bioengineered vaccines are produced at WRAIR and tested at the University of Maryland Vaccine Testing Facility.

- N. meningitidis (Group B) Vaccine is a protein-based vaccine for use in conjunction with licensed polysaccharide vaccines to protect military personnel against epidemic cerebrospinal meningitis. The vaccine is a bacterial sub-capsular protein complexed to polysaccharide antigens. The product is a collaborative effort between WRAIR and Connaught Laboratories and is necessary to protect soldiers against a larger number of strains of this organism.

- Schistosome Topical Antipenetrant is a niclosamide-based lotion originally designed at WRAIR and then formulated for application to human skin by Miles Laboratory. The niclosamide lotion prevents the penetration of free swimming schistosomal larva.

- E. coli Polysaccharide Vaccine is a particulate vaccine composed of E. coli LPS covalently coupled to toxin A. It is designed to prevent infection from wounds.

- Lipid A Analog Vaccine is composed of a derivative of gentiobiose heptaacetate, conjugated to a carrier, and induces immune reactions against lipid A. It will be used to treat gram negative sepsis.

- Insect/Arthropod Repellent, Clothing Impregnant is a chemical treatment of permethrin to the Battle Dress Uniform to provide protection of the covered areas from insect/arthropod bites. One treatment lasts for the entire life of the uniform. Reports on permethrin toxicology, risk benefit analysis, and risk assessment have been prepared. These are components of a registration application submitted to the Environmental Protection Agency (EPA) in January for a Military Use Only label.

- Insect/Arthropod Repellent Lotion (Materiel Change) is an improved, controlled release, topically applied insect repellent designed to provide protection from a broader spectrum of disease vectors and pests, especially biting midges and malaria vectors. This effort will focus on selection of the best of three candidate repellent formulations currently being evaluated for efficacy.

- Body Louse Toxicant is a powder formulation of malathion which will replace lindane as the standard pediculicide. Technical tests were completed on a commercially available

preparation and showed the need to add an anti-caking agent to permit compatibility with mass delousing equipment. The procurement specification was revised to incorporate the change, and the manufacturer of the formulation is seeking EPA registration.

MAJOR ACCOMPLISHMENTS

- An E. coli-vectored Shigella flexneri 2a vaccine was produced at the Salk Vaccine Production Facility. A pilot lot of Cell Culture Derived Smallpox Vaccine (Vaccinia) has been produced and is in the final stages of preclinical testing. Master seed, Production seed and bulk vaccine lots were prepared for a Vaccinia-vectored Korean hemorrhagic fever vaccine. Pilot lots of Dengue 1, 2, and 4 have been prepared. As a result of a tasking by the Assistant Secretary of Defense for Health Affairs, the Salk Facility performs tests to extend the shelf life of Vaccinia Immune Globulin (VIG) and, as such, is responsible for receiving, inventorying, storing, potency testing, and shipping this extended date product as directed. The Johns Hopkins subcontractor has initiated Phase 1 clinical trials with the Q fever CMR vaccine. Clinical testing of the first Liposome Vaccine (Liposomal-Sporozoite Malaria Vaccine) was completed, demonstrating an enhancing effect on antibody response. In another study, challenge of volunteers immunized with Malaria Sporozoite-Toxin A vaccine revealed little protection in spite of the presence of high levels of circulating antibody at the time of challenge.

- The University of Maryland Testing Facility found that a live E. coli vectored Shigella flexneri vaccine produced minimal symptoms in volunteers and protected most of them against a diarrheal challenge; the study will be expanded. Shigella immune milk fed to volunteers provided enough evidence of protection against diarrhea that the study will be repeated with a more potent immune milk preparation. A pharmacokinetic study of intravenously administered Klebsiella/Pseudomonas immune globulin was completed. Hepatitis B vaccine administered intradermally (0.1 ml) rather than intramuscularly (1.0 ml) in an attempt to reduce costs resulted in 15 percent of volunteers having inadequate antibody titers.

- The contract to identify and establish volunteer donors of vaccinia hyperimmune plasma was completed during the last quarter of the year. A Request for Proposal (RFP) was sent to Hyland Division of Baxter Healthcare Corporation, the only FDA licensed facility to manufacture Vaccinia Immune Globulin (VIG). The contract with Hyland to produce VIG should be finalized within the first quarter of calendar year 91.

- Three companies submitted kits for the **Rapid Identification System** capable of detecting plague antigen in less than 30 minutes. Contracts have been awarded to two of these companies to prepare 1000 kits for each of four agents. A kit for one agent was produced and fielded in support of Operation Desert Shield.

- The clinical section of an NDA for **Ribavirin** describing the field trials has been drafted.

- Clinical trials of the **J-5 Human Monoclonal Antibody** were completed. The U.S. Army will use the product as an Investigational New Drug.

- A contract was awarded for immune plasma. From this, **Klebsiella/Pseudomonas Immune Globulins** will be prepared.

- A Phase 2 study was initiated at Fort Campbell, KY, with Smith Kline and Beecham's **Hepatitis A Vaccine**. The vaccine was shown to be safe. Preliminary data indicate that the vaccine induced circulating antibodies in 100% of vaccines.

- The Salk Institute has prepared seed viruses and bulk **Vaccinia-Vectored KHF Vaccine**. Currently, the vaccine is in the final stages of preclinical testing at the Institute to obtain data in support of an IND application.

- The master and production seed lots of a new cell culture derived **Smallpox Live Vaccine** have been made and certified. A pilot lot of the vaccine has been produced and is in preclinical testing.

- The Phase 3, double-blind field trial of the **Argentine Hemorrhagic Fever Live Vaccine** involving approximately 6500 at-risk Argentine volunteers is nearly completed. Due to the largest outbreak of natural disease in several years in the study area, it will now be possible to break the code. During the field trial, no vaccine related reactions were noted, and all vaccinees seroconverted. Serological testing on sera from individuals in the study is virtually completed.

- Three consecutive lots of the **Japanese Encephalitis Vaccine** were tested in humans, and serological studies were initiated.

- Phase 1 studies indicated that a recombinant **Falciparum Malaria Sporozoite** protein covalently bound to Pseudomonas Toxin A generated a fourfold greater immune response than when admixed with alum. Challenge studies indicated little protection from

the laboratory challenge. Phase 2 studies were initiated in Kenya and Thailand. Phase 1 studies with FSV2 adjuvantized with RIBI DETOX™ and incorporated in liposomes indicated 5-10 fold increases in immune response.

- An IND application for **Q Fever CMR Extract Vaccine** was approved by the FDA. Independent Phase 1 clinical studies were initiated at USAMRIID and Johns Hopkins University in September 1990.

- The Phase 1 clinical trial for **Tularemia Live Vaccine** at USAMRIID resumed under a new protocol as a double blind study involving 30 vaccinees and controls to date. No unexpected local or systemic reactions have been noted. Serological results will be available at the conclusion of studies in 4QFY91.

- The first quantity of **Botulinum Toxoid Type F Toxoid Vaccine** was received, ahead of schedule, from Porton International, U.K., October 1990. Potency, resistance to challenge and sterility testing will be complete 10 December 1990.

- An OTSG Investigational New Drug Application for use of **Pentavalent Botulinum Toxoid** (ABCDE) was submitted to the FDA October 1990, IND-3723.

- A live, oral, attenuated candidate **Shigella Vaccine** is currently being tested in volunteers.

- The **Schistosome Topical Antipenetrant** successfully completed a Phase 1 safety trial by Johns Hopkins University and an Early User Test and Evaluation by the U.S. Army Medical Department Board. A Milestone I/II In-Process Review approved transition to the program into advanced development in preparation for field trials in Egypt.

- A new **Meningitidis Group B** vaccine IND was approved by the FDA, and a new vaccine was proved safe and antigenic in Phase 1 studies.

- An Investigational New Drug application was accepted by the FDA for **E. coli Polysaccharide Vaccine**, and the Phase 1 safety study has begun.

- A Milestone III IPR for the **Arthropod Repellent Clothing Impregnant** was conducted in July 1990. IPR members agreed to transition this project to Defense General Support Center (DGSC) pending EPA registration. Agreement was reached to field

multiple methods of permethrin impregnation with an Individual Dynamic Adsorption Kit (for individual use), 2-gallon sprayer method (for company size unit use), and pad roll method (for industrial application).

- A Correspondence Milestone I/III was submitted in March for the **Body Louse Toxicant**. The IPR members agreed to transition the project to DGSC pending EPA registration and determination of shelf life of the formulation.

PROJECTIONS

- A commercial scale lot of Cell Culture Derived Smallpox Vaccine (Vaccinia) will be produced at the **Salk Vaccine Production Facility**. Preparation and testing of Dengue 3 vaccine will be completed. An additional lot of inactivated RVF Vaccine will be prepared. Clinical trials at Johns Hopkins University will include Phase 1 evaluation of Tularemia, Q Fever CMR, and Malarial Vaccines.

- The **University of Maryland Vaccine Testing Facility** will perform an expanded study of a live, oral E. coli vectored Shigella vaccine. A more potent Shigella immune milk will be evaluated for protection against diarrhea. A reformulated live adenovirus vectored hepatitis B vaccine, and live dengue types 1 and 4 vaccines will be tested for safety and immunogenicity.

- A new contractor will provide 4500 liters of **Vaccinia Hyperimmune Plasma** to the manufacturer of **Vaccinia Immune Globulin**. Should the government elect to exercise contract options for additional 4500 liter lots, the contractor will begin collecting the plasma required under the first contract option.

- One thousand test kits for each of four biological agents will be manufactured during 1990 and 1991 and be available for CEP testing of the **Rapid Identification System** in 4Q91.

- **Klebsiella/Pseudomonas Human Immune Globulin** will be tested for safety and efficacy at the Veterans and six military medical centers.

- The IND for **Lassa Fever Immune Globulin** will be submitted and the Phase 1 trial conducted at USAMRIID.

- A Phase 3 study will be initiated in Thailand with the Smith Kline and Beecham killed **Hepatitis A Vaccine**.

- The Phase 1 evaluation of safety and immunogenicity of **Adenovirus Vectored Hepatitis B Vaccine** will be completed.

- Smith Kline Beecham's attenuated **hepatitis A** vaccine will be Phase 1 tested.

- Phase 1 studies with **Dengue 4** vaccine in yellow fever immunes will be completed. Phase 1 safety studies will be conducted on different passage levels of vaccines for Dengue serotypes 1, 2, 3, and 4.

- Preclinical tests on the first lots of **Vaccinia-Vectored Korean Hemorrhagic Fever (KHF) Vaccine** will be completed at the Salk Institute and an IND application prepared and submitted to the FDA by 3QFY91.

- Preclinical studies on the pilot lot of **Smallpox Live Vaccine** will be completed and the Phase 1 clinical studies initiated.

- It is anticipated that the Phase 3 field trial of **Argentine Hemorrhagic Fever Live Vaccine** will conclude in 1991. Upon breaking the code for this double blind study, the efficacy of the product may be assessed and if appropriate, a data package assembled for inclusion in a submission to the FDA of a Product License Application during 1991.

- The lot consistency study of **Japanese Encephalitis Vaccine** will be completed to 1 year after inoculation in military personnel.

- A study of **Chikungunya Vaccine** will be conducted at Fort Bragg, NC, to gain additional immunogenicity data.

- Phase 2 challenge studies of a liposome encapsulated **Falciparum Malaria Sporozoite Vaccine** will be completed.

- Safety and challenge studies (Phase 1 and 2) will be conducted on a new repeatless **Falciparum Malaria Sporozoite Vaccine** adjuvantized with RIBI DETOX™ and encapsulated in liposomes.

- Phase 1 clinical trials for **Q Fever CMR Vaccine** will continue at USAMRIID and Johns Hopkins University.

- The Phase 1 clinical trial for **Tularemia Live Vaccine** will continue through 4QFY91 at USAMRIID. An additional Phase 1 trial, designed to establish lot consistency required for license application, will be initiated at Johns Hopkins University during 2QFY91; data from this study will be available during 2QFY92.

- **Types F and G Botulinal Toxoids** will be prepared and tested in animals. Technical data package will be finalized for production and purification of these toxoids. INDs for each toxoid will be prepared.

- The genetically engineered **Shigella flexneri Vaccine** will enter Phase 2/3 field trials.

- Several formulations of candidate **Improved Extended Duration Topical Arthropod Repellents**, made by the 3-M Company under a CRDA, will be provided for continued laboratory and field efficacy testing by USABRDL, WRAIR, and the Navy Laboratory at Cairo, Egypt. Candidate compounds will be evaluated to determine their relative effectiveness when compared to the extended duration Deet formulation, which is the DoD standard issue repellent.

- A **Contingency Vaccine Storage Facility** (military) will be completed at the National Center for Toxicological Research, Little Rock, Arkansas.

- A Phase 2/3 Field Trial of the **Schistosome Topical Antipenetrant** will be conducted with Egyptian farmers. The study involves the daily application of lotion on 800 volunteers for 6 months and will determine the efficacy of the product in preventing schistosomiasis.

- A Phase 2 efficacy field trial of a new **Meningitidis** vaccine will undergo field testing in Chile.

- The feasibility of adenovirus as a live viral carrier for the expression of **hepatitis B** surface antigen will be determined in studies at the University of Maryland.

- The safety and immunogenicity of the **E. coli Polysaccharide vaccine** will be determined.

- **Lipid A Analog Vaccine** IND will be submitted to the FDA, and human studies will begin.

- An Investigational New Drug Application will be made to the FDA and a Phase 1 protocol for **Botulism Toxoid Type F Toxoid** will begin January-February 1990.

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PHARMACEUTICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Pharmaceutical Systems Project Management Division centrally manages the development and the initial production of pharmaceutical products (antidotes and drugs), related drug delivery systems (autoinjectors and transdermal patches) and decontamination products. These products are fielded as preventive, protective and therapeutic modalities for use against chemical and biological warfare threats, certain endemic diseases and the treatment of combat casualties.

MILITARY RELEVANCE

U.S. military forces must be prepared to serve anywhere in the world against any threat. This could result not only in conventional injuries sustained during combat but exposure to chemical and biological warfare agents as well as exposure to endemic diseases not commonly found in the United States. The development of products against these threats will help save lives, sustain the fighting force and enhance return to duty.

OBJECTIVES

The objectives of this division are to develop pharmaceuticals to be used for prophylaxis, immediate treatment and definitive treatment against a wide variety of naturally occurring diseases, threat force use of chemical and biological agents and combat-generated injuries. These pharmaceuticals include those for use following exposure to organophosphorus compounds, vesicants and cyanide, and those to protect or treat soldiers suffering from malaria, schistosomiasis and leishmaniasis. In addition, a topical skin protectant is undergoing development to protect the skin against the toxic effects of exposure to mustard and other percutaneous chemical threat agents. From a more conventional aspect, blood replacement fluids, and improved antimicrobial skin dressings are under development.

PRODUCT DESCRIPTIONS

- The <u>Convulsant Antidote for Nerve Agents (CANA)</u> is a diazepam 10 mg autoinjector intended to prevent or abate convulsions and prevent or reduce brain injury associated with nerve agent poisoning. Though currently fielded atropine, pralidoxime and pyridostigmine afford enhanced protection

against nerve agent lethality, this regimen does not prevent convulsions or brain injury. The diazepam autoinjector will be a soldier carried item to be used by buddy-aid in conjunction with the MARK I Nerve Agent Antidote Kit.

- Hypertonic Saline Dextran (HSD) is a safe and effective, small-volume resuscitative fluid suitable for rapid field administration that can be used to stabilize hypovolemic shock casualties. A Collaborative Research and Development Agreement (CRDA) is established with Pharmacia for the development of this product.

- Nerve Agent Pretreatment, Pyridostigmine (NAPP) is a pretreatment for use against nerve agent poisoning. When used in combination with atropine and 2-PAM, pyridostigmine is effective against all known nerve agents and is notably effective against soman.

- A Multichambered Autoinjector (MA) (single barrel) for the administration of nerve agent antidotes (2 mg atropine, 600 mg 2-PAM Cl) is being evaluated. The MA is a single autoinjector which contains therapeutic drugs in separate chambers and injects both antidotes through a single needle.

- WR 238605 is an 8-aminoquinoline derivative currently in the Concept Exploration Phase of development as an antimalarial drug. It is being developed as a replacement for primaquine for the treatment of Plasmodium vivax malaria.

- Halofantrine is a 9-phenanthrenemethanol antimalarial compound that is being jointly developed by the USAMRDC and Smith Kline and Beecham as an alternative treatment for use in mefloquine-resistant Plasmodium falciparum malaria. The development of halofantrine has been divided into treatment and prophylactic indications.

- Arteether is a sesquiterpene lactone produced by the extraction and purification of the substance artemisian from the botanical artemisia annua. This rapid acting blood schizonticide is being developed for the treatment of cerebral malaria.

- An Antimicrobial Dermal Dressing (ADD) will be capable of providing sustained release of antimicrobial agents at the site of superficial dermal injury to prevent infection and enhance wound healing.

- WR 6026 is an 8-aminoquinoline methanol derivative being tested as an oral treatment for visceral leishmaniasis.

- Pentostam, sodium stibogluconate, is a drug produced and marketed worldwide by Burroughs-Wellcome Foundation of Great Britain. Pentostam is being studied for the treatment of visceral and cutaneous leishmaniasis.

- The Topical Skin Protectant (TSP) is a perfluoroalkyl-polyether compound which, when spread on the skin, forms a lasting, thin, and breathable film surface capable of complete or significant protection, for a certain duration, against percutaneous penetration of chemical warfare agents. Use of the TSP enhances the effectiveness of fielded skin decontaminating systems. Doctrine for use of TSP is as an adjunct to mission-oriented protective posture (MOPP) gear, not as a substitute.

- Multi Shield is a commercially available product, sold to protect skin against exposure to industrial chemicals. Studies at USAMRICD have also demonstrated that it meets military requirements for protection against the vesicating effects of sulfur mustard (HD) by inhibiting agent penetration. This product is the result of an effort to field a skin protectant expeditiously in support of Operation Desert Shield.

- Ribavirin, Prophylactic is a synthetic nucleoside with a broad spectrum of antiviral activity in vitro. Ribavirin, Prophylactic is being developed for protection against viral hemorrhagic fever diseases.

- The Medical Aerosolized Nerve Agent Antidote (MANAA) is an atropine aerosol inhalant used by medical personnel for the supplemental treatment of nerve agent casualties after adequate injectable atropine has been given. The expected role of MANAA is to deliver atropine to the airway of spontaneously breathing and sufficiently lucid nerve agent casualties. The aerosol is intended for use at forward medical care facilities including battalion aid stations.

- The M291 Skin Decontaminating Kit (SDK) is a resin based system developed for Joint Service use. It will replace the current M258A1 Personal Decontamination Kit and M58A1 Training Aid. The M291 is envisioned as a superior, safe and effective skin decontaminating system for use against multiple percutaneous chemical threat agents.

- Morphine Repackaging is required to provide this analgesic in a dosage form that meets the field requirements of extended stability, greater durability, rapid administration and tamper evidence. Much of the morphine stock in the inventory is over 25 years old and is beginning to deteriorate.

MAJOR ACCOMPLISHMENTS

- The accelerated development of **CANA** which began in August 1987 was successfully completed in 1990. Definitive animal efficacy and human bioavailability studies were completed this year. On 10 October 1990, a Milestone IIIa IPR was held which recommended transition of CANA to USAMMA for production and deployment upon FDA approval of the NDA. The NDA was submitted on 15 October 1990, and was approved on 5 December. In August 1990, the Service Surgeon General Offices each initiated requirements for diazepam autoinjectors for support of Operation Desert Shield. A Request for Proposals was issued in August, an award was made in September, and autoinjectors were delivered in December.

- A Milestone I/II IPR for **HSD** was held on 10 April 1990 with the decision to proceed into Development Proveout. An NDA was completed and submitted to the FDA in September. A draft clinical protocol to answer certain military concerns about the employment of HSD on the battlefield was developed.

- The final sustained release formulation of **Pyridostigmine** was evaluated at Johns Hopkins University. The Initial Operational Test and Evaluation (IER) Final Report was delivered. Additional studies were conducted to evaluate the effects of heat, humidity and exercise on individuals taking multiple doses of pyridostigmine. A Milestone Ib IPR was held 11 December.

- Prototype **MA's** were obtained from two commercial sources under Cooperative Research and Development Agreements (CRDA). The mechanical reliability of these autoinjectors was tested in accordance with MIL STD 810-D by the U.S. Army Biomedical Research and Development Laboratory. A drug absorption study was conducted at Battelle Labs comparing the prototype **MA's** to the standard MARK I. A bioavailability study in humans was conducted in October.

- A Milestone I IPR was conducted for the antimalarial drug **WR 238605** on 13 December. This product was transitioned to the Demonstratior and Validation Phase.

- A Milestone IIIa IPR was held for the antimalarial drug **Halofantrine, Treatment** on 13 December.

- The results of the customer test of the adhesive properties of candidates for the **ADD**, conducted at Ft. Bragg in November 1989 were published; two dressings performed acceptably. Preclinical testing of antimicrobial agents continued at the U.S. Army Institute of Dental Research. Results from these studies prompted a reformulation by one of the manufacturers. Efficacy testing of the reformulated product is ongoing.

- WR 6026 phase II clinical trials began in Kenya for visceral leishmaniasis.

- A Milestone III IPR was conducted for the antileishmanial Pentostam on 13 December. It was decided that this drug would remain available under an IND for the treatment of the approximately 20 cases per year which occur in the military and that there would be no attempt to file an NDA.

- The Topical Skin Protectant transitioned to Advanced Development in September.

- On 24 September, a Council of General Officers recommended that Multi Shield be fielded expeditiously as a modified non-developmental item in support of Operation Desert Shield. The USAMRICD spearheaded a highly accelerated testing program to assess the safety, effectiveness and military utility of the product. An IND was filed with the FDA on 2 October. The Academy of Health Sciences prepared interim doctrine and a training package. The Assistant Secretary of Defense for Health Affairs granted approval to procure Multi Shield for use in Operation Desert Shield. A contract was awarded in December for the Production and Deployment of an estimated 3 million, four-ounce containers.

- Ribavirin, Prophylactic transitioned to Advanced Development in April. A draft Joint Services Operational Requirement was prepared. Because Crimean Congo Hemorrhagic Fever is endemic in the Operation Desert Shield Theater of Operations, Ribavirin, for use as a prophylactic and as a treatment, was procured and made available in November.

- An NDA for MANAA was submitted to the FDA on 5 February. A Milestone IIIa IPR was conducted on 28 March, and MANAA was transitioned to Production and Deployment contingent on NDA approval. The NDA was approved on 19 September.

- First article testing of the second Government-owned production line for manufacturing the M291 SDK was completed 5 June. Production of the first 1.5 million SDK's under a fixed price contract option began 13 July. All kits are being targeted for issue to units deployed in Operation Desert Shield.

- The Food and Drug Administration acted on two Abbreviated New Drug Applications (ANDA) for a 10 mg Morphine autoinjector. One ANDA was approved, and the other was determined to be "approvable."

PROJECTIONS

- **CANA** will transition to USAMMA 1Q91. The first production items will be available 1Q91. CANA training devices will be available during 1991. Procurement and deployment of the unflanged diazepam autoinjectors for Operation Desert Shield will continue during 1Q91.

- A post-NDA meeting will be held with the FDA for **HSD** 1Q91.

- **Pyridostigmine** will be transitioned to Production and Deployment 2Q91.

- A Milestone Ib IPR will be held for the **Multichambered Autoinjector** 2Q91.

- An IND will be filed for **WR 238606** 2Q91. Phase I clinical trials will be initiated 3Q91.

- An NDA for **Halofantrine, Treatment** will be filed 2Q91 by the U.S. Army and Smith Kline and Beecham.

- A Milestone I IPR for the **ADD** will be held 1Q91. Additional efficacy studies will be conducted on a reformulated dressing.

- A Cooperative Research and Development Agreement will be signed 2Q91 with two companies for the development of **TSP**. An IND will be prepared and submitted to the FDA 3Q91, and Phase I clinical studies will be initiated 4Q91.

- A Milestone I IPR will be held 1Q91 for **Ribavirin, Prophylactic**. An IND will be prepared and submitted to the FDA 2Q91, and Phase I clinical studies will be initiated 3Q91.

- Upon JSOR approval, 1Q91, **MANAA** will transition to USAMMA for production and deployment. A contract will be awarded 2Q91 to determine the feasibility of adapting the M40 Mask for trans-mask medical aerosol inhalation using the atropine aerosol.

- A contract for follow-on procurement of the **M291 SDK** will be awarded by USAMCCOM 3Q91.

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Albright, Deanna W. Unit Clerk SIDPERS Training, 5 June 1990

Albright, Deanna W. Power Communication Skills, Hagerstown, MD, August 1990

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Office of the Command Surgeon
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Division
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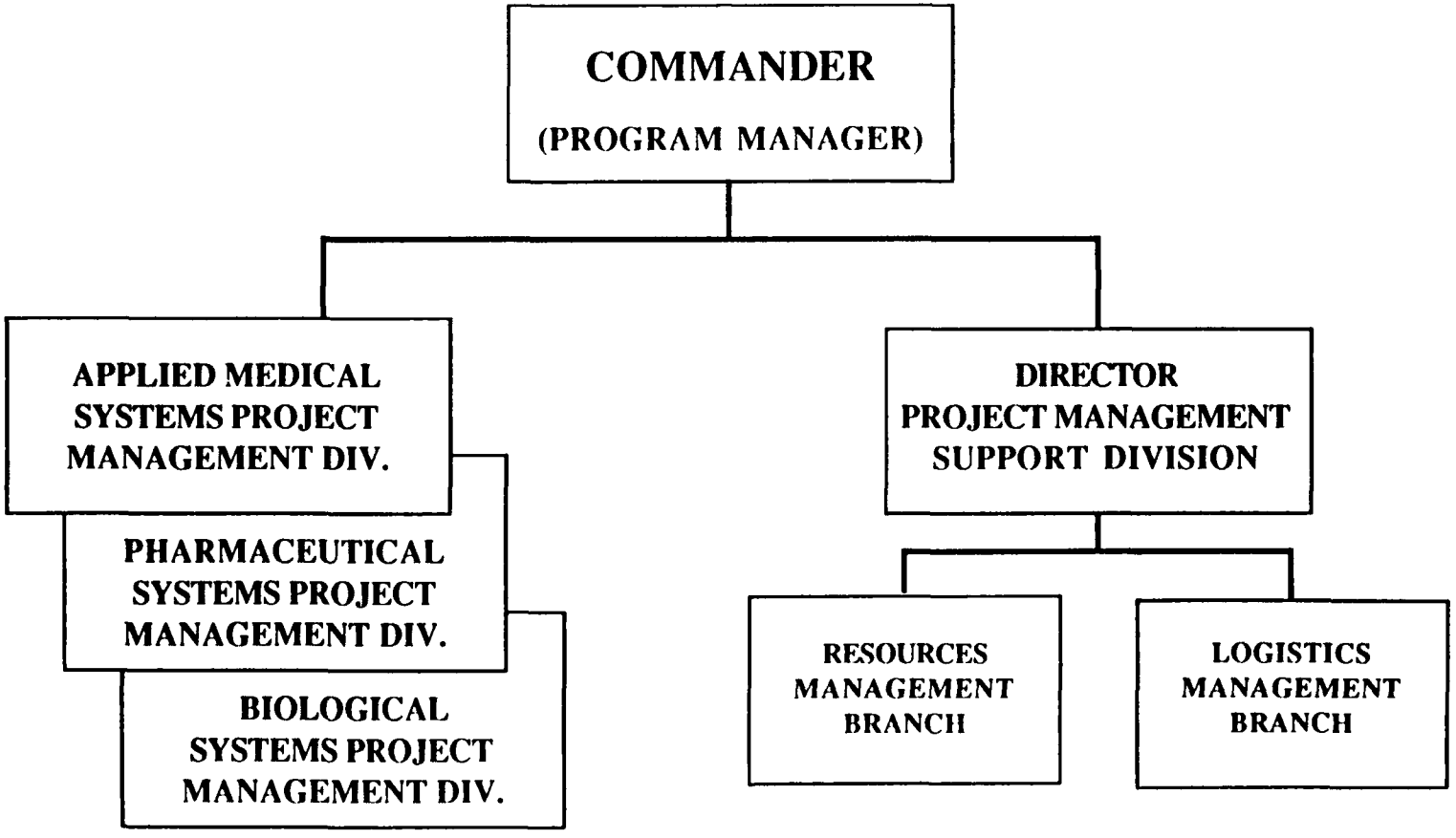
U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY ORGANIZATION



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1990 MEDICAL RDA MAMP PRIORITIZATION

PRODUCT	1990 AMEDD PRIORITY
Powered Ventilator	1
Resuscitation Device, Individual, Chemical	2
Field Medical Oxygen Generating and Distribution System	3
Resuscitative Fluids Production System (REFLUPS)	4
Convulsant Antidote for Nerve Agents (CANA)	5
Hypertonic Saline Dextran	6
External Rescue Hoist, UH-60	7
Nerve Agent Pre-Treatment Pyridostigmine	8
Multichambered Autoinjector (MA)	9
Antimalarial Drug, WR238605	10
Molecular Sieve Oxygen Generating System	11
Monitor, Vital Signs, NBC Casualty	12
Litter, Folding, Decontaminable	13
Klebsiella/Pseudomonas Intravenous Immune Globulin	14
Arthropod Repellent Clothing Impregnant	15
X-Ray System, Lightweight, Medical	16
Antimalarial Drug, Halofantrine Treatment	17
Antimalarial Drug, Halofantrine Prophylactic	18
Life Detector	19
X-Ray System, Dental, Miniature	20
Hepatitis A Vaccine	21
Sterilizer, Steam Vacuum Pulse	22
J-5 Human Monoclonal Antibody	23
Water Quality Analysis Set - Preventive Medicine (WQAS-PM)	24
Tularemia Live Vaccine	25
Shigella Vaccines	26
Plasmodium Falciparum Sporozoite Vaccine	27
Rapid Identification System	28
Rapid Bacteriological Test Kit	29
Multivalent Dengue Vaccines	30
Hepatitis A, Live Vaccine	31
Combat Digital Radiographic System (CDRS)	32
Plasmdoium Vivax Sporozoite Vaccine	33
Q-Fever CMR Extract Vaccine	34
N. Meningitidis, Group B Protein, Vaccine	35
Adenovirus-Vectored Hepatitis B Vaccine	36
Water Sampling Submission Kit (WSSK)	37
Vaccinia Vectored Korean Hemorrhagic Fever Vaccine	38
Korean Hemorrhagic Fever Vaccine	39
E. Coli Vaccine	40
Botulinal Polyvalent Toxoid	41
CT Scanner, Field	42
Japanese Encephalitis Vaccine	43

1990 MEDICAL RDA MAMP PRIORITIZATION

PRODUCT	1990 AMEDD PRIORITY
Arthropod Repellent Extended Duration Formula (MC)	44
Aerosol Generator, Ultra Low Volume, Electric (AGULVE)	45
Schistosome Topical Antipenetrant	46
Sprayer, Pesticide, Electric, Liquid	47
Vaccinia Vectored Venezuelan Equine Encephalitis Vaccine	48
Cell Cultured Derived Smallpox Vaccine (Vaccinia)	49
Antimalarial Drug, Arteether	50
Antidote, Nerve Agent, 2nd Generation	51
Lipid A Analog Vaccine	52
Antimicrobial Dermal Dressing	53
TNF Monoclonal Antibody	54
Ribavirin	55
Laser Protective Eyewear (MC)	56
Antileishmanial Drug, WR6026	57
Antileishmanial Drug, Pentostam	58
Calculator, Heat Stress, Hand Held	59
Monitor, Electric, Wet Bulb Globe Temperature	60
Chikungunya Live Vaccine	61
Argentine Hemorrhagic Fever Live Vaccine	62
Skin Protectant, Topical	63
Lassa Fever Immune Globulin	64
Rift Valley Fever Live Vaccine	65
Ribavirin, Prophylactic	66
M-40 Chemical-Biological Protective Mask Vision Correction (MC)	67

1990 USAMMDA INTERNAL (Z) PRIORITIZATION

Product	Z Priority
USAMMDA Administration and Management	0.10
Task Order Contract	0.02
Salk Vaccine Production Facility	0.03
Vaccine Testing Facility, University of Maryland	0.04
Regulatory Affairs	0.05
Toxicology, Hazleton	0.06
Phase I, JHU	0.07
Toxicology, University of Illinois	0.08
Configuration Management, Medical Materiel	0.09
Configuration Management, Pest Control Equipment	0.10
Formulation	0.11
Medical Research and Evaluation Facility (MREF)	0.12
SRI (Drug Formulations Studies)	0.13
Field Eval. of Drugs Against Infectious Disease of Mil Import.	0.14
Clinical Investigations	0.15
Maintenance Contract for UH-60SFTSS	0.16
Preclinical Vaccine Testing Laboratory	0.17
Field Medical Oxygen Generation and Distribution System	1.00
Resuscitative Fluids Production System (REFLUPS)	2.00
Convulsant Antidote for Nerve Agents (CANA)	3.00
Topical, Skin Protectant	4.00
Nerve Agent Pre-Treatment Pyridostigmine	5.00
Hypertonic Saline Dextran	6.00
Klebsiella/Pseudomonas Intravenous Immune Globulin	7.00
Multichambered Autoinjector (MA)	8.00
Laser Protective Eyewear (MC)	9.00
Hepatitis A Vaccine	10.00
Powered Ventilator	11.00
Shigella Vaccines	12.00
Resuscitation Device, Individual, Chemical	13.00
Sterilizer, Steam Vacuum Pulse	14.00
Rapid Identification System	15.00
Botulinal Polyvalent Toxoid	16.00
Cell Culture Derived Smallpox Vaccine (Vaccinia)	17.00
Antimalarial Drug, WR238605	18.00
Antimalarial Drug, Halofantrine Treatment	19.00
Antimalarial Drug, Halofantrine Prophylactic	20.00
M-40 Chemical-Biological Protective Mask Vision Correction (MC)	21.00
Litter, Folding, Decontaminable	22.00
Life Detector	23.00
Molecular Sieve Oxygen Generating System	24.00
X-Ray System, Dental, Miniature (Hand-Held Dental X-Ray Subsystem)	25.00
External Rescue Hoist, UH-60	26.00
Tularemia Live Vaccine	27.00

Product	Z Priority
Arthropod Repellent Extended Duration Formula (MC)	28.00
Schistosome Topical Antipenetrant	29.00
Japanese Encephalitis Vaccine	30.00
Plasmodium Falciparum Sporozoite Vaccine	31.00
Multivalent Dengue Vaccine	32.00
Q-Fever CMR Extract Vaccine	33.00
N. Meningitidis, Group B Protein, Vaccine	34.00
X-ray System, Lightweight, Medical	35.00
Arthropod Repellent Clothing Impregnant	36.00
J-5 Human Monoclonal Antibody	37.00
Adenovirus-Vectored Hepatitis B Vaccine	38.00
Vaccinia Vectored Korean Hemorrhagic Fever Vaccine	39.00
Hepatitis A, Live Vaccine	40.00
Antileishmanial Drug, WR6026	41.00
Antimalarial Drug, Arteether	42.00
Antidote, Nerve Agent, 2nd Generation	43.00
Plasmodium Vivax Sporozoite Vaccine	44.00
Korean Hemorrhagic Fever Vaccine	45.00
E Coli Polysaccharide Vaccine	46.00
Monitor, Electric, Wet Bulb Globe Temperature	47.00
Calculator, Heat Stress, Hand Held	48.00
Aerosol Generator, Ultra Low Volume, Electric (AGULVE)	49.00
Sprayer, Pesticide, Electric, Liquid	50.00
Monitor, Vital Signs, NBC Casualty	51.00
Vaccinia Vectored Venezuelan Equine Encephalitis Vaccine	52.00
Computer-Assisted Post-Mortem Identification System	53.00
Water Quality Analysis Set - Preventive Medicine (WQAS-PM)	54.00
Rapid Bacteriological Test Kit (RABTEK)	55.00
Water Sampling Submission Kit (WSSK)	56.00
Antimicrobial Dermal Dressing	57.00
Antileishmanial Drug, Pentostam	58.00
CT Scanner, Field	59.00
Ribavirin, Prophylactic	60.00
Ribavirin, Therapeutic	61.00
Antiparasitic, Malaria (Enpiroline)	62.00
Antibiotic, Drug, Microencapsulated	63.00
Medical Aerosolized Nerve Agent Antidote (MANAA)	64.00
Pesticide Dispersal Unit, Multicap., Helicopter Slung	65.00
Digital Imaging Network System (DINS)	66.00
Combat Emergency Medicine Expert System	67.00
Lightweight Intravenous Fluids Production System (IV Fluid Maker)	68.00
Draw Over Anesthesia Apparatus	69.00
Chikungunya Live Vaccine	70.00
Argentine Hemorrhagic Fever Live Vaccine	71.00
Lassa Fever Immune Globulin	72.00
Rift Valley Fever Live Vaccine	73.00

Product	Z Priority
Lipid A Analog Vaccine	74.00
TNF Monoclonal Antibody	75.00
Campylobacter Vaccine	76.00
Plasmodium Falciparum, Merozoite Vaccine	77.00
Japanese Encephalitis, Live, Vaccine	78.00
Anthrax Recombinant DNA Vaccine	79.00
Sterilizer, Ethylene Oxide	80.00
Staph Enterotoxin B	81.00
Pretreatment, Nerve Agent, 2nd Generation	82.00
Vaccine, ION Channel Blocking Toxin (SAXITOXIN)	83.00
Vaccine, Post-Synaptic Toxin	84.00
Vaccine, Pre-Synaptic Toxin	85.00
Bone Repair Material	86.00
Bone Splint, Biodegradable	87.00
Combat Digital Radiographic System (CDRS)	88.00
Antimalarial Drug, Mefloquine	89.00
Immune Enhancers	90.00
Pseudomonus Pilus Vaccine	91.00
Oxygen Carrying Blood Expander	92.00
X-ray System, Dental, Miniature (P31) (Filmless Dental Imager)	93.00
Skin Decontaminating Kit: M291	95.00
Ballistic-Laser Protective Spectacles (B-LPS)	96.00
Patient Wrap, CWA Protective	97.00
Morphine Repackaging	98.00
Botulinal Immune Globulin (Human)	99.00
Sterilizer, Special Operations Forces (SOF)	100.00
Optometry Field Set	101.00
Radiographic/Fluorographic System (High Capacity)	102.00
Hi-Capacity X-Ray (Materiel Change)	103.00
Antileishmanial Drug, Pentostam Liposomal	104.00
Antidote, Arsenical Self-Aid	105.00
Dengue Type 2 Live Vaccine	106.00
Dengue Recombinant DNA Vaccine	107.00
Dengue Type 4 Live Vaccine	108.00
Venezuelan Equine Encephalitis Vaccine	109.00
Rift Valley Fever Vaccine	110.00
Body Louse Toxicant Powder	111.00
Arthropod Repellent Topical Extended Duration Formulation	112.00
Refrigerator, Medical Field	113.00
Dental Operation Unit, Field	114.00
Cover, Dressing, Field CW Resistant	115.00