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AR103R1

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January 1993

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Executive Summary

MEDICAL TECHNOLOGY MODERNIZATION AND STRATEGIC PLANNING: SHAPING ARMY HEALTH CARE

The Army Medical Department (AMEDD) recognizes the need to better manage the modernization of its medical technologies if it is to be successful in an environment of tightening budgets and explosive technological change. The demand for bona fide medical technologies – drugs, devices, medical and surgical procedures, and the systems that deliver them – will continue to increase. However, if acquired and used inappropriately, medical technologies can be costly, ineffective or even unsafe. The AMEDD seeks process improvements that will ensure fielding of the right mix of technologies to achieve desired medical outcomes and health care delivery system performance objectives.

The key to the safe, cost-effective deployment and use of medical technologies is the relationship between those who order the use of technologies, those responsible for overall delivery system performance, and those who plan the acquisition and control the distribution of technologies. The quality of that relationship depends, in turn, upon reliable, high quality information. The plans to use a technology, and the underlying clinical policy that supports it, should be firmly based in the best, expertly interpreted, clinical outcomes information available. The plans to use the technology should be consistent with the overall plan for its acquisition and distribution and the plan governing the measurement of delivery system performance. All plans should be in agreement that likely clinical outcomes justify the risks and costs incurred given competing requirements and alternative medical technologies.

The Army health care delivery system – with its authorized beneficiaries, salaried staff, budget ceilings, medical traditions, and military nature – confronts medical technology modernization in the same way as its civilian health industry counterparts do and with nearly the same goal: to balance quality, access, and cost. The Army Medical Department's (AMEDD's) managed care initiative, Gateway to

Care, incorporates that goal and intends to use quality, access, and cost as performance measures for strategic planning and acquisition decision making.

Thus, technology modernization requires strategic planning, the rigorous evaluation of medical technologies, and selective distribution. It also requires the analysis of technology use results in order to make adjustments in clinical policy and distribution so that the levels of performance necessary to achieve delivery system goals can be attained and maintained.

We believe that the AMEDD's technology modernization process would better serve its needs if it were based on system-wide strategic planning. The AMEDD can develop strategic plans and achieve its goals through a technology modernization process significantly different from the one it currently follows – a process that considers most technology modernization to be equipment related; a process that does not, prospectively or retrospectively, fully assess the consequences of acquiring, distributing, and using new technologies; and a process that is absent the medical information base to support clinical outcomes research.

An improved technology modernization process will overcome those shortfalls, support the Gateway to Care program, and yield better technology distribution plans. The improved process we envision would enable the AMEDD to identify, assess, and introduce new technologies on the basis of centrally directed product line management with support from medical researchers and scientists and participation by the providers of health care delivery. To strike the desired balance among quality, access, and cost the AMEDD would be able to measure the clinical and economic consequences of acquiring, distributing, and using new technologies. The improved technology modernization process would enhance the relationship between providers and planners.

To be more successful in the acquisition and use of medical technologies we recommend that the AMEDD take the following actions:

- Define medical technology broadly to facilitate strategic planning and to integrate operations and modernization management.
- Use specialty consultants to The Surgeon General as strategic planners and medical service product line managers.

- Conduct centralized, prospective evaluation of medical technologies through scientific technology assessment and strategic product line management.

- Use its medical research and clinical investigation capabilities to monitor the technology base and to assemble data on assessed technologies or conduct technology assessments for AMEDD peacetime and wartime applications as necessary.

- Establish an AMEDD Strategic Technology and Clinical Policy Council to integrate the activities of product line managers, formulate strategic goals and plans, and determine the data collection requirements necessary to improve delivery system performance in the mid to long term in peace and in war.

- Appoint an Assistant Surgeon General for Research and Technology to implement the above recommendations and to manage formal AMEDD materiel modernization planning processes.

Successful implementation of these recommendations will enable the AMEDD to accurately measure and correctly value the clinical and economic consequences of alternative medical technology acquisition, distribution, and use decisions. It will also better align delivery system capacities and beneficiary requirements and increase the likelihood of successful implementation of the AMEDD's Gateway to Care Program.

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CHAPTER 1

INTRODUCTION

BACKGROUND AND PURPOSE

This report provides the Army Medical Department (AMEDD) with recommendations for making the best use of its modernization resources. Our recommendations will help the AMEDD make the coherent, persuasive arguments necessary to obtain the full funding and manpower essential for achievement of the AMEDD's key missions.

This report is also about specific medical technology modernization management tasks that must be performed by the AMEDD. Performing them well will help ensure that Army medicine is good medicine and good business.

About 9 million people are eligible to receive health care benefits provided by the Department of Defense (DoD). [1] The AMEDD supports the demands of approximately 3.2 million of these people. They are classified by beneficiary category as shown in Figure 1-1. [2] Each year, Army beneficiaries demand about 10 million clinic visits, 200 thousand admissions, 20 million prescriptions, and 150 million diagnostic tests of various kinds. [3]

Direct care Army facilities and equipment with an estimated replacement value of nearly $5 billion are used to meet the demands of these beneficiaries. [3, 4] The facilities include the medical centers and hospitals listed in Appendix A. The value of facilities and equipment employed in caring for Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) users would substantially increase the value of the total health care "plant"[1] were it known. If added, the value of "field" facilities and equipment along with the addition of the value of assets other Military

[1]We define "plant" as the sum of human resource assets (capabilities), and short-lived and long-lived materiel assets. Our intent is to convey the concept of productive health care capacity that is either (1) added to on the basis of investments and expenditures or (2) subtracted from through consumption, fair wear and tear, obsolescence, waste, and other factors.

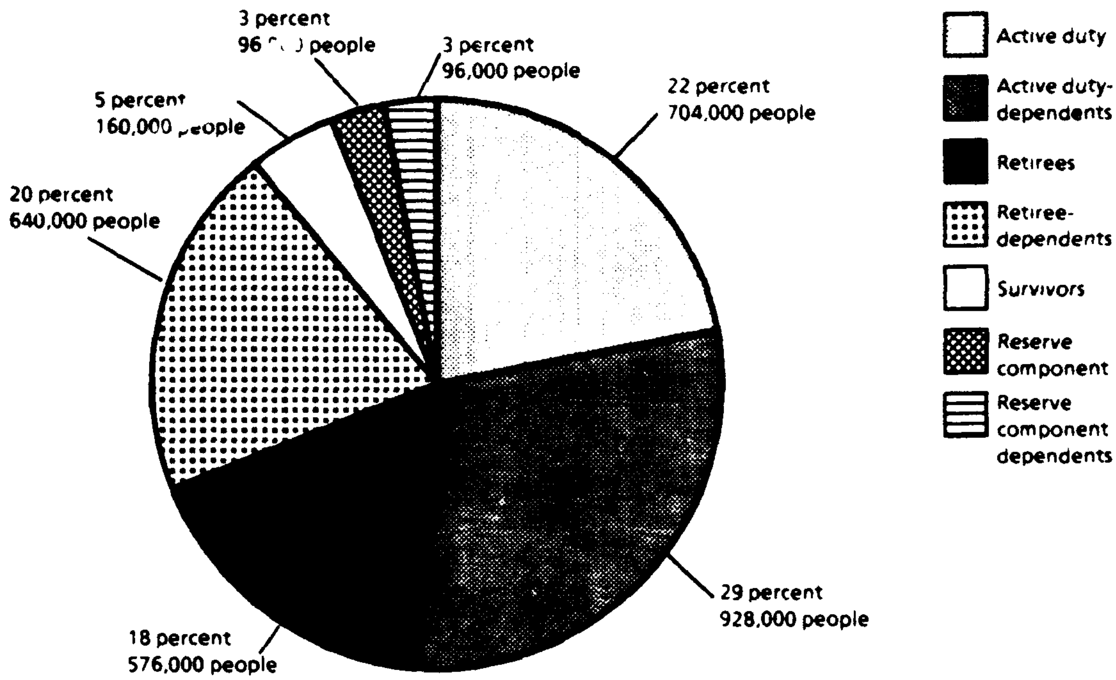

FIG. 1-1. COMPOSITION OF ARMY BENEFICIARY POPULATION OF 3.2 MILLION

Services use to care for Army beneficiaries would increase total plant value even more.

The AMEDD makes an annual investment of more than $100 million in the plant's "long-lived" assets.[2] In addition, each year the AMEDD spends about $4 billion to staff and operate its health care delivery system, to meet its research and development (R&D) commitments, and to equip and train field medical units. Nearly $300 million of this $4 billion operating expense is used to purchase consumable and durable medical supplies. [3] Whether these investments in long-term assets and expenditures for operations are too low or too high depends upon whether or not the same or better care could have been provided with less funding and the relative value that one places on alternative uses of the funds. [5]

[2]Real property (facilities) and personal property (equipment) with a useful life greater than 1 year. Long-lived assets affect the capacity of the plant for more than one accounting period. Because of this, long-lived assets are acquired ordinarily using capital budgeting procedures. Short-lived assets are, obviously, those materiel assets with useful lives of less than 1 year.

THE DILEMMA OF MEDICAL MODERNIZATION MANAGEMENT

Medical technologies are integral to the operation of the AMEDD's health service delivery system. The American Hospital Association (AHA), in its *Guideline Report* called *Payment of Hospital Cardiac Services*, defines medical technologies as the "drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is delivered." [6] The plant and its component technologies require modernization. Without modernization, the health care plant quickly becomes outdated and obsolete; the health care benefit provided during peacetime or wartime quickly loses its value. When coupled with limited funding, the need to continuously modernize requires that the AMEDD select the most appropriate technologies for its use. Today, hundreds of pharmaceuticals, biologicals, and some 1,800 devices, representing as many as 80,000 different products, produced and distributed by 14,000 domestic (and thousands of foreign) manufacturing companies are available to health care providers in the United States.

The value of new technologies is gauged by their effect (positive outcome) on the health of the beneficiary population and by their contribution to the productivity (cost effective) of the delivery system plant. Managing medical technology modernization implicitly or explicitly requires (1) a continuous effort to rank new or modified drugs, devices, medical and surgical procedures, organizational systems, and other supportive systems according to their estimated impact on the beneficiary population served and on delivery system plant operation; (2) making investment and expenditure decisions on the basis of these rankings and estimated impacts; and (3) evaluating the accuracy of rankings and previous investment and expenditure decisions by assessing their contribution to meeting the goals of the health care system. These three steps, however, present the AMEDD with a significant dilemma – how, when, where, and by whom should medical technology modernization be managed?

A broad, effective management approach is required for three reasons. First, opportunities to enhance patient care should not be missed. Second, the costs of new technologies must be controlled. As the pace of technological change quickens, the demand for seizing the opportunities and answering the questions presented by new technologies increases. Third, the policies, the procedures, and the organizational relationships necessary for identifying opportunities, formulating modernization strategies, and systematically going about meeting patient and physician demand in the future must be developed. The use of advanced technologies in health care has created some of the major dilemmas in society today.

One common approach to managing broad and unwieldy technology modernization (an approach traditionally used by hierarchical organizations like DoD, the Army, and the AMEDD) is to divide the planning effort by function or specialty and address each segment individually. For example, technologies can be divided into two groups: materiel-based and non-materiel-based technologies. Grouping technologies this way is consistent with a military organization where responsibilities – for personnel, operations, and training (nonmateriel) and for logistics (materiel) functions – are separated by assigning them to different organizational elements. At the "corporate level" within the Army, combat developers devise nonmateriel technology solutions. Doctrinal, training, leader development, and organizational solutions are included. Combat developers also identify needs that can be met through developmental or nondevelopmental acquisition procedures in collaboration with materiel developers. Finding the right materiel-based technology solution is the responsibility of the materiel developer in collaboration with the combat developer.

The strategic and pervasive nature of technology modernization presents a dilemma. Even as administering the modernization program is helped by the separation of operational functions – and the assignment of responsibilities and the delegation of authorities – the following seeds are sown: acquisition complexity, resource competition, parochialism, structural arrogance, miscommunication, failed coordination, defensive strategies, and financial and operational risks. Adding to the dilemma is the fact that new technologies are often "moving targets" constantly being revised, tested, and improved again.

In its modernization program, the AMEDD must take full advantage of the increased focus and resolution that specialization permits. At the same time, however, the AMEDD must also avoid the organizational pathologies and inefficiencies that a management approach requiring the division of labor and assignment of responsibilities risks. This is the dilemma facing the AMEDD as it plans its modernization.

RESPONSIBILITY FOR MANAGING MEDICAL TECHNOLOGY

The AMEDD divides responsibility for managing materiel-based medical technology modernization between field unit and fixed facility modernization programs. Medical technologies required for use by individual soldiers in the field and by field medical units – whether pharmaceuticals; biologicals; applied medical devices; or medical sets, kits, and outfits (SKO) – are acquired and fielded using the Army's Concepts Based Requirements System (CBRS).

The CBRS is administered by the Training and Doctrine Command (TRADOC). The CBRS employs combat developer and materiel developer concepts. The CBRS is associated with weapon systems like acquisition and total package unit materiel fielding (TPUMF) processes. The AMEDD's combat developer, the Health Services Command (HSC); its AMEDD center and school, which includes the Combat Developments Directorate; and the AMEDD's materiel developer and mission assignee, the Medical Research and Development Command (MRDC) and the U.S. Army Medical Materiel Agency (USAMMA), respectively, all play a role. The CBRS approval process requires a search for doctrinal, training, leader development, or organizational solutions before deciding on a materiel-based technology as the solution to an identified and validated capability deficiency. The materiel-based solution is felt to be the most expensive and the least desirable.

The TRADOC is an Army Major Command (MACOM). It serves as the "architect of the future Army." Its technology modernization priority is wartime missions. The CBRS integrates and coordinates the modernization activities of all-Army combat developers. Combat developers are ordinarily found at TRADOC branch schools (i.e., the Infantry school; the Armor school; the Field Artillery school; and the Quartermaster, Ordnance, and Transportation logistics schools). Integrating and coordinating the activities of this diverse array of specialty areas is intended to overcome the management dilemma presented by the dynamics of constantly advancing technologies and increasing specialization. Effectively integrating and coordinating these activities is intended to assure that future wartime operations result in defeat of the future threat. CBRS outputs include the Long Range Army Materiel Requirement Plan (LRAMRP) and the Long Range Research, Development and Acquisition Plan (LRRDAP). Competing demands for Army resources are adjudicated during the process of developing these plans. The different appropriations used for modernization are coordinated. The plans are inputs to the

Planning, Programming, Budgeting and Execution System (PPBES) that is used to obtain resources for DoD, the Army, and the AMEDD.

Technology modernization for medical organizations (i.e., fixed medical facilities) that do not operate in the field is accomplished outside of the CBRS. The combat and materiel developers are rarely involved in fixed medical facility modernization. Capital equipment for fixed facilities, defined by its unit price or its requirement's genesis in a military construction project, is acquired through the Medical Care Support Equipment (MEDCASE) program.[3] Medical devices with unit prices less than that needed to qualify as MEDCASE equipment have, in the past, been acquired using Capital Expense Equipment Program (CEEP) financing procedures.

The CEEP equipment is acquired from commercial sources through the supply system. New pharmaceutical and biological technologies and other durable and consumable devices not qualifying for equipment programs are obtained through the medical supply system. These technologies are ordinarily purchased commercially for delivery directly to the user, or for inventory stockage and distribution. Assuming an equivalent level of funding, MEDCASE and CEEP and the medical supply system provide a military fixed facility with, essentially, the same opportunity to acquire up-to-date materiel technologies that a comparable civilian health care facility would enjoy and, surprisingly, with about the same or even less paperwork. [7]

The rationale for modernizing fixed medical facilities outside of the CBRS, though it is not well documented, is twofold. The CBRS is not considered to be sensitive enough to the needs of fixed medical facilities that perform "real patient care," and it is felt to be slow in delivering products. The high degree of planning, standardization, and uniformity of fielding sought by the CBRS is bypassed in the name of patient care and expedience. Modernizing fixed facilities outside of the CBRS also

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[3]Some see the MEDCASE program and medical technology modernization as synonymous. This view, in our estimation, is mistaken. It is probably created by the notoriety that expensive and advanced, or "high-tech" equipment technologies receive. This view, however, is not an accurate one. It does not reflect the fact that, due to their greater numbers, technologies of low and moderate cost account for a much greater percent of total health care expenditures than do "big ticket" technologies. Furthermore, as genetically engineered pharmaceuticals and diagnostics and surgical techniques employing lasers and scopes are increasingly diffused throughout the health care establishment, lower priced technologies will account for an even larger percentage of expenditures and have an even more dramatic impact on the way that health care is organized and delivered than they do now.

presents the AMEDD with an opportunity to fight for the resources it needs at the Department of Army (DA) level rather than at arm's length through the complex and demanding LRAMRP and LRRDAP processes that take place at the MACOM level. Recently, as the responsibility for funding fixed medical facilities migrates to the Office of the Assistant Secretary of Defense for Health Affairs [OASD(HA)], the Army has increasingly resisted allowing the AMEDD to compete for Army resources during LRRDAP and PPBES processes. More and more, the Army sees DoD as responsible for funding fixed medical facilities.

As a result of modernizing its fixed facilities outside of the CBRS, the AMEDD may well have obtained more resources than it would have gained using the CBRS; in fact, it may have obtained new technologies more responsively. However, as result of modernizing fixed facilities outside of the CBRS, the AMEDD has not been required to accomplish the planning that TRADOC demands of those participating in the CBRS. Because no compensating demand for formal, comprehensive planning was substituted, a strategic plan for modernizing fixed facilities and the health service delivery system they constitute has not been developed. Furthermore, the relationship between fixed facility modernization and field facility modernization has not been effectively documented.

No organization or entity that identifies itself as the "architect" of future AMEDD fixed facility hospitals or health care delivery systems exists. The strategic planning that has been done has focused almost exclusively on AMEDD readiness roles and wartime missions. Under the Coordinated Care Program (CCP), however, OASD(HA) has initiated a strategy that requires coordinating and integrating the technology modernization requirements of AMEDD fixed facilities not only among themselves but also among the fixed medical facilities of the other Military Services, other Federal agencies, and those civilian facilities used by CHAMPUS beneficiaries as well. Of course, new materiel-based medical technologies must also be integrated with non-materiel-based technologies.

New non-materiel-based medical technologies, such as modernized medical and surgical treatments, are acquired through personnel education and training programs. Health care professionals who have been taught about the latest innovations are recruited and hired. Graduate-level and continuing medical education programs teach the existing staff about new developments in the academic, research, and industrial communities. Modernized organizational and supportive systems (including computer systems) are generally developed, acquired, and fielded using CBRS, weapon-system-like acquisition processes. Doctrinal, training, leader development, and organizational solutions to capability needs are seen as less expensive and more preferable to materiel-based solutions. Peacetime table of distribution and allowance organizations, emulate the personnel and logistical structure and composition of table of organization and equipment organizations. In wartime, this situation reverses itself, especially when large numbers of peacetime health-care-oriented reservists are used. Such changes in nonmateriel-based technologies frequently alter requirements for materiel-based technologies.

The execution of AMEDD modernization programs is controlled through a host of specialized management systems and reports. Examples include The Army Authorization Documents System; financial reports that detail the status of funding, committed, unobligated, obligated and dispersed, individual item delivery and fielding schedules; beneficial occupancy date-driven project management reports; readiness reports; and individual and collective training plans and career development strategies. The integrated logistics system approach is intended to serve as the management umbrella under which many functions are coordinated. A stable business environment is essential for the execution of modernization programs according to plan.

A MORE STRATEGIC APPROACH TO TECHNOLOGY MODERNIZATION

Technology modernization spans functional and organizational boundaries. One need only examine the revolution in laparoscopic surgery to confirm this fact.[4] Physician training, nurse staffing, medical materiel, and facilities utilization are all affected. Therefore, a valid management approach to technology modernization must consider the integrated accomplishment of missions and the close coordination of different organizations. A health care system composed of fixed facilities also needs its own streamlined version of the CBRS. It needs policy and procedural devices that integrate and coordinate the modernization activities of the entire AMEDD. The AMEDD needs a fixed facility modernization plan comparable to the LRRDAP and

[4]Laparoscopic surgery is performed by inserting a small video device and other instruments into a patient's body. The video device magnifies internal organs and shows them on a television screen. The surgeon can perform such operations as the removal of gall stones or the gall bladder using these instruments. Laparoscopic surgery requires less hospitalization than equivalent "open" surgeries.

the LRAMRP.[5] In the AMEDD's fixed facility modernization plan, the demands for resources would be prioritized and adjudicated. The different appropriations used for modernization would be coordinated to best accomplish the AMEDD's mission of providing health benefits during peacetime and wartime. The fact that the AMEDD has not, and cannot, strategically reconcile its beneficiary population and its service delivery plant demonstrates the need for such a plan.

Multidisciplinary committees serve to plan, integrate, coordinate, and control the introduction of small segments of medical technologies (to one degree or another and at one organizational level or another) in order to accomplish some management goal whether related to standardization, quality, readiness, or finance. Examples of such committees are as follows: Joint Working Groups, Test Integration Working Groups, In-Process Reviews, Diagnostic Imaging and Radiotherapy Boards, Hospital and Medical Command Standardization Committees and Therapeutics Agents Boards, Program Budget Advisory Committees, Medical Systems Review Committees, Teaching Chiefs Conferences, the AMEDD Technical Committee, the Defense Medical Standardization Board, Defense Personnel Support Center Customer Support Meetings, the Defense Health Council and, recently, the HSC's Strategic Technology and Clinical Policy Council (ST/CPC). Committees, however, are not directly accountable entities. They recommend and advise. Numerous committees often give conflicting, incremental, or uncoordinated advice. Because of this, the commander or organization head must ensure that committee efforts are effectively integrated so that the thrust and direction of the organization reflects his/her intent. Strategic planning and technology management cannot be delegated completely because they are absolutely vital to the success of the delivery system.

Whether AMEDD programs, including technology modernization programs, are uniform and sufficiently integrated and coordinated to work or not, is a matter of considerable debate. Comprehensive, objective, and independently verifiable measures of overall health service system performance are not used. Total health care costs and the growth rate of those costs have been widely recognized as indicators of system financial performance only within the last several years. As a result of the lack of performance measures, the system is evaluated from a large

[5]We examined the strategic and long-range plans of the OASD(HA), Office of the Surgeon General (OTSG), HSC, and MRDC. Their focus is primarily on readiness for support during wartime. They do *not* reflect specific plans and activities aimed directly at improving quality, controlling costs, or integrating the fixed facility health care plant.

number of perspectives. Anecdotes and isolated occurrences frequently receive disproportionate attention as a result. Image often becomes more real than substance. Examples include:

- Many military providers, particularly those with management responsibilities, state that the quality of military health care is the best in the world. However, many beneficiaries, as the CHAMPUS Reform Initiative in California and in Hawaii indicates, would prefer CHAMPUS providers to direct care, especially if copayments, deductibles, and cost shares are minimized and the "hassle" of filing claims is reduced or eliminated.

- The General Accounting Office (GAO) indicates that the military medical establishment would have failed had Operation Desert Storm casualties been high. [8] The Army Surgeon General counters that the system was prepared and, in fact, is to be commended for the sheer massiveness of its deployment.

- The HSC argues that its modernization goals may not be met without increased funding of more than $100 million. "Bill payers"[6] for such amounts are scarce.

- Members of Congress express skepticism about the acceptability and viability of the DoD's CCP. Skepticism can also be found at the grass roots operational level, especially concerning such program features as computer automation, specialized treatment facilities, and cost data for decision-making. Leadership at the departmental level feels that such skepticism is unwarranted and that technical obstacles can eventually be overcome.

Through all of the debate several points are clear. It is clear that the Military Health Services System (MHSS) operates. It receives, treats, and discharges patients. Nevertheless, it is also clear that no one, including the MHSS leadership, is completely satisfied that medical technologies – in the correct quantities and capacities to achieve the desired beneficiary population benefits and the optimal delivery system operating characteristics – have been properly deployed to accomplish peacetime and wartime health care missions. It is also clear that an optimized health care delivery system has not yet been designed or strategically planned to meet existing threats and patient demographics. The civilian, for-profit

[6]Army funds are limited. When HSC funding programs are increased, other Army or AMEDD programs must be reduced in order to remain within fund limitations. The programs that are reduced "pay the bill" for increased HSC programs; hence, they are "bill payers."

and not-for-profit health care systems that we studied concentrated on delivery system design. [9]

In a resource-constrained environment, and to discourage the discontinuities fostered by specialization, technology modernization management must achieve and preserve a "single, level technology acquisition playing field." All technologies – preventive or curative, diagnostic or therapeutic – compete fairly and as objectively as possible for approval and funding on such a field. A technology's overall contribution to the advancement of health service goals should be the basis for competition. Such an integrated and coordinated technology playing field must be a prominent characteristic of any valid technology modernization management system. The CBRS attempts to achieve this ideal. However, while it is strong in concept, it is weak in implementation possibilities. The AMEDD is justified in using this concept with caution. The AMEDD should, however, strategically plan the delivery of health services that CBRS would demand if it were used. A number of actions can be taken to enhance strategic planning.

Technology modernization can be effectively consolidated and leveled. The relationships between health care delivery goals, plans for the care of individual beneficiaries, requests for resources, resource allocations, expenditures, actual performance-to-plan, and system-wide mission accomplishment can be improved. Collectively, these actions are a collaborative, evolutionary strategy for enhanced medical technology modernization management and the delivery of health benefits to authorized beneficiaries.

The remainder of this report describes the actions required for managing diverse, rapidly changing medical technologies. Our recommendations span the full range of medical modernization management issues. They are consistent with evolving military management practice. They are also consistent with good business practice to the maximum feasible extent.

CHAPTER 2

MEDICAL TECHNOLOGY APPLICATION AND COSTS

PRACTICAL APPLICATION OF MEDICAL TECHNOLOGIES

The decision on whether to use a medical technology is often complex and uncertain. Technology is the application of knowledge gained from scientific experiments to achieve objectives. [10] For example, medical technology is learning about monoclonal antibodies and making use of that knowledge to develop and produce pharmaceuticals for the prevention and control of disease. The approach to achieving objectives through the application of technologies can be divided into three stages. The first part involves the invention or discovery of new knowledge. It is called basic research or, simply, research. Invention and discovery spring from curiosity, relativity, and a desire to solve problems and to improve. The second part involves the development and testing of new knowledge. It is ordinarily called applied research, clinical research, or, simply, development. Last, the new technology is applied to accomplish either the original or revised objectives. Use depends on the success of the first two efforts. It is in the latter two stages where things start to go wrong. [11]

By definition, when a bona fide new technology is applied or used properly in patient care settings, medical care improves. The technology works. Patients benefit. The technology pays off. However, application requires precision. Applied improperly or for the wrong purpose, new medical knowledge or technologies can be unsafe and wasteful. Patients do not benefit. Any modernization management system must ensure, and contribute to, appropriate technology use. This is the function of technology assessment. We discuss technology assessment in detail in the next chapter.

Medical knowledge, including the medical knowledge of military providers, must incorporate a thorough understanding of the proper application and use of medical technologies in actual practice. The technologies that must be understood are the pharmaceuticals, biologicals, medical devices, medical and surgical treatments, and the organizational and supportive systems. According to Dr. David

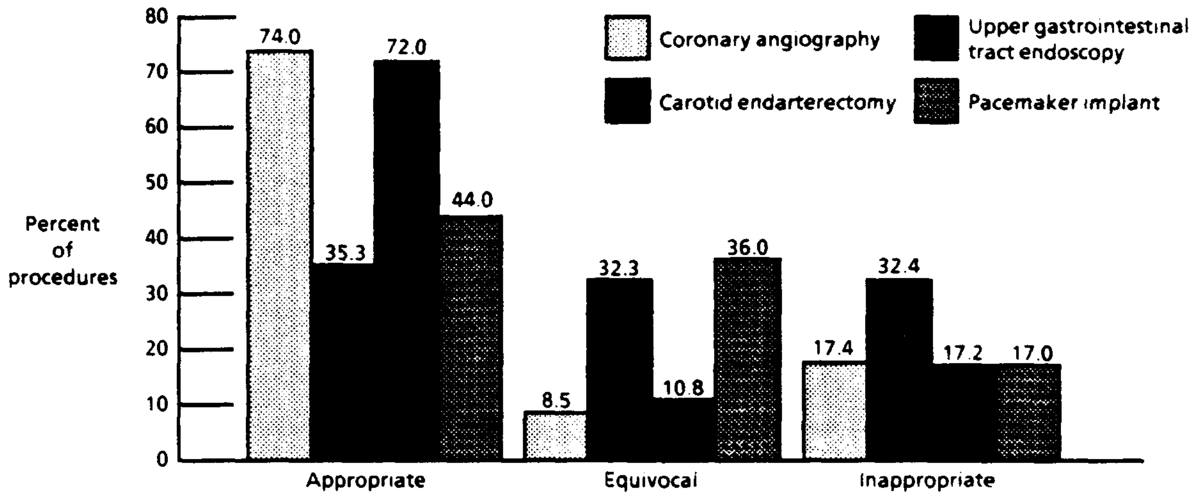
Eddy, an author of numerous health care policy articles, and according to many other experts, unfortunately "the information base for medical practice is extremely poor." [12] Which technologies work and which do not is not known with sufficient precision. Furthermore, physicians do not typically learn or apply the decision analysis skills necessary for deciding when it is proper to use a technology and when it is not. [13] Lacking essential information and decision analysis skills, medical services are delivered more heterogeneously than one might expect. The impact of a technology on patient outcomes is not known with certainty nor predictable at a high confidence level.

INAPPROPRIATE TECHNOLOGY USE, VARIATION IN CARE, AND HEALTH CARE COSTS

Studies of civilian health care have produced evidence of broad variation in care. Such variation may indicate the wasteful and inappropriate use of medical technologies. Evidence of the variation in the quality of care is found in three sets of key areas:

- The use of medical technologies varies widely by geographic region, patient age, patient sex, and other demographic, social, and economic factors. The range of deviation is so large that it cannot be entirely explained by the variation in patient populations. Some care falls outside of the range of acceptable quality limits.
- Many procedures and products used to diagnose and to treat illness have not been scientifically proven to be effective.
- The assumption that doing something (some form of medical intervention) is better than doing nothing is pervasive.

On the basis of findings such as these, researchers have concluded that medical technologies may be used improperly on a frequent and large-scale basis. As shown in Figure 2-1, a 1986 study indicates, for example, that 17.4 percent of coronary angiographies were inappropriate and another 8.5 percent were equivocal. [14] Some theorists suggest that as much as one-third of the resources devoted to health care today are being spent on ineffective, unproductive, or improper care. Some believe that the selective reduction or elimination of technological impropriety can generate savings large enough to preclude the "rationing" of health care in the United States for the time being. The money saved could then be shifted to provide access to health care for millions of people not now insured. [13] In dollar terms, the annual cost of using medical technologies improperly in the United States may be $200 billion. The implications for the funding and acquisition of new technologies are obvious.



Source: Medical Device and Diagnostic Industry.

FIG. 2-1. ESTIMATED APPROPRIATENESS OF SELECTED MEDICAL PROCEDURES

DECISION SUPPORT INFORMATION IS NEEDED

Table 2-1 provides insight into the difficulty of using technologies appropriately. It arrays alternative 25-year screening strategies for a 50-year-old man who is at high risk, for colorectal cancer. The costs associated with each screening strategy and the likely outcome of that strategy are provided. The chart displays the kind of decision-making information that should be made more available to physicians. [15]

What is a proper use of technology and what is an improper use of technology? When is a device improperly used? When is a pharmaceutical improperly prescribed? When is a surgery improperly performed? It is difficult to generalize answers to these common questions. Sometimes marginal care makes headlines. Sometimes the improper use of a technology is tragically evident even to the layman. Pressure (e.g., from the threat of medical malpractice suits) to practice "defensive medicine" often results in, and aggravates, the inappropriate use of technologies. At other times, an episode of inappropriate care might only be identified by experts after thorough and lengthy study. On many occasions, patients demand, perhaps appropriately, perhaps inappropriately, the latest technology. While appropriate use of technologies is

TABLE 2-1

THE NEED FOR INFORMATION IN DECIDING BETWEEN ALTERNATIVE COLORECTAL SCREENING STRATEGY OUTCOMES IN A HIGH-RISK 50-YEAR-OLD MAN

Outcomes	Screening test and time frame[a]						
	No screen	F1 & S3	S3	B5	C5	F1 & B5	F1 & C5
Benefits							
Probability of getting colorectal cancer (percent)	10.3	7.3	8.4	4.7	3.8	4.2	3.5
Probability of dying of colorectal cancer (percent)	5.3	2.9	4.0	2.0	1.5	1.5	1.2
Harms							
Probability of false +, FOBT (percent)	N/A	40	N/A	N/A	N/A	40	40
Probability of false +, Barium Enema Exam (percent)	N/A	N/A	N/A	16	N/A	16	N/A
Probability of perforation (percent)[b]	N/A	0.3	0.3	0.09	0.9	0.09	0.9
Inconvenience, discomfort							
FOBT, number of tests	N/A	26	N/A	N/A	N/A	26	26
Scope, number of tests	N/A	9	9	6	6	6	6
Costs (dollars)[c]							
Screening	N/A	643	584	568	1,418	647	1,476
Treatment	1,155	1,106	1,069	672	548	775	676
Net	1,155	1,749	1,653	1,240	1,966	1,402	2,152

Source: *Journal of the American Medical Association.*

[a] F = fecal occult blood test (FOBT); S = 60-cm flexible sigmoidoscope; B = air-contrast barium enema exam; C = colonoscopy; 1 = every year; 3 = every 3 years; 5 = every 5 years; N/A = not applicable.

[b] This is the probability of perforation due to endoscopy, barium enema exam, or workup of a false positive FOBT.

[c] These are present values, discounted at 5 percent, a $4 FOBT, $135 60-cm flexible sigmoidoscopy; $200 air-contrast barium enema exam, and $500 colonoscopy are assumed as a high-risk, 50-year-old male, screened to age 75.

important to the physician's "do-no-harm" credo, on a more fundamental level, the proper use of medical technologies is essential for controlling health care costs.

MEDICAL QUALITY ASSURANCE MECHANISMS FOR QUALITY HEALTH SERVICES

Institutional mechanisms intended to help ensure the delivery of high-quality health services exist at all levels of health care administration, from the individual physician and patient to the Department of Health and Human Services. The Food and Drug Administration (FDA), by making determinations about the safety and efficacy of drugs and medical devices, enforces laws that regulate the introduction of medical technologies into interstate commerce. [16] Professional and Peer Review Organizations oversee the practices of their respective specialties through testing and certification, thereby establishing broad clinical policy and upholding standards of care. New organizations such as the Agency for Health Care Policy and Research

(AHCPR) are intent on furthering the development and dissemination of sound practice policies. The National Institutes of Health (NIH) hold consensus conferences that address thorny and contentious scientific issues bearing directly on the decision-making knowledge base of physicians. State and local governments validate the credentials of providers and license the practice of medicine and the operation of hospitals, nursing homes, and clinics within their jurisdictions.

The Joint Commission on Accreditation of Hospitals Organization (JCAHO) plays a formidable role in assuring the quality of delivered care at individual hospitals. Of course, the entire utilization review and quality assurance industry has been created to detect the inappropriate use of medical technologies on a "real time" basis. Utilization reviewers anxiously await the publication of outcomes research and practice policies and guidelines by AHCPR and other authoritative sources. They constantly monitor practice patterns to detect, as early as possible, those providers who begin to stray from accepted norms and standards. Control over physician use of technologies is taken to high levels in some health maintenance organizations (HMOs) by providing physicians with profit and loss responsibilities that include incentives to use technologies sparingly yet appropriately. Because of the abundance of these controls, excessive interference with the relationship between physicians and their patients is seen by some as a real threat to high-quality, personal care.

LESS INTRUSIVE, MORE EFFECTIVE CONTROLS STILL NEEDED

Even with control mechanisms and incentives in place, the improper use of medical technologies is still an issue. United States health care expenditures over the past several years have continued to increase. In 1991, they hit an all-time high: $670 billion. Sustained "unsustainable" growth is predicted. Health care costs are projected to top the $1.5 trillion mark by the end of this decade. [12] These results and projections have been recorded despite at least a decade-long, ever-intensifying attack on health care costs across the entire spectrum of health care organizations. The attack has included the Medicare Prospective Payment System, all manner of HMOs, Preferred Provider Organizations (PPO), and other managed care arrangements, capitation budgeting, global budgeting, and recent physician payment reforms.

Although much activity is underway to correct the situation just described, little has actually been accomplished to address the fundamental lack of information upon which physicians and patients can base decisions about when to use/request a technology and when not to. Some allege that the control mechanisms noted earlier, such as the FDA's determination of drug and device safety and efficacy, do little to provide physicians with operationally useful outcome information (e.g., the type of epidemiological data shown in the colorectal cancer screening chart previously discussed). The information that is provided is said to have been developed under such sterile, structured, academic, or ideal circumstances that it is only remotely related to the day-to-day information needs of a busy medical practice. [13] Evidence about actual, "real-world" performance of technologies (outcomes research) is lacking. Of course, without this information, physicians, managers, and planners are unable to effectively discriminate between valuable and less valuable technologies. Table 2-2 arrays the decision they face. The demand for a broad variety of technologies is therefore questionable. Demand may actually be driven by provider pride and reputation, suboptimizing competitive pressures, fiduciary relationships, and other factors unrelated to legitimate patient care demand. [17]

TABLE 2-2

COMPARING NEW TECHNOLOGIES AND EXISTING ALTERNATIVES

The New Technology Adoption Decision

Benefits	Costs		
	More	Same	Less
More	Tough choice	Adopt	Adopt
Same	Do not adopt	Toss up	Adopt
Less	Do not adopt	Do not adopt	Tough choice

Source: International Journal of Technology Assessment in Health Care.

New medical technologies are sometimes scarcely understood before they are redesigned, changed, or rendered obsolete. [18] Reflecting the continuing evolution of medical technologies and the associated omnipresent requirement to plan for change, each year the FDA receives 15,000 requests to approve the use of drugs and devices in the nation's health care institutions. (This number does not include a broad variety of non-materiel-based technologies.) Many of the requests received are for products that are similar to items already in use. Some of the requests ask to use previously approved technologies in new and different ways. A few of the requests are for products that push the limits of science, render other products and technologies obsolete, and dramatically advance the state of the medical art. Occasionally a request is presented by an AMEDD R&D activity. [19] To receive FDA approval, proposed new products must be demonstrated to be safe and effective when used as prescribed. Once approved, products may be distributed and sold to pharmacies, hospitals, and other health care organizations for resale to patients or use in diagnosis and treatment. Similar "regulating" and "approval" functions are performed by professional colleges and other peer review, "specialty policing," and standards-setting organizations for nonmateriel treatment techniques and procedures.

Methods for planning and making medical technology distribution decisions can be improved. This is equally true within private sector and DoD and AMEDD health care delivery networks. An exceedingly fine line exists between the over-distribution and the under-distribution of a medical product line or new medical technology. When a technology is too widely distributed, acquisition costs are too high and the risk of inappropriate and costly overuse of the technology increases. When a technology is not distributed widely enough, the resulting under-use deprives beneficiaries of the level of care, the range and quality of services, and the convenience to which they are entitled. It also leads to physician dissatisfaction. In the United States, of the two errors, over-distribution or under-distribution, the former may represent the path most taken. It appears to be easier to justify the acquisition of a new technology than it is to avoid its acquisition or limit its distribution. Comparisons of the number of computer-assisted tomography (CT) scanners, magnetic resonance imaging (MRI) and lithotripter units, or cardiac catheterization laboratories per 100,000 population are measures used to compare the relative "lavishness" or "austerity" of the health care systems of various nations. Almost without exception, the United States has more expensive, high-tech equipment per unit of beneficiary population than any other industrialized country, yet it experiences about the same health outcomes. [20] Since technology acquisition costs represent about 5 percent of the nations health care bill, and since technology use costs add another 40 percent to that bill, [11] controlling the distribution and use of medical technologies, particularly those whose total costs to the Government are highest, is critical to containing investment expenses and health care costs. We believe that the best way to control distribution of technologies is to control the authorization to perform specific services at specific locations.

For all but the most expensive technologies, those exceeding $1 million in purchase price, DoD and the AMEDD decentralize technology distribution decision-making to hospital commanders and their staffs. [21] Much like decentralizing the decision to use direct care or to use CHAMPUS to the beneficiary, the decentralization of medical technology acquisition and distribution decisions can produce a nonintegrated, poorly coordinated, and overly expensive delivery system that has excess service capacities. Under today's decentralized decision-making, the impact of technologies on system-wide demands and costs – including the life cycle cost of training and providing the trainers, operators, and maintainers – are not adequately considered. Indeed, the impact of a new technology on the operating costs at the acquiring facility is seldom adequately considered. Such decentralized decision-making, especially in the absence of strategic plans and necessary operational and financial controls, differs radically from typical corporate business practices where capital budgets fully explore the impacts not only on the revenues and expenses at the given facility but also on the system-wide corporate bottom line. Furthermore, a policy of decentralized technology decision-making is inconsistent with a medical practice information base that is characterized as "extremely poor" and the often-made claim that "quality" is the most important attribute of military health care; when quality depends in some measure on the consistent and appropriate application of technology. We believe achieving quality health care warrants an increase in the control of product line distribution and a stronger linkage between centralized strategic health care delivery planning and technology modernization.

Medical technologies are likely to be improperly used in AMEDD direct care and CHAMPUS. Some safeguards against improper use are installed. What additional safeguards or mechanisms, if any, may be necessary? With the current CCP and Gateway to Care (GTC) program, an opportunity exists to more thoroughly integrate the planning for new medical technologies into the fabric of strategic and tactical health care delivery planning in ways that both enhance the quality of care *and* conserve resources.

In the remainder of this report, we explore the steps for improving DoD and AMEDD medical technology modernization management.

CHAPTER 3

MEDICAL TECHNOLOGY ASSESSMENT

INTRODUCTION

In this chapter, we discuss technology assessment and the role it can play in AMEDD modernization planning. We also discuss who should conduct technology assessments and the specific uses that should be made of assessment documentation. Taken in total, the discussion presents a more strategic technology modernization management approach. In Chapter 5, we make specific recommendations for adopting and implementing the approach we describe.

At the introduction, we briefly discussed the Army beneficiary population, its demand for health care, and the value of the AMEDD plant used to support it. Modernization of medical technologies needs to be evaluated in terms of its value to beneficiaries and in terms of its ability to contribute to delivery system goals. However, due to its fragmented approach to managing technology modernization and its lack of readily measured delivery system performance objectives, the AMEDD does not estimate the overall contribution of various technologies to direct patient care or to the accomplishment of delivery system goals. Therefore, allocating resources to modernize technologies is largely an exercise in position, personality, and the availability of funds. Allocating modernization resources is not sufficiently linked to delivery system performance whether measured in terms of patient care, in terms of costs, or in terms of strategic goal attainment. This is symptomatic of organizational pathologies associated with the modernization management dilemma. A more objective, long-range, results-oriented approach to technology modernization is needed.

The decision to use a technology is often complex and uncertain. Nonetheless, control of the quality of health care services and their costs depends, in part, on using technologies with precision. Because of uncertainty and the requirement for precision, some risks, including operational and financial risks, are associated with the acquisition and distribution of technologies. (Operational risk relates to the quality of services, and financial risk can be seen as the probability that resources will be wasted.) Given the nation's high health care bill and its "average" health status, many have concluded that health care overhead accounts are out of control or that the costs of using medical technologies often outweigh the benefits. [20] Both conclusions suggest a conservative, cautious approach to the acquisition and distribution of technologies. Caution is exercised through the careful evaluation and control of a technology as it is introduced to, and diffused in, the health care delivery system. "Technology assessment" is the name for the careful evaluation of technology in the interest of control. It occurs at the junction of scientific R&D, and the management of health care operations.

Medical technology assessment is a "process of examining and reporting properties of medical technology used in health care such as safety, efficacy, feasibility, and indications for use, cost and cost effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended." [22] While technology assessment does not make modernization decisions, it provides the analyses necessary for informed modernization decision-making.

When properly performed, technology assessment identifies the costs and consequences of alternative technologies, measures the magnitude of each cost and benefit in appropriate units, displays these measurements in an organized framework that permits comparison of alternatives, reminds decision-makers of any relevant costs or benefits that have not been measured, highlights areas of disagreement and uncertainty (thus, focusing any debate and discussion), and identifies where further information would be helpful and where it would not. [23] Assessment attempts to quantify, without bias, the impact of a technology on beneficiaries and on the ability of the delivery system to accomplish its goals whatever they may be.

CLINICAL TRIALS, PATIENT REQUIREMENTS, AND ECONOMIC EVALUATION

Although there are those who argue that costs should not encumber clinical decision-making, the reality is that they do and they must. [24] Medical technologies must be assessed on the basis of both their utility and their costs. The consequences of technologies are their clinical outcomes and patient preferences. Clinical outcomes can be estimated on the basis of prospective clinical trials or the synthesis of retrospective data from many completed trials.

Technology costs are determined in many ways. They include capital costs (for buildings, equipment, and loan interest), operating costs (for labor and supplies, e.g., costs to third-party payers), costs that the patient and his or her family must bear, community social service costs, and the discounted cost of future health care demand. Costs can also be grouped as direct and indirect, fixed, variable, marginal or incremental, and tangible and intangible. Benefits likewise can be grouped as direct, indirect, tangible, intangible, and marginal or incremental. Such groupings facilitate economic evaluations. Listing and defining all costs and benefits as precisely as possible, describing who bears each and every cost and receives each and every benefit, and how each can affect decision-making, requires careful thought and a systematic, well-reasoned approach. How this is done can influence how a technology is valued. [24] For example, using laparoscopes and endoscopes for surgical procedures can reduce inpatient length of stay. The hospital administrator and the third-party payer see reduced length of stay as very valuable. The patient's family, however, can view convalescence and care at home from a different perspective. They may have to hire a nurse or miss work to care for the discharged patient. In such a situation, the family may be substantially less enthusiastic about the value of short lengths of stay. In any event, the viewpoint of the technology assessor is an extraordinarily important part of any assessment. It should be explicitly considered.

Clinical trials and economic evaluation judgments aid modernization decision-makers in answering the following fundamental questions about new technologies: [25]

- What are the alternative technologies (for comparison)?
- Who and how many patients will be treated?
- What are the additional new technology costs and who bears them?
- What are the new or additional health outcomes?
- How important are additional health outcomes to patients and payers?
- What are the other alternative uses for the same funds (opportunity costs)?
- Considering all this, is the new technology worthwhile?

Clinical trials and economic evaluations take various forms. Clinical trials are intended to determine, on the basis of reliable evidence, if a technology produces the specific clinical effects it is purported to produce. Clinical trials are conducted by completing randomized controlled trials (RCTs), cohort studies, case-control studies, and uncontrolled case series analyses.

The RCT is generally considered by the scientific community to be the strongest, most scientifically valid experimental design for establishing causal inferences between treatments and outcomes. [26] The RCT uses control mechanisms like placebos and control groups to ensure scientific validity. RCTs are expensive and time-consuming. Furthermore, because of their "ideal" yet very restrictive, narrow, and rigid design, RCTs may not be able to be generalized for everyday medical practice where patients that are potentially eligible for the technology do not present themselves in ways that precisely conform to the experimental trial design. Cohort studies, case-control studies, and case series studies are less ideal with respect to their scientific validity and inferential power. They are, relative to RCTs, less controlled and more general in nature. [26] Nonetheless, they do provide valuable information.

A trade-off exists between "internal" scientific validity and the ability to generalize in the "external," "real world." This trade-off is a prominent feature of the AMEDD's modernization management dilemma. How certain must an AMEDD provider be before a specific treatment or test is given? Need the treatment or test be of only potential value or must the likely "actual" value be established? [26] To what degree of risk should the patient be exposed?

Is consensus about technology diffusion and clinical policy possible? Since 1977, over 60 Consensus Development Conferences have been held by NIH to answer this question. Issues addressed at the national level range from breast cancer screening, CT scanning of the brain, and liver transplantation to traveler's diarrhea, infantile apnea, and home monitoring. [27] However, because of its current approach to modernization management, the AMEDD does not always see the trade-off in terms of clinical policy affecting health care costs and quality control. Instead, the trade-off is often seen by the AMEDD researcher/investigator as impatience and risk on the part of the provider – and by the provider as delay and bureaucracy on the part of the researcher and the acquisition system.[1] We believe AMEDD policy needs to address issues related to the trade-off between scientific certainty and day-to-day medical practice.

Economic evaluations depend on valid, reliable data on the effects of therapies. Like clinical trials, economic evaluations can take several specific forms. The form of economic analysis used depends on the technology or technologies being assessed, the purpose of the assessment, and the viewpoint taken when defining assessment variables. The types of economic analyses and their respective purposes are shown in Table 3-1. Further discussions of these methods of analyses are provided in Appendix B.

TABLE 3-1

TYPES OF ECONOMIC ANALYSES

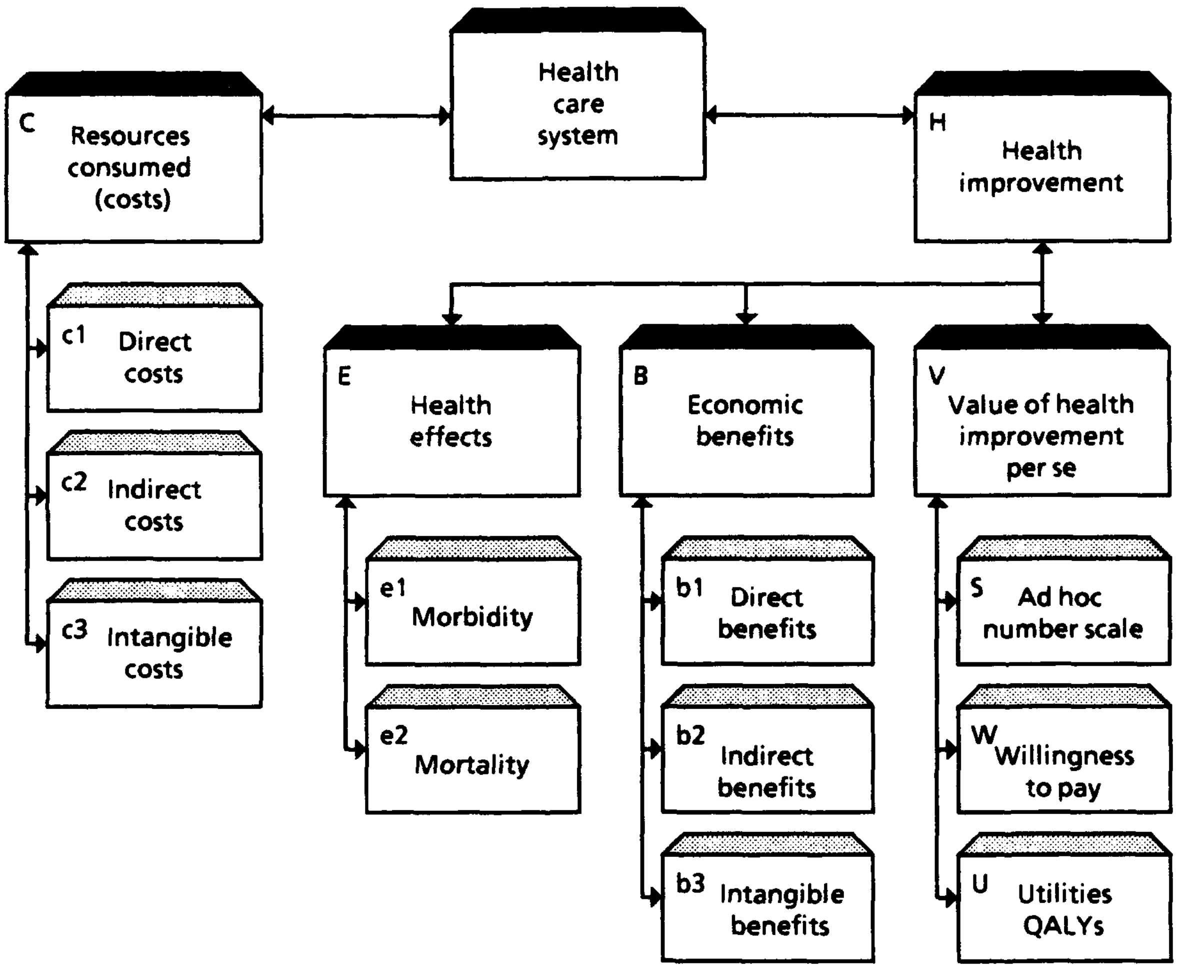
Analytical method	Objective of the method
Cost of illness	To determine the total economic impact of a particular disease
Cost minimization	To compare treatment alternatives that have equal effectiveness, but different cost
Cost effectiveness	To compare treatment alternatives with outcomes of the same type
Cost utility	To compare any/all treatment alternatives by using a generic outcome such as Quality Adjusted Life Years (QALYs)
Cost benefit	To compare any and all treatment alternatives by using dollars as a generic outcome

Source: Center for Health Economics and Policy Analysis, McMaster University.

The use of each of these types of economic analyses can be illustrated using an oversimplified model (Figure 3-1) of the health care system that reflects the components of economic evaluation. [23] For example, a cost-of-illness analysis may include direct treatment costs (including the costs of social services and education)

[1]This conclusion was originally drawn from lengthy discussions that occurred at the Medical Research and Development Command in 1989. Representatives of the following AMEDD "communities" participated: Research and Development, Logistics (including MEDCASE and readiness constituencies), Nursing, OTSG consultants, Combat Developments, Testing, Medical Maintenance, Financial Programming, and Acquisition. Continued interviews and research since that time have not altered the conclusion.

(component c1 in Figure 3-1), indirect costs consisting of productivity losses, (component c2 in Figure 3-1), and intangible costs such as patient pain and suffering, (component c3 in Figure 3-1). Cost-of-illness analyses could be useful for ranking illnesses for the purpose of prioritizing research efforts and for targeting areas for cost containment or for identifying opportunities to expand medical services through modernization. Used in this way, cost-of-illness analysis could play a key role in strategic planning efforts.



Source: Center for Health Economics and Policy Analysis, McMaster University.

FIG. 3-1. COMPONENTS OF ECONOMIC EVALUATION

Cost minimization studies are appropriate when clinical trials establish that the health improvement (component H in Figure 3-1) for two alternative technologies are the same. A study would concentrate on any differences between direct, indirect, and intangible costs (components c1, c2, and c3 in Figure 3-1) between the two alternatives. Cost effectiveness analysis, when viewed from the perspective of the health care system administrator, could take the form of the equation:

$$\frac{c1 - b1}{E}$$

where direct costs include man-hours and medical supplies and where direct benefits include the discounted value of avoided future medical episodes. When viewed from the Army or DoD perspective, an assessment of the cost effectiveness of a technology might be viewed as the equation:

$$\frac{c1 + c2 - b1 - b2}{E}$$

where direct costs and benefits are the same as above but where indirect costs include overhead such as research, development, and time lost from the job, and indirect benefits include any production gains associated with improved health or lower morbidity.

It is important to carefully define costs and benefits and consider how they might be measured differently when viewed from different perspectives. Cost-utility analyses would be stated as the equation:

$$\frac{c1 - b1}{U}$$

where the utility function would be established on the basis of an individual decision-maker's or a representative group's aversion to risk or time tradeoffs relative to alternative health states. Finally, a cost/benefit analysis could be formulated as easily as $b1 - c1$ where all relevant costs and benefits were defined in the two terms or in more complex ways by expanding the viewpoint and adding additional terms to the equation. Of course, all relevant costs and consequences should be considered in a cost/benefit analysis. Each type of cost and each type of benefit requires specific definition in the context of the accounting system or systems used and the sources of health improvement information available. These systems and information sources exert powerful influences on technology assessments. Insofar as feasible, systems should be designed to provide essential support to those responsible for technology assessment. Estimates of costs and benefits requiring many assumptions due to missing data, excessive data manipulation, or data substitutes lessen the robustness of the analysis.

Benefits described as the "value of health improvement per se" would include those defined by *ad hoc* numeric scales such as the Sickness Impact Profile (SIP) or other instruments used by clinicians to gauge improvements in clinical outcomes in such areas as ambulation, alertness behavior, body care, and so forth. Patients' (or, in a reimbursement system, the payers) "willingness to pay" for new technologies would be determined by gauging elasticities of demand at various technology prices. Willingness to pay and technology utility are measures of a technology's value as perceived by individual patients. Such measures are intended to accommodate individual preferences. Willingness to pay and utility are established using such instruments as time tradeoffs, standard gamble questionnaires, and carefully designed surveys. The results obtained using these types of instruments are intended to represent, in statistically valid ways, the views and choices of the "prototypical or average patient" who uses a specific technology. Identification of an average patient is needed for decision-making in centrally managed, or nationalized, health care delivery systems such as the one operated by DoD, where markets are not relied upon to allocate resources.

Employing economic evaluations that are linked to clinical trial information, such as the cost-utility analyses described above, permits the comparison or ranking of different medical technologies. Table 3-2 reflects comparative cost-utility analysis results compiled by Canadian researchers. [27] The studies used similar but not identical methods; the discount rates, preference weights, and costs are not completely consistent. Nevertheless, the results provide an example (and an example only) of the use of technology assessment information to link patient care, costs, and delivery system goals.

Repetitive economic analyses permit refinement in underlying assumptions, methodology, and data collection. Refinement should also reduce limitations placed on analysts. Such analyses should even drive improvements in patient accounting, clinical practice, and managerial accounting computer systems. When appropriate, peer review and the publication of economic analyses should be encouraged. Statistical rigor equal to that used when assessing consequences clinically should be afforded cost estimates. Discounting future costs and benefits should also be accomplished with care, consistency, and according to generally accepted uniform accounting principles. Once completed, technology assessment studies must be updated to reflect prevailing costs and benefits.

TABLE 3-2

COMPARATIVE COST-UTILITY ANALYSIS RESULTS FOR SELECTED MEDICAL PROCEDURES

Medical procedure and year of study	Cost per quality adjusted life-year gained[a]
Coronary artery bypass surgery for left main coronary artery disease (1981)	$4,200
Neonatal intensive care, 1,000 to 1,499 gm (1983)	$4,500
Treatment of severe hypertension (diastolic > 105 mm Hg) in males age 40 (1977)	$9,400
Treatment of mild hypertension (diastolic 95 to 104 mm Hg) in males age 40 (1977)	$19,100
Neonatal intensive care, 500 to 999 gm (1983)	$31,800
Coronary artery bypass surgery for single vessel disease with moderately severe angina (1981)	$36,300
Hospital hemodialysis (1984)	$54,000

Source: Center for Health Economics and Policy Analysis, McMaster University.

Note: > = greater than; gm = grams; mm = millimeter; Hg = mercury.

[a] Adjusted to 1983 U.S. dollars.

A good technology assessment study possesses the following features: [23]

- A well-defined question and analytic viewpoint
- Relevant alternatives
- Factual medical evidence
- A relevant range of costs and consequences
- Accurate measurement of costs and consequences
- Credible valuation of costs and consequences
- Adjustment for differential timing (discounting)
- Incremental analysis of findings
- Sensitivity analysis of findings
- Clear discussion of the relevance of findings.

THE MEDICAL TECHNOLOGY LIFE CYCLE FROM INNOVATION TO EVALUATION

Figure 3-2 reflects the life cycle of a medical technology. The stages of the technology life cycle include innovation, development, diffusion, and evaluation. [26]

The figure shows the location in the cycle where early and late adoption of the technology by a health system might occur. It also reflects the risk associated with abandonment and/or obsolescence of the technology. The extent that a specific technology is used depends on its position on the life-cycle curve. Placement of a technology on the curve should be supported by valid clinical evidence. The numbers shown on the curve correspond to the following types of evidence:

① Promising clinical reports

② Professional and organizational adoption

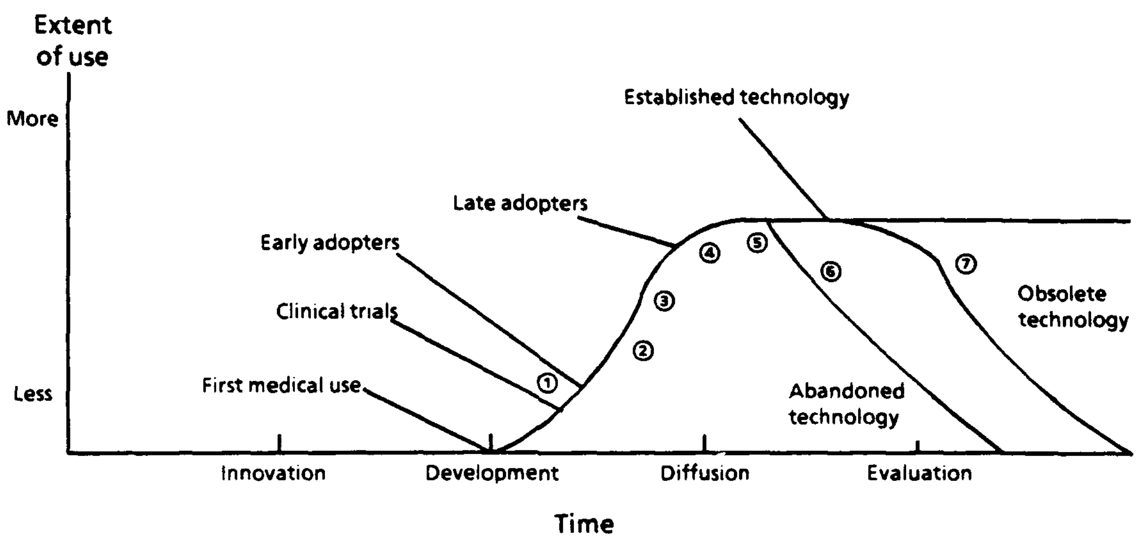
③ Public acceptance and third-party payer endorsement

④ Standard procedure and observational reports

⑤ RCT results

⑥ Professional denunciation

⑦ Erosion and professional discreditation.



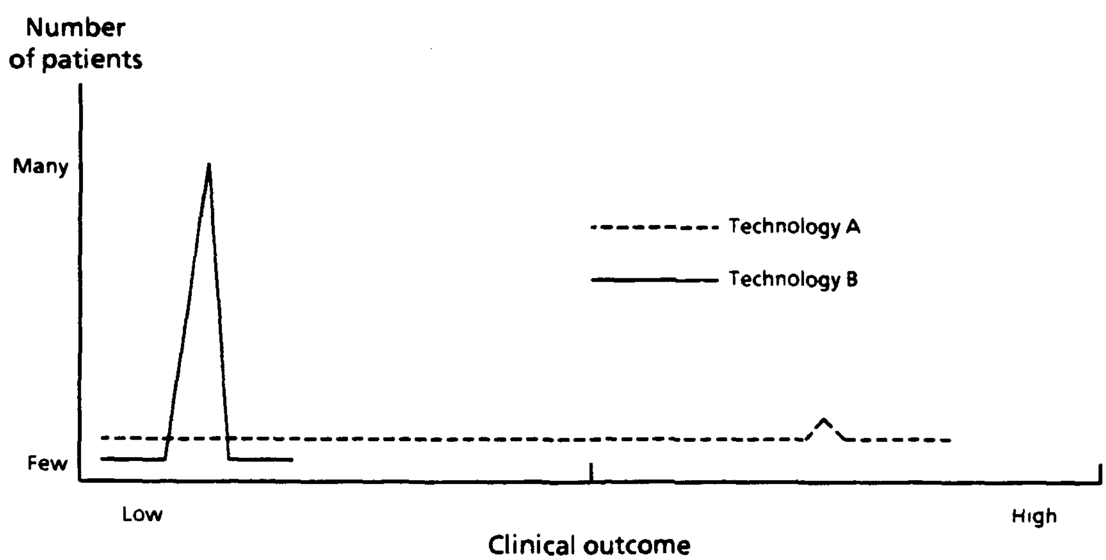
Source: Center for Health Economics and Policy Analysis, McMaster University.

FIG. 3-2. INNOVATION, DEVELOPMENT, TIME, DIFFUSION, AND EVALUATION OF MEDICAL TECHNOLOGIES

In addition to clinical evidence, the determination of the "extent of use" should also reflect consideration of the costs and risks associated with the technology – i.e., its likely overall impact on the beneficiary population and on the health care plant.

On the basis of this assessment, AMEDD management should, as part of its strategic planning, decide how to position itself as an early or late adopter and then justify that decision on the basis of system performance. To the extent practical, objective technology assessments, incorporating good clinical and economic information, should underpin determinations about the extent of the use of a technology in a delivery system. Those assessments should include "sensitivity-analyzed" examinations of alternative distributions and should fully recognize and explicitly address such factors as staff training requirements and graduate medical education (GME) residency and fellowship programs.

The clinical and economic bases of the distribution decision should also be consistent with the strategic goals of the delivery system. Is the system's goal to treat many patients on a basic level or a few patients on a very comprehensive basis? Consider Figure 3-3. [17] A technology with a relatively low expected value (clinical outcome effectiveness multiplied by number of patients) may qualify for an extent of use equal to the number of network facilities of a certain size with a specified mission, a qualified staff, and a minimum patient base — or it may qualify for an extent of use for only one facility. As the approach to the technology, facilities failing any "extent-of-use" criteria should plan to refer and/or evacuate eligible patients.



Source: *International Journal of Technology Assessment in Health Care.*

FIG. 3-3. TWO TECHNOLOGIES WITH LOW EXPECTED VALUE

A high-cost, high-risk technology – say, organ transplants – at the developmental stage may qualify for an extent of use equal to only a single medical center until clinical and cost/benefit data suggest alternative distributions. This "conservative" strategy would limit risk. In such a case, the cost of, say, transporting patients and family members would vary as the technology's distribution changed.

A technology in the innovation stage may not qualify for use in a delivery system. Indeed, the lack of FDA approval may preclude it. However, due to market potential or ability to solve specific community problems, the AMEDD may be willing to expend funds in order to closely monitor the technology. Data concerning costs, benefits, and risks, developed on the basis of clinical trials and economic evaluations, could be collected with a view toward possible purchase if and when circumstances permitted.

TECHNOLOGY ASSESSMENTS IN THE AMEDD

We said earlier that technology assessment occurs at the junction of scientific research, development, and the management of health care operations. This relationship is not unlike that of today's combat and materiel developers. In the AMEDD, these functions are performed by HSC and MRDC. The clinical investigations undertaken by HSC also play a role in technology assessment since they are concerned with clinical outcomes and clinical trials, and they operate laboratories and acquire equipment in support of GME efforts. Both the MRDC and HSC, including the clinical investigation community, are interested in assessments. Researchers and investigators are interested because the rigorous assessment and approval of their work can be personally and professionally rewarding, to say nothing of the contributions that can be made to patient care, Army missions, and national security. Hospital commanders and health system administrators are interested because assessed technologies promising favorable clinical outcomes or increased health care productivity are, or will soon be, in demand.

The financial resources necessary to learn about and acquire technology must be sought. Plans must be made to acquire, employ, and control the technology to preclude any inherent operational or financial risks. Opportunities to improve service and reduce costs must also be seized.

In the AMEDD, however, formal technology assessment, for the purposes of supporting acquisition and modernization decisions, is provided for only under the auspices of CBRS and the acquisition system described in Army Regulation (AR) 40-60, *Policies and Procedures for the Acquisition of Medical Materiel*, 15 March 1983. Technology demonstrations, prototyping, and technical testing of the kind that may approach RCTs in objectivity and scientific rigor are accomplished under the auspices of the formal acquisition system. That system, however, is not used for modernizing fixed facilities. As a consequence, the assessment of technologies used throughout the AMEDD direct care delivery system is not systematically accomplished early in the technology life cycle. (Ultimately, these same technologies will probably be used in Medical Force 2000 units and Deployable Medical Systems.) Instead, assessment is delayed or neglected until the CBRS-driven acquisition system "reacts" to the technology.

There is nobody in the AMEDD systematically exploring the fixed hospital and health care delivery system "technology base" nor is there anyone integrating the requirements for training operators, and maintainers into the AMEDD from a system perspective. The implications of technologies for beneficiaries and for the delivery system are not considered early on. Instead, fixed-facility health-care providers, on the basis of unstructured and unsystematic stimuli, are left to initiate action to acquire new and modernized technologies through MEDCASE, CEEP, and the medical supply system. For the operators and maintainers, difficult and costly contractual arrangements often replace life-cycle personnel management. The written justifications used when acquiring new equipment reflect these limited perspectives and assessment weaknesses. Unnecessary exposure to risk and waste may be incurred.

Fixed facilities are modernized outside of the CBRS. MEDCASE, CEEP, and medical supply system procedures are used for modernization. The provisions of AR 40-61, *Medical Logistics Policies and Procedures*, 30 April 1986, apply. AR 40-61, Section III, Chapter 2, provides for the demonstration, examination, and evaluation of new technologies. However, these "clinical trial-like" demonstrations, examinations, and evaluations are infrequent and limited in scope. Generally, they are not sufficient for making authoritative and reliable "extent of AMEDD use" determinations and distribution decisions.

Other than existing, elementary, and limited quality assurance measures – utilization review for example – no formal and systematic evaluation of the use of medical technologies and their outcomes is accomplished in the AMEDD.

Furthermore, seldom are justifications and results compared or audited. Often, contracting procedures, rather than a technology's performance characteristics (based on sound clinical trial data), serve to ensure that "requirements" are met. Frequently, medical maintenance personnel perform acceptance inspections that compare items to contract specifications. Contract specifications normally deal with technical data concerning reliability, maintainability, and durability. Of course, although necessary, this falls short of the rigorous technology assessment necessary to answer the question of whether or not an item meeting contract specifications will achieve desired clinical outcomes when used. Clinical utility is not, and has not been, a criterion for Government approval of a technology. [29] Assessing technologies for clinical utility can expose products and technologies of limited value. Such studies explicitly inform clinicians and administrators concerning the appropriate use of the technology. Such studies assist in making "extent-of-use" and system-wide distribution decisions, and more directly assure AMEDD beneficiaries of high-quality care.

AMEDD R&D and/or clinical investigators ("the professors") are the most capable and likely to perform or interpret clinical trials, which assess the outcomes of a technology; they are the most likely to communicate the results in professional circles and publications. They are, however, most often not even aware of the need for an assessment of clinical utility in support of fixed facility modernization nor are they asked to conduct one. Instead, fixed facility modernization and assessment are left to hospital practitioners who have the least time to devote to work requiring such precision. This seemingly backward practice is not consistent with the existence of a "poor medical information base," and it is not consistent with the need to ensure quality through the controlled use of technologies.

Because of the inconsistencies and the need to evaluate technologies on the basis of (1) individual and aggregate outcomes and (2) system-wide economics, rather than on the basis of unit price, we conclude that the AMEDD should strategically manage the introduction and diffusion of technologies in AMEDD's fixed facilities through the direction and coordination of technology assessment activities.

The Prospective Payment Commission (ProPAC) has undertaken a comparable, corporate-level endeavor for the Medicare system. ProPAC makes recommendations regarding reimbursement rates that should be used to pay participating hospitals for the adoption of "quality-enhancing, cost-increasing technologies for Medicare patients." These recommendations are included in the Scientific and Technological Advancement (S&TA) allowance. The S&TA represents the ProPAC's judgment about the financing required for these advances in the upcoming fiscal year. To arrive at an informed judgment on the appropriate level of this allowance, ProPAC sponsored a study by the Project HOPE Center for the Study of Health Affairs. Project HOPE developed estimates of the incremental effect on Medicare operating costs of rapidly diffusing major technologies in FY93. [30]

The technologies included in Project HOPE's estimate were required to meet four criteria. First, technologies had to have a significant effect on Medicare operating costs. Second, only technologies that were at least 5 percent diffused in the Medicare population were included. Third, the technologies could be no more than 75 percent diffused in the Medicare population. Fourth, each technology had to be considered safe and effective. These criteria, as well as the methodology employed, according to ProPAC, tend to understate the effect of cost-increasing technologies. Nevertheless, using these criteria and other analytical techniques, Project HOPE identified 18 cost-increasing, quality-enhancing technologies for inclusion in the study.

The study distinguished between existing cases and new cases. Only the costs associated with existing cases are included in the S&TA allowance. These costs are admissions that would have occurred even if a new technology were not available. The costs associated with new cases, or patients admitted solely because a new technology is available, are not included because they generate a full payment in the prospective payment system. Other costs associated with increases in case complexity from the use of new technologies are accounted for in the case-mix change component of the prospective payment update factor. The 18 technologies identified in the Project HOPE study are shown in Table 3-3.

The estimated incremental impact of these technologies on inpatient operating costs was estimated to be between $429 million and $635 million. The best estimate was $531.9 million. On the basis of the best estimate of incremental costs in FY93, Medicare inpatient operating payments would have to increase by about 0.9 percent to account for these costs. ProPAC found the technology-specific approach useful for deriving more informed estimates of the costs of scientific and technological advances. More informed estimates of costs contribute to better technology modernization decisions. Applying the 0.9 percent factor to a FY93 AMEDD

TABLE 3-3

ESTIMATED IMPACT OF COST-INCREASING TECHNOLOGIES FOR PROSPECTIVE PAYMENT SYSTEM HOSPITALS - FY93

Technology	Cost ($ millions)
Monoclonal antibodies	202.5
Percutaneous transluminal coronary angioplasty	72.6
Computers (advances)	66.8
Automatic implantable cardioverter defibrillators	53.5
- lead replacements	6.4
Single photon emission computed tomography	29.4
Thrombolytic therapy	21.5
Low osmolar/nonionic contrast agents	18.4
Ultrasound (advances)	14.6
Electrophysiologic studies	11.1
Positron emission tomography	10.7
Percutaneous transluminal angioplasty	7.1
Pacemakers (advances)	5.1
Computed tomography (advances)	3.8
Implantable infusion pumps	3.6
Atherectomy	1.9
Magnetic resonance imaging	1.5
Stereotactic radiosurgery	0.8
Cytomegalovirus immune globulin	0.6
Total	531.9

Source: Prospective Payment Assessment Commission.

operations and maintenance (O&M) budget of $2 billion suggests that the AMEDD would be underfunded by at least $18 million if the AMEDD adopted the listed technologies in the manner envisioned by the Project HOPE study. By accounting for only "existing cases," the study methodology probably substantially understates the impact of the listed technologies on hospitals or health care delivery systems such as the AMEDD that are not reimbursed by the Prospective Payment System. Of course, capital costs were not directly included.

The next section describes a corporate-level AMEDD capability and operational concept for strategically managing the introduction and diffusion of technologies in AMEDD's fixed facilities through the direction and coordination of technology assessment activities.

USING TECHNOLOGY ASSESSMENT TO MODERNIZE THE HEALTH CARE DELIVERY SYSTEM

As previously stated, the AMEDD obtains new materiel technologies through one of four programs. The first is CBRS and its associated weapon-system-like acquisition process; the second is the MEDCASE program; the third is CEEP. The fourth program is the supply system. These programs are based largely on existing Army materiel management and financial programming and accounting policies.

Army Regulation (AR) 40-61 says that the AMEDD's intention is to comply with Army materiel management policy. [31] Therefore, in order to understand medical equipping programs, it is necessary to appreciate Army equipping programs.

The Army's acquisition and logistics regulations (e.g., AR 70-1, *Systems Acquisition Policy and Procedures*; AR 710-1, *Centralized Inventory Management of the Army Supply System*; AR 735-5, *Policies and Procedures for Property Accountability*; and AR 710-2, *Supply Policy Below the Wholesale Level*) are based upon a series of DoD Directives (DoDDs) and Instructions (DoDIs) related to various facets of logistics and acquisition management and property accounting. Among these documents are DoDI 7500.1, *Report on Real and Personal Property*, and DoDI 4140.18, *Inventory Management Reports of Materiel Assets*. These DoD documents have, in turn, been promulgated to meet the higher level requirements of Section 2701 of Title 10 United States Code, National Security Act of 1947 (as amended). [32]

The Act requires the Secretary of Defense to maintain records of fixed property, installations, major equipment items, and stored supplies of the Military Departments and to report once each year to the Congress and the President on property records retained under this section of the act. DoDI 7500.1 is intended to satisfy this reporting requirement providing guidance to the Components for reporting real and personal property inventory totals. The real property (i.e., real estate) owned and reported by the Components is the dollar value of land and construction in progress. The personal property owned and reported by the

Components is divided into five categories: (1) weapons and other military equipment in use; (2) equipment, materiel, and supplies in stock; (3) plant equipment; (4) industrial fund inventories; and (5) excess, surplus, and foreign excess property inventories.

The DoDI 4140.18 requires the Components to report annually (as of 30 September) all principal and secondary items in use and in stock. Principal and secondary items are defined as follows:

> *Principal Items*: End items and replacement assemblies of such importance that management techniques require centralized individual item management throughout the supply system to include depot level, base level, and items in the hands of using units. Specifically, these include items of which, in the judgment of the Military Services, there is a need for central inventory control, including centralized computation of requirements, central direction of distribution, and central knowledge and control of all assets owned by the Military Services. Principal items normally will be selected on the basis of their essentiality for combat or training, high monetary value, difficulty of procurement or production, or criticality of basic materials or components. Tanks are probably the most often cited example of an Army principal item.
>
> *Secondary Items*: End items and consumable and reparable items other than principal items. Examples of secondary items include transmissions, repair parts, clothing, and medical equipment and supplies.

Since FY87, *Inventory Management Reports of Materiel Assets* regarding secondary and stock funded items have been submitted by the Army's Deputy Chief of Staff for Logistics (DCSLOG) using stratification data DCSLOG receives from the Army Materiel Command quarterly. The data for principal items is extracted from the Total Army Equipment Distribution Program (TAEDP). To the extent that the dollar values of medical items are included in these data bases, they are included in the inventory reports. The asset value information reported has essentially no bearing on the likely acquisition of new or modernized medical technologies. However, the reporting requirement and process require the classification of items into real property and personal property. Personal property has several subclassifications that are interpreted to consist of principal and secondary items.

The classifications and subclassifications of medical items have much to do with the methods of modernization. Classifications determine the special procedures to be followed when justifying, and obtaining the resources necessary for, modernization. The most important classification distinction is made between investment and expense.[2] The investment-versus-expense cost decision logic is depicted in Figure 3-4, taken from AR 710-1.[33] Figure 3-4 also explains item coding procedures.

As shown in Figure 3-4, major end items are classified as investments to be funded with the procurement appropriation (PA) for principal items. Though not reflected in the figure, the expenditure of research, development, test and evaluation (RDT&E) funding usually precedes the investment of PA funds for weapon systems. [34] The purpose of RDT&E expenditures is to ensure, corporately, a wise and productive modernization investment by thoroughly examining technologies and testing candidates for acquisition. For this reason, RDT&E and investment funding are ordinarily linked. However, there are no major medical, principal, weapon system, or class-seven items; there is no formal RDT&E effort associated with fixed medical facility modernization.

Figure 3-4 also shows medical end items that the U.S. Army Medical Materiel Agency (USAMMA), in the process of cataloging medical items, assigns Reportable Item Control Code 2 (RICC-2). The RICC-2 is assigned for readiness reporting and asset visibility purposes. The RICC-2 items are "standard" items that equip field medical units. Items associated with major medical equipment sets, such as x-ray machines and operating room tables, are examples of RICC-2 items. Requirements for RICC-2 items are often developed using the CBRS.

Medical sets, kits, and outfits themselves, however, deviate from Figure 3-4. They frequently are assigned RICC-2. They frequently cost more than $15,000, but they are not purchased (as either initial issues or as replacements) with investment funds. Instead, O&M and stock funds are used. The reason for this deviation from policy is, apparently, the belief that O&M funds are more readily available than investment funds. The consumable and commercial nature of the components of sets, kits, and outfits (SKO) is also said to lend weight to funding sets using O&M funds rather than procurement funds.

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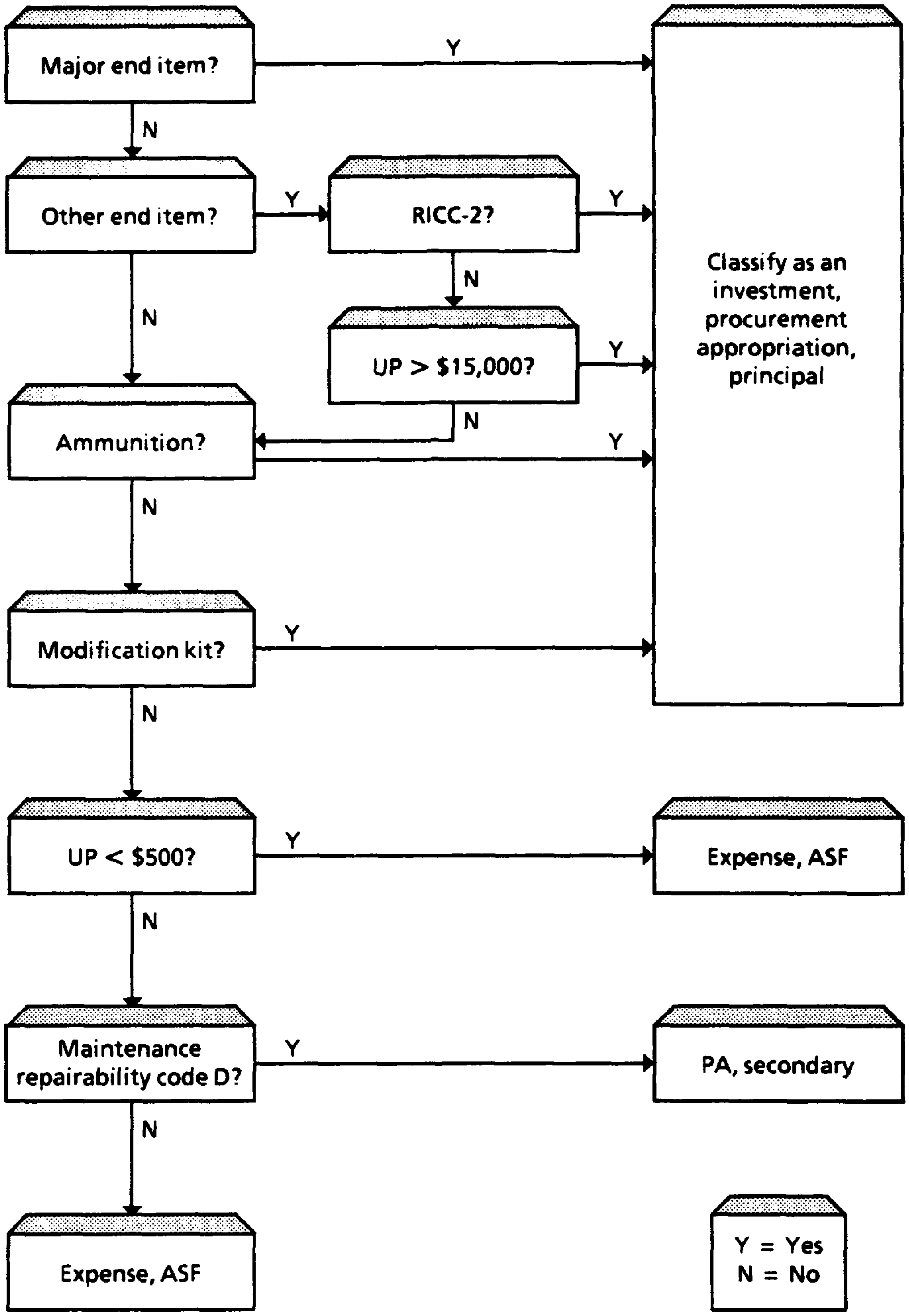
[2]Military construction is not explicitly considered in this discussion of the classification of investments and expenses. The omission is not accidental. For the sake of brevity, we chose not to include it. New construction, however, is an investment of large, lasting, and strategic impact. Army technology modernization literature, on the other hand, is largely silent with respect to the modernization of facilities. Technology modernization is seen mainly as a logistical or acquisition function. The "separation" of specialties for modernization management purposes supports our contention that modernization management poses a dilemma.



Source: AR 710-1, *Centralized Inventory Management of the Army Supply System*, 1 February 1988.

Note: UP = unit price; ASF = Army Stock Fund; RICC-2 = Reportable Item Control Code 2; PA = procurement appropriation.

FIG. 3-4. INVESTMENT VERSUS EXPENSE COST DECISION DIAGRAM

All Army units must periodically report RICC-2 items on hand. The item reports are recorded in the files of the Continuing Balance System – Expanded (CBS-X) and the TAEDP. The USAMMA uses CBS-X and TAEDP files to determine requirements for RICC-2 items and to initiate requisitioning or procurement and distribution action. This provides USAMMA the opportunity to directly influence unit readiness. They use funding that has been specifically programmed and earmarked for this purpose. A direct link between funding requirements and unit readiness (if not medical or clinical readiness) is provided.

Fixed facility x-ray systems, operating room tables, and other investment items are normally "nonstandard" items; they are not typically assigned RICC-2. USAMMA does not usually determine distribution requirements for nonstandard, fixed facility medical items. Instead, organizations that operate fixed facilities are given authority to order replacement or modernizing investment items. They can make investments until their funding authority is exhausted. Their investments are subject to a review for propriety at the facility, Medical Command, and OTSG levels. The level of review depends upon unit cost. The criteria used to determine propriety are not documented. The determination of propriety is normally made by specialty consultants at each succeeding organizational level. The link between propriety approval, funding, and organizational performance is not strong.

Nevertheless, on the basis of requirements that have been "propriety approved," USAMMA and the Logistics Division, OTSG, collaborate in programming for investment funds. They program funds for RICC-2 investment items. They also program investment funds for items with a unit price that is greater than $15,000, including items for clinical investigation services. These, of course, are MEDCASE items. (Procurement funds are also programmed for items that have unit prices of less than $15,000. These items are needed to equip new facilities; they too are MEDCASE items.)

The investment funds earmarked for RICC-2 items are held by USAMMA. USAMMA cites these funds on requisitions that result in shipment of RICC-2 items to medical units that need them. Frequently, the receipt of RICC-2 item shortages directly raises a unit's readiness rating as reported under the provisions of AR 220-1, *Unit Status Reporting*. The investment funds earmarked for MEDCASE items are administratively allocated by OTSG and USAMMA to the Medical Commands. The Medical Commands, in turn, advise USAMMA about how to distribute funding to their subordinate facilities. Each organizational element reserves an amount of funding authority for special projects, contingencies, and obligation adjustments. The rapid expenditure of available funds is "evidence" that "needs are great" and that funding programs are being "executed." Fixed facilities often work to establish large backlogs of unfunded, propriety-approved requirements. Such a backlog, they feel, justifies greater allocations of funding authority. Higher levels of funding authority, it is believed, provide increased management flexibility and a higher quality of care for a greater number of patients. Once funds are available, any approved requirement can be funded and purchased. The linkage to performance is not validated, nor is the most productive investment necessarily made.

Figure 3-4 also shows that ammunition, class V, and modification kits that upgrade the capability of equipment already in the Army inventory are funded as investments using PA, principal. It also shows that selected reparable items such as engines and transmissions should be acquired using investment appropriations earmarked as PA, secondary. Finally, Figure 3-4 indicates that items not qualifying for procurement funding should be classified as an expense. These items are purchased from Stock Fund-owned inventories or commercial sources using O&M funds. Medical CEEP items and medical supplies are such items. There is virtually no "corporate level" oversight of expenditures for these items except in dollar terms.

The medical investment threshold has varied since the early 1980s when it was $3,000. In 1986, the AMEDD changed its investment threshold to $10,000 when the Army changed its threshold figure to $25,000 (used to define a small purchase). In 1989, the medical investment threshold was changed again, this time to $15,000. The small purchase threshold has changed in order to reflect changing price levels caused by inflation. An additional reason for the changes is that the Army and the AMEDD have used the threshold as a programming, management control, and workload "tuning knob." A higher threshold means more items must be approved for purchase and funded at lower organizational levels. Conversely, a lower threshold moves greater numbers of requirements to higher organizational levels for approval. The use of the investment threshold as a management control can readily be seen. The current MEDCASE threshold of $15,000 is justified because it permits DA-level control for about 70 percent of all MEDCASE procurement funds, yet it generates an approval paperwork workload that is "manageable."

The decision diagram in Figure 3-4 explains the rationale for funding both field and fixed facility materiel requirements using various appropriations with or without an associated expenditure of RDT&E funding and with or without a formal cataloging and/or standardization effort. The diagram does not, however, establish the link between funding and performance. It assumes that expenditures for items that are classified as investments or expenses are justified.

Expenditures, whether investments or expenses, should be justified on the basis of their contribution to mission performance. The contribution to mission performance is stated in terms of the services provided to beneficiaries and in terms of the operation of the delivery system. The contribution made to mission performance should be the evaluation criterion used to justify new and replacement technologies for both field and fixed facility applications. In other words, technologies should be justified on the basis of costs and consequences, clinical and otherwise. The vital role technology assessments play in justifying expenditures is apparent.

Again, Figure 3-4 only explains item coding procedures. It explains how item classifications and unit prices govern fixed facility modernization procedures. It does not explain how clinical outcomes and total system life-cycle capital and operating costs influence modernization. Modernization is, instead, seen in terms of narrowly defined and fragmented financial programs, budgets, and procedures whose definitions have little to do with clinical outcomes, health care cost control, and strategic goals. Access to fixed facility modernization funding programs is based solely upon justifications and approvals that are often subjective and *pro forma* in nature, single-facility oriented, and held to very little rigorous, objective assessment and oversight. The justifications written and the approvals provided would seldom withstand the scrutiny of objective technology assessment. They would frequently fail to survive the approval tests provided by highly competitive, cost-conscious for-profit and not-for-profit health care delivery systems. We believe the linkage between the effects of technologies and system performance needs to be strengthened.

Despite operational weaknesses, the classification of the proposed purchases as either investments or expenses is also practiced by civilian health care delivery systems. In civilian systems, as in the AMEDD, the classification of purchases as investment or expense establishes the budgeting process that will be used to obtain approval and funding. However, the similarity stops at this point. The AMEDD accounts for its equipment by using property book procedures prescribed by AR 735-5, *Policies and Procedures for Property Accountability*, and the Army Medical Department Property Accounting System. Property procedures result in continuous responsibility for Army property and the establishment of a detailed audit trail. Maintenance expenditures are captured and equipment replacement planning is accommodated. However, neither the Army nor the AMEDD makes a serious attempt to match capital expenditures with the benefits those expenditures were originally intended to generate. Often, the important factor is that the property is not lost, damaged, or destroyed.

Civilian systems, on the other hand, generally establish less detailed property records. Instead they record new depreciable assets for cost accounting, financial management, and income tax reporting purposes. The AMEDD's classification of purchases as an investment or expense is rather arbitrary and, as the discussion above suggests, is not directly and objectively related to improved mission performance. A "return on assets" is not measured. Nor is the "consumption," via depreciation, of the physical plant measured. On the other hand, civilian classification decisions are watched closely by state and Federal tax authorities, financial analysts, lending institutions, and reimbursement regulators such as the Health Care Financing Administration. Expenditures improperly classified as expenses depress income and reduce tax liabilities. Expenditures improperly classified as investments can lead to understated expenses and overstated income for the current accounting period making the institution's financial performance appear more attractive than it is. [22]

The cost accounting, financial management, and income tax reporting functions (as well as technology assessment in many large systems) differentiate civilian and AMEDD peacetime, fixed facility health care delivery systems. These differences have a profound effect on medical technology modernization management. The civilian modernization process is far more focused and disciplined than the military process. Increased discipline results from a much more rigid matching of the expenditures for new technologies with the benefits realized from those expenditures (i.e., revenues but not necessarily outcomes). Thus, the financial operations of a civilian health care facility are tied much more directly to the population it serves. Beneficiaries served and their third-party payers are the sources of that revenue. The Defense Business Operating Fund (DBOF) is intended to more clearly establish such links within DoD. Consideration is being given to bringing medical services under the DBOF operating concept. [35]

From the above discussions, we see that the AMEDD medical technology modernization process is a materiel strategy that is defined by its fragmented programming, research, and accounting processes rather than by its strategic long-range approach to the improved delivery of health care services. How, then, might the AMEDD achieve a tighter fit between the population it serves and its technology expenditures? How might AMEDD overcome the modernization management dilemma presented by fragmented technologies, split modernization processes, and fragmented programming and budgeting systems? Because it requires the detailed consideration of all costs and benefits in both tactical and strategic contexts, we believe that technology assessment holds the answer. Better integration of high-quality technology assessment into AMEDD modernization processes can more tightly link beneficiary care and delivery system performance. It is the answer that nationalized health care delivery systems have chosen.

In the past, the AMEDD established its own investment expense criteria in coordination with the Army staff. Whether or not that is done again is not important. The financial programming and accounting systems must be recognized for what they are. They do not plan and they do not modernize. They support those processes and they record data. Real value-added modernization occurs when technologies are monitored and assessed, and their deployment is strategically planned. The CBRS demands this. Fixed facility modernization management does not. This, of course, returns us to technology assessment as a vehicle for strategic planning, quality management, and cost control.

Technology assessment should be used to support virtually all aspects of modernization management. The extent of use a technology enjoys within the AMEDD should be controlled. The purpose of the control is to help ensure the quality of delivered services and to help contain acquisition and operating costs. The procedures envisioned for controlling the entry and diffusion of technologies are not much different than the procedures used today but adjustments are required. We explain them in Chapter 5.

CHAPTER 4

CONCLUSIONS

The AMEDD's peacetime health care delivery system has evolved by accretion. Modest steps have been taken to solve particular problems rather than as a result of a grand, preconceived vision. It "has operated in a reactive mode." As medical science has evolved, so has Army health care. The AMEDD has not been challenged to strategically plan because of its less-than-full participation in CBRS. Strategic plans existed prior to the initiation of the CCP and the GTC program, but their focus was on readiness for wartime roles and missions. The day-to-day delivery of health care through a network of Government and civilian fixed medical treatment facilities is not strategically planned. Much about the beneficiary population requiring service is unknown. Clinical policies are loosely and unevenly managed. The acquisition and distribution of medical facilities and technologies is a function of fragmented or decentralized decision-making.

During the course of our study, we were unable to readily identify why or how the AMEDD health care delivery system evolved as it has. Interviews tended to reinforce the idea that the system has grown by gradual addition and fusion in response to both external and internal pressures. Furthermore, the changes necessary to modernize the system to control costs, treat more beneficiaries, and improve the quality of care were not routinely identified. Indeed, the costs of specific health services were not accurately known. The relationship between the demand for patient care and the size and configuration of the health care plant was not clear. Alternative health care delivery strategies were not systematically explored.

Instead, some combination of military planning and stationing, military health care and personnel management policy, prior investment (or lack of it), history and tradition, physician preference, politics, and the relative attractiveness of various geographic areas merged to create today's health care delivery system. The prevailing state of this delivery system served as a lightning rod for concern and criticism. This concern led to the GTC program – the AMEDD's implementation of DoD's CCP initiative.

Against the backdrop of delivery system planning weaknesses and managed care initiatives, we explored medical technology. We found it exceptionally complex, diverse, and difficult to manage. It includes the drugs, devices, and interventions used in medical care, and the organizational and supportive systems within which care is delivered.

We learned that, for a given complaint, many diagnostic and treatment strategies were often available to physicians. The varied strategies often differed widely in cost and effectiveness. We also learned that the decision to use a medical technology was often based on intermediate-level results. That is, the use of the technology would produce a small but measurable effect that was assumed, in the longer term, to yield the desired clinical outcome. In many cases, however, no one had taken the time to establish whether such a use was valid. The FDA required only that the technology be "safe and effective." They defined effectiveness in terms of the intermediate result. The likely outcome or long-term effect of using the technology was not known with precision.

As a consequence, today, the medical community, including the military medical community, is being charged by its own members and by third-party payers with delivering care that varies widely by geographic location, and by the patient's sex, income level, age, and race. Delivered care has even been alleged to be of poor quality and excessively costly. We found only limited controls within the AMEDD fixed facility health care delivery system that would overcome these shortcomings. We believe that the delivery of cost effective quality services depends on information about the cost and effectiveness of technologies used in the AMEDD fixed facility health care delivery system. Without such information, it is difficult to make rational, systematic modernization management decisions and to control costs and quality. However, the information needed is not readily available. If available at all, it is dispersed, difficult to locate, and even more difficult to use with any degree of confidence. Hard work is required to dig it out. The AMEDD's information requirements should be revised to address its assessment needs.

Increased effort to assess medical technologies is needed. The ideal information base, however, a broad and comprehensive base of outcomes research and randomized controlled trials, is not readily available and is not likely to be available for some time. But interim actions can be taken. The AMEDD's scientific community, consisting of researchers and clinical investigators, in collaboration with "expert" strategic planners, should be required to reliably provide "informed" interpretations of available data. Members of the scientific community should also fill information gaps through reasonably rigorous quick-reaction testing. They should evaluate a broad range of technologies as far in advance of the receipt of modernization proposals as possible. The purpose of the evaluations would be to facilitate resource allocation decisions and advance, rather than retard, health care delivery system performance.

We believe that the AMEDD must take a series of steps to accomplish enhanced technology modernization management and we discuss these steps along with our recommendations in Chapter 5.

CHAPTER 5

RECOMMENDATIONS

This chapter is divided into two sections. The first section summarizes our recommendations. The second section discusses implementing the recommendations.

SUMMARY OF RECOMMENDATIONS

We recommend that

- For planning purposes, the AMEDD define medical technologies broadly and strategically rather than in accordance with funding program criteria. Specifically, medical technologies should be defined as the drugs, devices, and procedures used in medical care, along with the organizational and supportive systems supporting delivery of such care. A consistent, strategic definition enables a single unified approach to technology modernization strategic planning.

- The AMEDD revise AR 40-60, AR 40-61, AR 40-3, *Medical, Dental, and Veterinary Care*, SB 8-75-MEDCASE, and other related documents to reflect the strategic definition of medical technology. Policies flowing from the definition to be incorporated in documents (and regulations, where appropriate) include the following:

  - Technologies proposed for adoption should be consistent with the AMEDD strategic plan for the delivery of health services.

  - Technologies should be ranked on the basis of their relative contribution to the performance of AMEDD's health care delivery system.

  - Technologies that best serve beneficiaries and facilitate operation of the health care system should receive funding priority.

  - Modernization proposals[1] for individual fixed facilities should be of secondary importance to proposals for strategic technology modernization and distribution.

  - Plans to change medical service delivery capabilities at a single facility or a series of facilities should be considered a modernization proposal. Capability changes include increasing the volume of services; changing

[1]The purpose of modernization proposals is to improve clinical practice and patient outcomes through more appropriate and effective health care services.

the nature of a service via new or different technologies, facilities, or both; and changing the mode of service delivery (e.g., direct care versus CHAMPUS).

- Modernization proposals should be required to discuss marginal costs and benefits, total life-cycle costs and benefits, consistency with the strategic plan, system-wide distribution strategies, and any requirements for assessments needed for decision-making purposes.

- Modernization proposals should require commander approval and specialty consultant product line manager approval.

- Modernization proposals should be submitted by specialty consultants, providers, researchers, and clinical investigators.

- The AMEDD manage services as product lines.

- The AMEDD designate specialty consultants to act as service product line managers for the Surgeon General. They will

  - Strategically plan and recommend the deployment of their service product line to improve the organization and delivery of health care services.

  - Review modernization proposals and direct assessment, recommending approval or disapproval.

- The AMEDD establish a Strategic Technology and Clinical Policy Council (ST/CPC). The ST/CPC would be made up of the specialty consultant service product line managers and other modernization planners. The ST/CPC should create a new *Strategic Technology Plan.* This plan would be analogous to the current *CBRS Mission Area Materiel Plan (MAMP).*

- The AMEDD support the specialty consultants/service product line managers by providing them with essential authorities and access to assessment resources. Specifically,

  - Specialty consultants should retain the ability to make recommendations with respect to personnel assignments within their specialty.

  - In full coordination with the appropriate commanders, supervisors, and raters, speciality consultants should be empowered to identify functional managers as part of their team or teams. Teams would assist the consultants by,

    - Monitoring emerging technologies that may have an impact on the medical specialty and the provision of services.

- Formulating recommendations regarding the employment and deployment of technologies.
- Making mission, investment, and programming proposals.
- Reviewing modernization proposal packages received from AMEDD field organizations and recommending approval or disapproval of those proposals.
- Conducting and reporting independent post-purchase evaluations.
- Evaluating the cost and quality of the service product lines.
- Reviewing functional requirements for automated systems that capture data needed for outcomes research, thorough technology assessment, and strategic planning.

- The AMEDD evaluate the service product line management approach to technology modernization through a comprehensive, biannual comparison of military health care with the state-of-the-art health care delivery system used in the private sector. The comparison would result in the creation of a medical technology modernization plan. The responsibility for developing such a plan should be assigned to the ST/CPC. The results of this evaluation should be briefed to the AMEDD leadership to obtain their guidance and direction.
- The AMEDD assign technology modernization a management priority equal to the priority assigned to the implementation of the GTC program.
- The AMEDD designate a Deputy Assistant Surgeon General for Research and Technology to oversee the research and materiel aspects of technology modernization management. (We made a similar recommendation in our earlier report entitled *Streamlining the Medical Materiel Acquisition Process: Central Direction, Better Requirements.)* Nonmateriel technologies (i.e., personnel and training) would be overseen by a Deputy Assistant Surgeon General for Health Care Operations. Specialty consultants should form the AMEDD's strategic planning and integration nucleus.

  Establishment of a Deputy Assistant Surgeon General for Research and Technology enables streamlining peacetime and wartime medical technology strategic planning, assessment, clinical policy formulation, and materiel acquisition processes. Creating such an assignment gives technology modernization management visibility equal to the priority assigned to the implementation of the GTC program.

IMPLEMENTING THE RECOMMENDATIONS

Increased control over technology use can be achieved through six key straightforward steps. These steps will not lengthen the time needed to acquire new technologies. In fact, applied with dedication and skill, following the steps will contribute to the reduction of acquisition lead time through better planning and a sharper focus on demand-driven requirements.

Step 1: View Technology Impacts Broadly

The first step is to create an environment where medical technologies are viewed broadly and strategically. This can be done by revising the medical technology modernization management policy contained in several documents of which the AMEDD is the proponent. The documents are AR 40-60, AR 40-61, SB 8-75-MEDCASE and AR 40-3. The thrust of the revised policies would be to link modernization to changes in medical capabilities – in terms of the volume of patients, the types of service, or the delivery of the service.

Changing capabilities could require revising the method of delivery of an existing service from, for example, direct care to CHAMPUS or vice versa. A new service or a revised clinical policy or guideline enabled by a relatively inexpensive monoclonal antibody pharmaceutical would be described in a modernization proposal – just as a plan for establishing a new MRI capability is. Modernization proposals would be made by virtually anyone. Primary proposers, however, would be specialty consultants, researchers, clinical investigators, and front-line patient care providers. Modernization proposals would require consideration of the strategic viewpoint. The proposer would be required to recommend a diffusion strategy and the system-wide deployment of the technology proposed for adoption. Proposals would be submitted through command channels for approval much as they are today. Financial program thresholds and divisions would not constrain initial programming. However, strategic issues, operational and financial risks, and total system life-cycle costs would influence approval levels. Unit price would no longer split processing into a number of different procedures. That could occur after approval. To facilitate the review of modernization proposals, less emphasis would be placed on proposals submitted for routine replacement of equipment. That decision would be decentralized to a greater extent.

All technologies might be used in all facilities and locations, but the question would be asked whether this would be correct to do given existing and likely constraints. Technology modernization is not, and should not be, a function of facility requests alone. It should result from planning *and* the facility's requests. Today, the modernization questions are the following: Assuming a specific facility wants a technology, what must it do to get the technology and use it? What funding program should it use? What forms should it complete? How can it get the technology request approved? The answers to the more strategically important questions of whether or not system performance will be enhanced and whether patient benefits justify the cost are assumed because, historically, hospitals have been the focus of planning rather than the health care delivery system. However, making such assumptions leads to a subjective modernization process.

Step 2: Assign Responsibilities for Technologies

The second step is to assign responsibility for identifying and monitoring technologies with effects on potential delivery systems. Their development and use within the AMEDD delivery system would be strategically planned; clinical policy would be formulated to support anticipated propriety approval decisions. Individuals most capable of discerning and forecasting the impact of technologies on the health care system and on individual patients should be assigned responsibilities for technology planning.

In cases where high risk and expensive technologies seem promising, a clinical policy advisory could be published indicating AMEDD's position on that technology. The advisory might indicate the concerns and opportunities the AMEDD sees in the technology and the person or office monitoring/managing further developments. A technology in the innovation stage may not ordinarily qualify for use in a delivery system at all. However, due to its potential for widespread application or ability to solve MHSS access, quality, or cost issues, the AMEDD may be willing to accept greater risk. The technology may be worth following as either an intramural or extramural project by the AMEDD R&D or clinical investigation communities. Costs, benefits, and risks would be developed on the basis of clinical trials and economic evaluations. For example, laparoscopic cholesystectomy may have qualified for such monitoring several years ago. The gamma knife, the PET scanner, implantable defibrillators, and some very expensive monoclonal antibody-based pharmaceuticals (such as centoxin) and the use of non-ionic contrast media may qualify for such treatment now. Assembling clinical outcome and economic evaluation information for these technologies at this time will result in more informed, better clinical policies and modernization decisions in the future. Waiting until a practitioner asks to use the technology probably will not result in sound modernization decisions. The principal source of reports that generate technology advisories would likely be reputable, peer-reviewed scientific and medical journals.

On the basis of surveillance information, technology "extent-of-use" determinations could be planned by speciality consultants. Such determinations would serve as a tentative fixed facility authorization or distribution strategy. The distribution strategy should be formally coordinated with the graduate medical education (GME) programs established at AMEDD facilities as well as the AMEDD training and education programs that provide the other professional and technical personnel. Like technologies, the distribution of GME programs would be linked to the strategic needs of the AMEDD. [35] Like technologies, GME programs would be evaluated in terms of their impact on beneficiaries and in terms of the ability of the delivery system to accomplish its strategic goals in both peacetime and wartime. Like technologies, GME would be monitored by specialty consultants. GME programs produce and diffuse non-materiel-based technologies. Periodic audits and updates of technologies and GME programs should result in adjustments to the extent of use determinations and distribution schemes. The purpose of these deliberations would be to control the diffusion of the technology, thereby reducing risks and costs while enhancing quality. Clinical investigation activities that support GME could be employed to conduct materiel-based technology assessments

The responsibility for directing and coordinating such activities should be assigned to product line managers. Consultants (those currently approving MEDCASE requirements for medical propriety at the OTSG level) should be product line managers. Consultants' specific duties should consist of publishing technology advisories, placing and defending specific technologies on an AMEDD "extent-of-use" (or authorization) curve, and making recommendations regarding the assignment and continuation of clinical missions. Consultants would review modernization proposals affecting their specialty, direct the evaluation of those proposals, and subsequently make approval or disapproval recommendations. They would also serve as resources for making decisions such as when to offer services via direct care or CHAMPUS.

Step 3: Provide Technical Support to Product Line Managers

The third step is to provide product line managers with the technical support they need to accomplish their modernization duties. Specialty consultants/product line managers should be able to initiate taskings of elements within the R&D and clinical investigation communities to assemble clinical trial and economic evaluation data for subsequent use in strategic planning and modernization decision-making. Full use would be made of specialist sponsors who nominate, and are interested in promoting the adoption of, a technology within the AMEDD. [36] This effort would complement the process used to perform market surveillance, market surveys, and market investigations and would include tapping the academic and commercial sources of technology assessment information. The difference is that increased effort would be focused on clinical trial and outcomes data (proprietary or otherwise). Requirements (e.g., documents) would be used to initiate taskings. Providers considering initiating requirements for specific technologies should be encouraged to use data assembled on the technology for informational purposes and to refine their modernization proposals. Ultimately, approval of proposals would be contingent upon technology assessment and planning considerations. Once fully refined, an interactive technology assessment data base would be employed, reflecting advisories, "extent-of-use" determinations, compiled reports, clinical trials, and bibliographies.

As determined by the monitor, manager, or sponsor of the technology, on the basis of revised clinical and/or cost data, positioning on the "extent-of-use" curve could be reevaluated and acquisition decisions could be coordinated. By analogy, the MRDC Medical Systems Review Committee does the same thing for products within the AMEDD "tech base" that are proposed for transition to development. A similar mechanism is used for managing the transition of technologies from early trials through diffusion. A transition committee is presently prescribed for medical products moving from the developmental stages of the life-cycle system management model to the production and deployment stages. Ordinarily, this committee consists of representatives of the U.S. Army Medical Materiel Development Activity (USAMMDA) and the U.S. Army Medical Materiel Agency (USAMMA). [37] Once developed, clinical trial data and economic evaluations used by the technology manager, monitor, or sponsor, could be updated either intramurally or extramurally as circumstances dictated. Naturally, maximum use should be made of research efforts already completed or underway within the DoD, AMEDD, academia, or industry – provided they are reliable and of sufficient quality. The AMEDD would initiate its own clinical trials and testing only when justified in doing so.

Currently, however, neither the MRDC nor the clinical investigation communities play key roles in the modernization of AMEDD fixed facilities. The reasoning for this situation is that technology assessment duplicates research that has (or may have) already been done in the marketplace. However, this rationale neglects the fact that the deployment and employment of a technology is specific to a health care delivery system. There is no generic and uniform method for using technologies. Technologies affect the services offered and the capacities of delivery systems. This is increasingly true in delivery systems implementing coordinated care. It will be increasingly true as technologies shift the focus of health care from hospitals to specialized facilities such as ambulatory surgery and imaging centers. One assessment does not fit all. The discussion of varying viewpoints concerning costs and benefits indicates that assessments must be tailored to the delivery system. Technologies must "fit" the service delivery system. Failure to make a fit results in unnecessary costs and may degrade service quality. Hospitals are not the technology repositories they once were. Allocating resources for technologies using algorithms such as "one per hospital" fails to recognize the quality assurance and cost control issues implicit in technology modernization requirements.

We remarked above that "neither the MRDC nor the clinical investigation communities play key roles in the modernization of fixed facilities." In the minds of those communities abstinence is entirely justifiable.

The MRDC states its reasons on page 1-1 of the *Medical Technology Base Master Plan* where the Army Medical Technology Base is addressed. "The U.S. Army Medical Research and Development Command (USAMRDC) has a challenging and critical mission; to discover, design, and develop military medical countermeasures against threats to health of military personnel." The command conducts medical research and development in the Army medical laboratories and institutes and in non-Government laboratories through contracts and cooperative agreements with universities and industry. The research programs address unique military medical problems in order to preserve the health and safety of soldiers. Approximately 3,000 military and civilian personnel are assigned to the headquarters and 11 subordinate units. Officers, enlisted soldiers, and civilians provide a wide variety of medical, scientific, and technical expertise. Approximately 85 percent of assigned officers, 5 percent of enlisted soldiers, and 29 percent of civilian employees have graduate degrees.

Attempts to suggest alternative employment of the substantial resource represented by the command will likely meet stiff resistance – resistance reflecting an unwillingness to open a dialogue on participation in modernizing the peacetime health care delivery system. Even though the focus of MRDC is clearly not on the modernization of fixed facilities, that focus could be changed to provide technical support to the product line managers.

As for clinical investigations, physicians, dentists, and other health care providers participate in clinical investigation activities to further knowledge in their areas of specialization. Army medical centers have clinical investigation activities as part of their mission to support their GME programs. Part of the residency and fellowship requirements is a clinical investigation component.

The historic rationale for GME has been its role as a tool to enhance recruitment and retention of physicians. Recently, the role of GME in DoD's CCP, and specifically its Specialized Treatment Facilities initiative, has been evaluated by the Assistant Secretary of Defense (HA) staff. Based upon this evaluation, the benefits of GME are said to include the following:

- Attraction and retention of creative, high-quality professionals
- The critical evaluation of current clinical practices
- Dissemination of quality throughout MHSS as residents and staff move to other medical facilities
- Facilitation of the dissemination of higher quality, cost effective diagnostic and therapeutic approaches and technologies through patient referrals
- Renewal and upgrade of skills of other providers as they rotate through teaching centers.

GME is not the only generator of clinical investigation studies. Providers in any medical treatment facility can submit a protocol or study plan that states how a proposed clinical investigation project is to be carried out. Once the protocol is approved at the local level, it is reviewed by the Health Care Studies and Clinical Investigation Activity (HCSCIA), a field operating agency of the Health Services

Command (HSC), before it is approved and funded. Each month about 60 to 70 protocols are received by HCSCIA. They are looked at in terms of legal requirements – meeting Federal, DoD, and HSC regulations – as well as ensuring the protection of human participants. About 2,000 clinical investigation studies are currently active.

The research studies done by HSC and MRDC are often confused. "HSC is primarily looking at clinical investigations that will lead to better patient care. MRDC, in contrast, performs military relevant research where a project to be researched is decided upon by the needs of the Army." [3] In our opinion, the "health and safety of the soldier" and "better patient care" are simply two aspects of the same broad health care mission. Better patient care *is* a need of the Army. Seeing to the health and safety of soldiers is better patient care. The science underlying each aspect is common. Investments and modernization proposals in one aspect must be integrated and prioritized with investment and modernization proposals in the other aspect. To do less denies the overall health care mission the most productive use of available resources. The conduct of technology assessment for the purposes of fixed facility modernization management need only be integrated and prioritized in research and clinical investigation approval and funding mechanisms in order for the AMEDD to derive maximum benefit from its scientific and clinical experts.

The integration will, however, encounter organizational resistance to change that will have to be overcome. Similar issues are faced in many organizations and, increasingly, the competition for resources compels change. Deciding what R&D to undertake and at what level of resources and priority is one of the most complex and critical decisions top management faces today. In today's environment, strategic R&D planning is too important to be left to the researchers alone. One of the most decisive factors in the overall success of R&D is the selection of strategically worthwhile R&D goals. Today's changing military and medical environments demand the selection of responsive, accurate technology assessment as a strategic coordinated care and R&D goal. The specialty consultants/product line managers should be supported by the MRDC and clinical investigation communities in their endeavor to identify, assess, and appropriately distribute medical technologies for the purposes of providing the health care benefit in both peacetime and wartime.

Step 4: Evaluate System Technological Competitiveness

The fourth step is to provide a mechanism for ensuring that military health care remains abreast of the state of the art and to provide senior AMEDD leaders with a planning mechanism for controlling the strategic and long-term direction of the AMEDD health care delivery system. This can be done through the *Fixed Facility Technology Modernization Plan* (FFTMP). The plan would be a collaborative effort between the combat developer, the materiel developer, and the AMEDD ST/CPC, consisting of product line managers and supporting and related administrative staffs. User input, in the form of modernization proposals, would also be incorporated. The allocation of resources would be accomplished on the basis of the modernization plan. The goal of resource allocation would be to maximize the number of productive, appropriate technologies used while minimizing the financial assets depleted to acquire them. [21] The role of technology assessment in achieving this goal is obvious. The results of this evaluation would be briefed to the senior AMEDD leadership.

The pace of technological change often does not permit extensive clinical trials and economic evaluations. In some cases, technologies are overtaken by new improvements in less time than it takes to assess them. Therefore, resources must be focused on conducting proper assessments at the right times, and the technology assessment effort should be prioritized.

The Army's mechanism for prioritizing capability requirements is found in the CBRS. Mission area analyses are conducted by the combat developer to identify mission performance deficiencies and opportunities amenable to correction and/or exploitation by new or modernized technologies, materiel-based or otherwise. Applying a similar logic in attempts to get ahead of the technological change "power curve", deficiencies discovered through review of epidemiological data can drive training programs, R&D efforts, and the search for even newer technologies. Asking clinical questions that give rise to clinical investigations helps achieve like goals. A MAMP is developed to support combat developers, materiel developers, and resource programmer interactions. One purpose of the MAMP is to integrate, coordinate, and prioritize the use of selected AMEDD modernization resources. As such, the MAMP reflects the results of the competition that occurs on a "level technology playing field" where products are prioritized on the basis of their ability to cost effectively overcome mission area deficiencies (i.e., to cost effectively produce more desirable outcomes and to accomplish delivery system goals). The AMEDD FFTMP would clearly benefit from a speedy, CBRS, MAMP-like mechanism. Only HSC's ST/CPC now addresses these issues. [38]

The current HSC ST/CPC, although it is limited in scope due to its relatively narrow focus on only high-dollar value equipment, has much to recommend it. It relies on technology-specific subcommittees that conduct research independently or at the direction of the committee or the Chief Technology Officer (CTO). Subcommittees report to the CTO and/or the ST/CPC as a whole. Nevertheless, strategic planning and technology assessment are duties inherent in modernization management. Modernization management should not be relegated to the committee process with the expectation that good strategic decisions will result. A separate organizational chain should not be established for the specific purpose of managing modernization. Instead, responsibility for performing these duties must be appropriately assigned to adequately supervised, operating line management and their staffs. As HSC is doing today through the submission of business plans for new or revised health care delivery strategies, modernization procedures should permit input from staff planners at the strategic or corporate level as well as input from staff planners and operators at the individual facility level. The resulting medical mission area FFTMP would reflect competition, or integration and prioritization on a "level technology playing field."

Step 5: Evaluate Product Line Performance

The fifth step for controlling the entry and diffusion of technologies is difficult but central to technology modernization planning. The AMEDD and its treatment facility commanders must be able to evaluate service product lines, individually and by specialty, on the basis of quality, cost, and the beneficiary population served. On the basis of these evaluations, recommendations can be made to change service missions at single facilities, at local networks, regionally, or on a system-wide basis. Demand forecasting occurs during this operational step. The fundamental building blocks of strategic planning are arranged at this step. Beneficiary enrollment and vertically integrated delivery principles are employed at this step. The employment of recommended technologies for providing specific services occurs at this step. Commanders and (local, regional, and national/global) network managers refine, implement, and execute technology modernization plans on the basis of evaluations.

Being able to evaluate product line performance requires that the AMEDD ST/CPC members, individually and collectively, review functional requirements for beneficiary/patient accounting systems that capture demographic data, clinical systems that capture quality assurance information, and financial and materiel accounting systems that capture information on health care delivery system costs. The purpose of such a review would be to ensure that the systems provide sufficient capability to formulate recommendations regarding the deployment and use of technologies. The council would make consensus recommendations on changes to those systems to improve the product line performance evaluations.

Step 6: Increase the Priority Assigned to Modernization Management

For the purpose of modernizing AMEDD fixed facilities, technology assessment is a matter of medical management priority. Because of the strategic planning opportunities that managed care and technology assessment jointly present, the priority assigned to technology assessment should equal the priority currently enjoyed by the GTC program. That priority also applies to the capability to translate research and technology assessment data developed elsewhere into information usable by AMEDD health care delivery planners and modernization decision-makers.

Technology assessment is an essential part of fixed facility delivery system modernization. It is an integral component of the strategies needed to deliver high-quality service, to control costs, and to meet the needs of authorized beneficiaries. However, the AMEDD does not assess medical technologies for the purpose of modernizing its fixed facilities. Instead, it decentralizes the function. As we have pointed out, this is not consistent with what is known about the practice of medicine, and it is not consistent with sound strategic planning and the delivery of quality services.

The AMEDD can use technology assessments not only to identify and rank cost effective technologies for the purposes of developing modernization proposals and product distribution strategies, but also to estimate the increased amount of O&M funding that will be needed to meet the increased costs associated with new technologies.

Technology assessment is intended to distinguish between worthwhile technologies and those that are less worthwhile. Technology assessment permits the ranking of technologies for possible investment and provides the AMEDD with recommendations for making the most of the modernization resources it receives. Hopefully, the recommendations would also contribute to a further and perhaps ultimate purpose – the making of coherent, persuasive arguments necessary to obtain the full funding and manpower essential for optimum performance of the AMEDD mission.

The designation of a Deputy or Assistant Surgeon General for Research and Technology to oversee the research and materiel aspects of technology modernization management is the capstone to the steps needed to plan and control the diffusion of medical technologies in the AMEDD. Nonmateriel technologies (i.e., personnel and training) could be overseen by a Deputy or Assistant Surgeon General for Health Care Operations. Specialty consultants would form the AMEDD's strategic planning and integration nucleus. Assignment of a Deputy or Assistant Surgeon General for Research and Technology enables the streamlining of peacetime and wartime medical technology strategic planning, assessment, clinical policy formulation, and materiel acquisition processes *and* gives technology modernization management visibility and priority equal to that given the GTC program. The two efforts parallel one another. Implementation of either one without the other simply delays the inevitable requirement for, and difficulty in, accomplishing new technology integration while strategic plans are in the execution process.

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APPENDIX A

MAJOR ARMY MEDICAL TREATMENT FACILITIES

TABLE A-1

MAJOR ARMY MEDICAL TREATMENT FACILITIES

Facility	Location	Estimated operational beds	Medical property book value ($000)	Nonmedical property book value ($000)
Brooke	Texas	500	36,140	4,906
Eisenhower	Georgia	361	27,419	6,083
Fitzsimmons	Colorado	451	34,917	9,986
Letterman	California	266	29,849	4,901
Madigan	Washington	363	34,439	7,353
Tripler	Hawaii	475	49,277	8,483
Walter Reed	Washington, D.C.	769	54,126	41,230
Beaumont	Texas	392	32,796	8,743
Frankfurt	Europe	400	18,592	4,493
Landsthul	Europe	400	26,687	4,194
Augsburg	Europe	150	6,336	2,887
Belvoir	Virginia	79	6,487	2,921
Benning	Georgia	217	15,237	2,820
Bad Canstat	Europe	150	8,783	2,297
Bremerhaven	Europe	50	5,733	913
Berlin	Europe	100	6,039	1,288
Bragg	North Carolina	241	15,262	3,884
Campbell	Kentucky	146	13,549	2,949
Carson	Colorado	128	17,507	143
Dix	New Jersey	81	9,118	2,194
Heidelberg	Europe	100	9,729	3,300
Hood	Texas	190	18,217	211
Jackson	South Carolina	135	11,386	1,900
Japan	Pacific	10	769	277
Knox	Kentucky	125	13,592	5,231
Korea	Pacific	100	12,662	3,667
L. Wood	Missouri	131	15,815	3,534

TABLE A-1

MAJOR ARMY MEDICAL TREATMENT FACILITIES (Continued)

Facility	Location	Estimated operational beds	Medical property book value ($000)	Nonmedical property book value ($000)
Wurzburg	Europe	100	10,063	1,867
Nurnburg	Europe	100	17,079	5,259
Ord	California	128	13,646	2,938
Polk	Louisiana	87	8,087	5
Riley	Kansas	109	9,919	10
SHAPE	Europe	75	3,992	1,031
Sill	Oklahoma	130	11,243	214
Stewart	Georgia	96	9,252	3,165
Alaska	Arkansas	40	11,443	1,801
Panama	USARSO[a]	80	9,175	37
Devens	Massachusetts	25	5,024	1,116
Eustis	Virginia	44	5,157	1,141
Huachuca	Arizona	48	4,992	1,797
Leavenworth	Kansas	20	4,347	48
Lee	Virginia	56	4,332	1,280
McClellan	Alabama	48	5,961	1,665
Meade	Maryland	53	8,934	2,579
Monmouth	New Jersey	18	3,812	1,044
Redstone	Alabama	27	3,844	1,123
Rucker	Alabama	44	5,869	9,076
West Point	New York	54	5,712	1,464
Drum	New York	0	N/A	N/A
Ben Harrison	Indiana	10	2,405	1,003
Irwin	California	17	2,877	1,315
Vincenza	Europe	25	3,280	661

[a]U.S. Army Southern Command.

APPENDIX B

ECONOMIC EVALUATIONS - EXAMPLES

ECONOMIC EVALUATIONS – EXAMPLES

COST OF ILLNESS

Use: Determines the total annual economic impact of a particular disease

Includes:
- Direct treatment cost
- Direct costs of social services, education, etc.
- Indirect (productivity) costs
- Intangible costs (pain and suffering).

Example: Cost of illness for asthma in the United States for 1990 is $6.2 billion (see Table B-1).

TABLE B-1

COST-OF-ILLNESS ANALYSIS

	$ millions	Percent
c1		
Hospital care	2,045	33.0
Physicians	493	7.9
Medications	1,100	17.7
Caregiver's time	900	14.5
c2		
Lost work time	346	5.6
Lost housework time	503	8.1
c3		
Mortality – lost time (discounted 4 percent per year)	819	13.2
Total	6,206	100.0

COST MINIMIZATION

Use: To compare alternatives that have equal effectiveness.

Example: Drug with equal efficacy or effectiveness, as demonstrated through clinical trails, but a better side-effect profile. Saves costs through reduced treatment of side effects. Sometimes used as a first step in investigating a new treatment or a drug. Results may be strong enough without proceeding to costly Quality Adjusted Life Year (QALY) or willingness-to-pay studies.

COST EFFECTIVENESS

Use: To compare alternatives with outcomes of the same type.

When to use:

1. When there is one unambiguous objective:
   a. Alternative variations of a single program, e.g., hypertension screening and treatment ($/mm Hg)
   b. Alternative programs for same medical problem, e.g., end stage renal disease [dollars/life year ($/LY) gained]
   c. Alternative programs for different medical problems, but the same primary outcome, e.g. mammography screening versus kidney dialysis ($/LY gained).
2. When there are several objectives, but the alternative interventions have the same impact on all but one objective, e.g., similar levels of complications.
3. When there are multiple objectives, attained differentially, but one program "wins" on all.

Otherwise:
- Use scorecard display, basket of goods display, *Consumers' Reports* style
- Use a prior preemptive ordering or relative weights
- Use cost-utility analysis.

Example:

Treatment: Beta blocker for 6 years after acute myocardial infarction.

Costs:

- Drug, \$208/year
- Assumed no savings in follow-up medical treatment costs
- Assumed no cost of side effects.

Effects: Gains in life expectancy (for age 55)

Low risk:	0.10 years
Medium risk:	0.34 years
High risk:	0.47 years

Cost-effectiveness ratio (for age 55)

Low risk:	\$13,068/life-year gained
Medium risk:	\$3,618/life-year gained
High risk:	\$2,357/life-year gained.[1]

COST UTILITY

Use: To compare any/all alternatives by using CEA with a generic outcome, QALY.

When to use:

1. When there are multiple objectives, attained differentially, and one program does not "win" on all.
2. When quality of life is the important outcome, e.g., arthritis.
3. When quality of life and quantity of life are both important outcomes, e.g., neonatal intensive care.
4. When there is a wide variety of disparate programs that must be compared, e.g., typical health planner's problem.

Example:

Treatment: Neonatal intensive care of very-low birth weight infants

[1]Goldman, Sia, Cook, et al., *New England Journal of Medicine*, 1988, p. 152.

Costs: Incremental costs of neonatal period (hospital, physician); follow up (rehospitalizations, physicians, appliances, drugs, special services, special education); future work time lost/gained (earnings).

Effects: Incremental changes in quantity and quality of life measured in QALYs gained

Cost-Utility Ratio: $1,000/QALY gained, 1000 – 1499 gms

$17,500/QALY gained, 500 – 999 gms.[2]

COST BENEFIT

Use: To compare any/all alternatives by using a generic outcome, dollars.

When to use:

1. Same as cost-utility analysis for disparate programs.
2. The difference is that the subjective judgments and tradeoffs regarding the health outcomes are made by willingness to pay rather than utilities/QALYs.
3. Added advantage is that a definitive statement can be made regarding a program's value rather than a relative statement.

Example:

Treatment: Taking cholesterol-lowering agents for 7 years.

Options: Cholestyramine resin, colestipol, oat bran.

Costs: Treatment including drugs, physicians, dietitian, laboratory.

Benefits: Medical care costs of averted events (myocardial infarction, coronary artery bypass graft, new angina), work-time gained (earnings) (see Table B-2).

[2]Boyle, Torrance, Sinclair, et al., *New England Journal of Medicine*, 1988, p. 1330.

TABLE B-2

COST BENEFIT

(Per case)

	Cholestyramine	Colestipol	Oat bran
Cost	$10,030	$6,150	$1,730
Benefits			
Averted events	240	240	240
Work gain	680	680	680
Subtotal	920	920	920
Net economic benefit	– $9,110	– $5,230	– 810
Effects (per case)			
Life-years gained	0.08	0.08	0.08
Cost effectiveness ratios			
Cost/life-years gained	$117,440	$70,900	$17,800
Net economic cost/life-year gained	$108,800	$63,500	$9,200

Source: Kinosian and Eisenberg, *Journal of the American Medical Association*, 1988, p. 2249.

APPENDIX C

GLOSSARY

GLOSSARY

AHA	=	American Hospital Association
AHCPR	=	Agency for Health Care Policy and Research
AIDS	=	Acquired Immune Deficiency Syndrome
AMEDD	=	Army Medical Department
AR	=	Army Regulation
ASF	=	Army Stock Fund
CBRS	=	Concepts Based Requirements System
CBS-X	=	Continuing Balance System – Expanded
CCP	=	Coordinated Care Program
CEA	=	Cost Effectiveness Analysis
CEEP	=	Capital Expense Equipment Program
CHAMPUS	=	Civilian Health and Medical Program of the Uniformed Services
CT	=	computer-assisted tomography
CTO	=	chief technology officer
DA	=	Department of Army
DBOF	=	Defense Business Operating Fund
DCSLOG	=	Deputy Chief of Staff for Logistics
DHHS	=	Department of Health and Human Services
DoD	=	Department of Defense
DoDD	=	DoD Directive
DoDI	=	DoD Instruction
FDA	=	Food and Drug Administration
FFTMP	=	Fixed Facility Technology Modernization Plan

FOBT	=	fecal occult blood test
FY	=	fiscal year
GAO	=	General Accounting Office
GI	=	gastrointestinal
GME	=	graduate medical education
GTC	=	Gateway to Care program
HCSCIA	=	Health Care Studies and Clinical Investigation Activity
HMO	=	health maintenance organization
HSC	=	Health Service Command
LOS	=	length of stay
LRAMRP	=	Long Range Army Materiel Requirement Plan
LRRDAP	=	Long Range Research, Development and Acquisition Plan
MACOM	=	Major Command
MAMP	=	Mission Area Materiel Plan
MEDCASE	=	Medical Care Support Equipment
MF2K	=	Medical Force 2000
MHSS	=	Military Health Services System
MRDC	=	Medical Research and Development Command
MRI	=	magnetic resonance imaging
NIH	=	National Institutes of Health
OASD(HA)	=	Office of the Assistant Secretary of Defense for Health Affairs
O&M	=	operations and maintenance
OTSG	=	Office of the Surgeon General
PA	=	procurement appropriation
PET	=	positron emission tomography
PPBES	=	Planning, Programming, Budgeting and Execution System
ProPAC	=	Prospective Payment Commission

QALY	=	Quality Adjusted Life Year
RCT	=	randomized controlled trial
R&D	=	research and development
RDT&E	=	research, development, test and evaluation
RICC	=	Reportable Item Control Code
SIP	=	Sickness Impact Profile
SKO	=	sets, kits, and outfits
S&TA	=	Scientific and Technological Advancement
ST/CPC	=	Strategic Technology and Clinical Policy Council
TAB	=	Therapeutics Agents Board
TAEDP	=	Total Army Equipment Distribution Program
TPUMF	=	total package unit materiel fielding
TRADOC	=	Training and Doctrine Command
USAMMA	=	U.S. Army Medical Materiel Agency
USAMMDA	=	U.S. Army Medical Materiel Development Activity

REPORT DOCUMENTATION PAGE

Form Approved OPM No. 0704-0188

1. AGENCY USE ONLY *(Leave Blank)*

2. REPORT DATE
Jan 93

3. REPORT TYPE AND DATES COVERED
Final

4. TITLE AND SUBTITLE
Medical Technology Modernization and Strategic Planning: Shaping Army Health Care

5. FUNDING NUMBERS
C MDA903-90-C-0006
PE 0902198D

6. AUTHOR(S)
George L. Slyman
Gilbert L. Goldman

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Logistics Management Institute
6400 Goldsboro Road
Bethesda, MD 20817-5886

8. PERFORMING ORGANIZATION REPORT NUMBER
LMI-AR103R1

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Commander
U.S. Army Research and Development Command
Ft. Detrick, MD 21701-5012
Commander
U.S. Army Health Services Command
Ft. Sam Houston, TX 78234

Monitor:
COL John C. Slaughter
MD, MC
Falls Church, VA 22041-3258

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT
A: Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

The Army Medical Department (AMEDD) requires a well-conceived and well-managed health care delivery system to provide authorized beneficiaries with high-quality medical services, quickly and inexpensively. Such a delivery system depends upon the modernization of the medical technologies it uses to produce services. However, the AMEDD equates medical technology primarily with expensive equipment or unique military applications of preventive medicine. This incomplete view denies the AMEDD an essential appreciation of the full scope and nature of its performance measurement and technology modernization challenge. The risk of harm and excessive cost, therefore, is higher than it needs to be. The AMEDD's Gateway to Care program for managed care contains many initiatives for improved health care delivery. Unfortunately, Gateway to Care policy perpetuates the traditional medical technology culture. Decisions to acquire and employ medical technologies remain decentralized. Overall system performance may suffer while individual hospitals remain autonomous. We recommend that the AMEDD adopt centralized methods for prospectively evaluating medical technologies. Key to these evaluations is establishing an AMEDD Strategic Technology and Clinical Policy Council – with membership from the consultant staff – to oversee the technology assessment and product line management process. Linking medical technology modernization and strategic planning will improve health care delivery and help achieve quality, access, and cost performance goals established for the Gateway to Care program.

14. SUBJECT TERMS
Medical Technology, Strategic Planning, Health Care Delivery, Technology Assessment

15. NUMBER OF PAGES
99

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	UL

NSN 7540-01-280-5500

Standard Form 298, (Rev. 2-89)
Prescribed by ANSI Std. 239-18
299-01

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