Program Evaluation and Methodology Issue Area

Active Assignments
Foreword

This report was prepared primarily to inform Congressional members and key staff of ongoing assignments in the General Accounting Office's Program Evaluation and Methodology issue area. This report contains assignments that were ongoing as of July 6, 1995, and presents a brief background statement and a list of key questions to be answered on each assignment. The report will be issued quarterly.

This report was compiled from information available in GAO's internal management information systems. Because the information was downloaded from computerized databases intended for internal use, some information may appear in abbreviated form.

If you have questions or would like additional information about assignments listed, please contact Kwaicheung Chan, Director, Program Evaluation in the Physical System Area on (202) 512-3092; or Robert York, Director, Program Evaluation in the Human Services Area on (202) 512-5885.
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- Biotechnology Risks and the Adequacy of Regulatory Agency Reviews.  
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- FDA's Layers of Safety for the Blood Supply.  
- Vaccines for Children: Critical Issues in Measuring the Impact of the Program.  
- New, FDA's Review of Medical Devices.  
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- Analysis of the Scientific Foundation and Effectiveness of the National Cholesterol Education Program (NCEP).  
- Evaluation of the Methodology of DOD's Bottom-Up Review.  
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Program Evaluation and Methodology

EXISTING PROGRAMS/POLICIES

**TITLE: OPERATION DESERT STORM: EVALUATION OF THE AIR WAR (973364)**

**BACKGROUND:** Rep. Dingell and Senator Pryor asked to be added as requesters to the evaluation of the Desert Storm air campaign job originally requested by Rep. Ireland and Senator Wirth, who are now retired. We have completed our design phase and have briefed the new requesters' staffs.

**KEY QUESTIONS:** (1) What were the objectives of the air campaign? (2) How was the campaign planned in terms of allocating aircraft and munitions for different targets? (3) How was the campaign actually carried out? (4) What were the costs and the comparative effectiveness of the weapons?

**TITLE: BIOTECHNOLOGY RISKS AND THE ADEQUACY OF REGULATORY AGENCY REVIEWS (973395)**

**BACKGROUND:** Public concern about the safety of certain classes of biotechnology end products, such as food products, has triggered controversy about what risks biotechnology poses. The biotechnology debate in turn has led to questions about how well the federal government, particularly FDA and USDA, addresses these risks through its regulatory processes.

**KEY QUESTIONS:** (1) What are the current and emerging biotechnology applications? (2) What risks have been associated with biotechnology introductions? (3) To what extent does the federal regulatory process address the risks associated with these biotechnology introductions?

**TITLE: A SURVEY OF ASSESSMENT INSTRUMENTS IN MEDICAID WAIVER PROGRAMS FOR HOME AND COMMUNITY-BASED LONG-TERM CARE (973412)**

**BACKGROUND:** The proposed Health Security Act includes a new home and community-based long-term care benefit for people with disabilities, requiring a uniform needs assessment. It is not known to what extent the assessment process in Medicaid waiver programs results in a comprehensive evaluation of the client.

**KEY QUESTIONS:** (1) Are Medicaid assessment instruments adequate to be used in the implementation of the new disability benefit described in the Health Security Act? (2) How can they be modified to make them useful for this program?
## Program Evaluation and Methodology

### EXISTING PROGRAMS/POLICIES

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<td>BACKGROUND:</td>
<td>The Food and Drug Administration has instituted controls over the collection and distribution of blood products which it has termed &quot;layers of safety.&quot; These steps are designed to ensure that contaminated blood and blood products are screened from the nation's blood supply. Nevertheless, patients continue to receive transfusions of infected blood.</td>
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<td>KEY QUESTIONS:</td>
<td>(1) How has the FDA implemented the concept of &quot;layers of safety&quot; for the nation's blood supply? (2) What are the actual and potential vulnerabilities in the layers of safety which may present a threat to the public health?</td>
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<td>BACKGROUND:</td>
<td>The Vaccines For Children Program is designed to increase childhood immunization rates. However, the extent to which vaccine costs are a barrier to immunization or whether VFC program can address &quot;pockets of need&quot; remain questionable.</td>
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<td>KEY QUESTIONS:</td>
<td>1-What is the quality of evidence regarding the cost of vaccine as a barrier to immunization? 2-What are the various approaches to identifying and addressing &quot;pockets of need&quot;? 3-What are the critical issues in measuring the impact of the VFC program on immunization rates?</td>
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<th>VACCINES FOR CHILDREN PROGRAM: HOW IS CDC ADDRESSING IMPLEMENTATION ISSUES RAISED (973422)</th>
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<td>BACKGROUND:</td>
<td>The Vaccines for Children Program is intended to increase childhood immunization rates. The program is scheduled to begin October 1, 1994. However, our previous GAO report determined seven areas in which implementation issues remained unresolved.</td>
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<td>KEY QUESTIONS:</td>
<td>How is the Center for Disease Control responding to the seven areas of implementation concern identified in our previous report?</td>
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EXISTING PROGRAMS/POLICIES

**TITLE:** FDA'S REVIEW OF MEDICAL DEVICES (973425)

**BACKGROUND:** The Food and Drug Administration (FDA) is authorized to regulate medical devices for safety and effectiveness. Different types of tests are required to ensure software safety. As a consequence FDA issued guidelines specifically for computer controlled medical devices. Are these measures for ensuring software safety adequate?

**KEY QUESTIONS:** Of new devices entering the market under FDA guidelines for computerized medical devices, what percentage experienced problems which may have caused or contributed to death, illness or injury? Of those problems, what percentage were the result of software related errors? What subsequent steps were undertaken by FDA to address software related problems?

**TITLE:** COST-EFFECTIVENESS OF MEDICARE PREPAYMENT SCREENS (973431)

**BACKGROUND:** GAO has found that most claims are automatically paid without determining the medical necessity of the procedure. At the same time, very little is known about the cost-effectiveness of the pre-payment screens, including the effectiveness of provider profiling in this regard. This study will address these questions.

**KEY QUESTIONS:** 1) How rigorous are the methods used by HCFA to evaluate cost-effectiveness of prepayment screens? 2) Do these screens impact providers most responsible for denials? 3) How do reversal rates for appealed claims influence cost-effectiveness estimates?

**TITLE:** AN EVALUATION OF EPA EMERGENCY RESPONSE ACTIVITIES (973788)

**BACKGROUND:** The EPA is responsible for providing emergency planning and response for chemical emergencies and disasters. EPA participates in a complex emergency response process that relies greatly on the ability to characterize the health and environmental effects of chemical wastes. Concerns have been raised about the effectiveness of the program.

**KEY QUESTIONS:** 1. What has been the historical trend in the incidence of chemical emergencies? 2. Are there certain types or categories of chemical emergencies that are more frequent than others? 3. How well prepared is EPA to assess a chemical emergency? 4. How effectively does EPA respond to these events and communicate the associated risks to the public?
EXISTING PROGRAMS/POLICIES

**TITLE:** COST CONTAINMENT MECHANISMS AND THEIR IMPACT ON QUALITY OF CARE FOR BONE MARROW TRANSPLANTATION (973790)

**BACKGROUND:** A central concern of the current debate on health care reform is how best to control costs. All national health care systems attempt to limit cost but vary in the mechanisms they employ to achieve this goal. Despite this variation, little is known about how each mechanism of cost containment affects the availability and appropriateness of health care services.

**KEY QUESTIONS:** How do three major mechanisms of cost containment—global budgets, capacity controls, and medical appropriateness guidelines—influence the quality of care with bone marrow transplantation?

**TITLE:** WHAT PROGRAMS HAVE HELPED UNMARRIED TEENAGE MOTHERS ACHIEVE ECONOMIC SELF-SUFFICIENCY. (973793)

**BACKGROUND:** Recent welfare reform efforts have focused on unmarried teenaged mothers and their special risk for welfare dependency. Employment and education programs also aim to increase self-sufficiency and reduce welfare dependency. As part of a joint effort with HEHS to answer the full request under 105392, PEMD will review formal evaluations of such programs.

**KEY QUESTIONS:** What services or approaches help poor teenaged mothers become self-sufficient and avoid welfare dependency?

**TITLE:** AMERICANS WITH DISABILITIES ACT EMPLOYMENT PROVISIONS (973795)

**BACKGROUND:** The Americans with Disabilities Act (ADA) includes safeguards against discrimination in the employment of persons with disabilities including hiring, accommodations, promotions, terminations, and benefits. The impact the law has had on the lives of persons with disabilities and on businesses is unknown, but widely speculated upon.

**KEY QUESTIONS:** What have been the costs and benefits of the employment provisions of the ADA? How has the ADA changed the employment rate for persons with disabilities? How does the composition of the disabled population in the workforce compare to that of the unemployed?
PROGRAM EVALUATION AND METHODOLOGY

EXISTING PROGRAMS/POLICIES

TITLE: WELFARE TO WORK SYNTHESIS (973796)

TITLE: EVALUATING THE EFFECTIVENESS OF EXPERT SYSTEM TECHNOLOGY APPLICATIONS FOR IMPROVING FEDERAL PROGRAM PERFORMANCE (973798)

BACKGROUND: Expert systems are computer programs used in government and business, including the Big 6 accounting firms, to improve productivity and/or reduce expenditures by emulating experts' decision making processes. With the federal government's focus on streamlining its operations, an evaluation of the utility of applying expert systems is needed.

KEY QUESTIONS: 1. Where have expert systems been deployed in civilian federal services? 2. How are they used? 3. What standards have been used to verify, validate and accredit expert system applications? 4. What difference have they made in productivity? 5. Where in the federal government can expert systems be used to increase productivity and aid in downsizing?

TITLE: FDA NEW DRUG REVIEW AND APPROVAL PROCESS (973799)
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EXISTING PROGRAMS/POLICIES

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<td>BACKGROUND: The rapid movement toward managed care has blurred the former lines of demarcation between fee-for-service medical practice and health maintenance and other managed care organizations. Little is known about the implications of specific elements of managed care practice (e.g., different ways of paying for physician services) for health care quality.</td>
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<td>KEY QUESTIONS: What are the implications of different dimensions of managed care for processes of health care delivery, patients' health outcomes and other quality of care indicators?</td>
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PROPOSED PROGRAMS/POLICIES

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<th>TITLE: ADVANTAGES AND DISADVANTAGES OF ESTABLISHING A THIRD CLASS OF DRUGS (973392)</th>
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<td>BACKGROUND: The U.S. has two classes of drugs: prescription and over-the-counter (OTC). However, many other countries have a category of drugs for which a prescription is not required but which can only be dispensed by a pharmacist. Counseling on the proper use of the drug can then be given by the pharmacist.</td>
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<td>KEY QUESTIONS: For 10 selected countries and the EC: (1) What are the drug distribution systems? (2) What is known about the development and operation of these systems? (3) What is the drug classification history of 14 selected drugs within the systems? (4) What is the nature and scope of pharmacists' counseling?</td>
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<th>TITLE: MODEL NUTRITION MONITORING SYSTEM (973397)</th>
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<td>BACKGROUND: The current national nutrition monitoring system involves a complex collection of activities administered by different federal agencies (mostly under HHS and USDA). The system has been criticized for poor coordination among the components and concerns about data quality and comparability.</td>
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<td>KEY QUESTIONS: This assignment will address three questions: (1) What are promising alternative models of nutrition monitoring? (2) What are the strengths and weaknesses of the models compared to the current nutrition monitoring program? and (3) What are the barriers to and channels for implementing the models?</td>
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**Program Evaluation and Methodology**

**PROPOSED PROGRAMS/POLICIES**

**TITLE:** FUTURE STRATEGIES FOR THE DEFENSE INDUSTRIAL BASE (973421)

**BACKGROUND:** Since the collapse of the Soviet Union, programs to convert portions of the defense industrial base to civilian production have been implemented. However, there is concern that these programs may be subsidizing noncompetitive production facilities at very high and long-lasting costs in both the civilian and defense industrial sectors.

**KEY QUESTIONS:**
1. Is the likely effect of defense conversion activity to increase or decrease productivity and competition in the DIB?
2. How do competition, productivity, and prices currently differ within the DIB and between it and the civilian sector?
3. What criteria are currently being used in Congress and the executive branch to select candidates for conversion?

**QUALITY OF POLICY INFORMATION**

**TITLE:** ANALYSIS OF THE SCIENTIFIC FOUNDATION AND EFFECTIVENESS OF THE NATIONAL CHOLESTEROL EDUCATION PROGRAM (NCEP) (973389)

**BACKGROUND:** The cost of public and private efforts to test and lower cholesterol may be as high as $10 billion annually. In light of these costs, the Committee is interested in the quality of the scientific evidence used to justify such expenditures, particularly as it relates to the guidelines established by the National Cholesterol Education Program.

**KEY QUESTIONS:**
1. What evidence is there that lowering serum cholesterol: a) reduces risk of CHD; b) reduces the risk of death from CHD; c) extends overall survival? Do outcome differ for different types of treatment or for different population sub-groups? What evidence regarding these outcomes has been used to support the NCEP guidelines?

**TITLE:** EVALUATION OF THE METHODOLOGY OF DOD'S BOTTOM-UP REVIEW (973404)

**BACKGROUND:** The requester has asked that PEMD perform a methodological review of DOD's Bottom-Up Review and report back to him in early spring 1994.

**KEY QUESTIONS:**
1. What was the methodology of the Bottom-Up Review, and how was it applied?
2. How were major decisions made, and how were they supported by the data and analyses that were performed?
3. What were the methodology and analyses relative to the consolidation of duplicative roles and missions among the military services?
QUALITY OF POLICY INFORMATION

TITLE: ESTIMATING ALL IMMIGRATION STATUSES (973792)

BACKGROUND: Current immigration policy issues would be informed by more accurate data on the numbers of foreign-born persons in specific immigration status categories in local areas. Government agencies do not conduct surveys to collect such data. GAO proposes to explore the feasibility of an alternative to the usual data collection and estimation methods.

KEY QUESTIONS: (1) What are INS and/or Census Bureau plans, if any, for collecting relevant data—and what do agencies see as the barriers to collecting such data? (2) What are the strengths and limitations of existing data collection approaches? (3) Can the proposed new method be further developed and refined to the point that its practicality is clear?

TITLE: SUCCESSFUL PRACTICES IN LEARNING AND IN THE WORKPLACE (973801)

BACKGROUND: Little is known about successful practices in schools and the workplace. To assist it in performing its program review responsibilities, the Subcommittee seeks information on practices that research results show are successful in learning and in the workplace.

KEY QUESTIONS: (1) What learning and workplace practices have proven to be successful? (2) What processes, practices, and programs have not worked? (3) What characterizes practices in five successful workplace and school sites? (4) What core factors or benchmark characteristics distinguish successful from unsuccessful practice in each area?

TITLE: NONIMMIGRANT OVERSTAYERS: INS’ ESTIMATION METHODOLOGY NEEDS REVISION (973802)

BACKGROUND: Illegal immigration is reaching crisis proportions. One troubling form of this problem consists of foreign visitors who legally enter the United States, but fail to depart. The Immigration and Naturalization Service (INS) estimates that visa overstayers are as numerous as illegal border crossers, calling into question the primary focus of U.S. efforts on border security.

KEY QUESTIONS: How valid is INS’ estimate of visa overstayers?
QUALITY OF POLICY INFORMATION

TITLE: PILOT WORK AUTHORIZATION STUDIES: HOW ARE THEY BEING EVALUATED? (973804)

BACKGROUND: The Commission on Immigration Reform has recommended a national worker verification system to prevent the employment of illegal aliens. The Immigration and Naturalization Service (INS) is planning pilot studies to develop such a system, test its feasibility, and assess its impact in areas such as discrimination.

KEY QUESTIONS: (1) What questions does INS believe the pilot studies are intended to answer? (2) What additional questions, if any, does the House Subcommittee believe the studies should answer? (3) Are the evaluation designs INS has developed for the pilot studies sufficient for answering these questions?