
Index

- abortion, 48
- anencephaly, 48
- arthroscopy, 82
- artificial heart, 48-49, 75
- assessment
 - clinical trials in, 130-137
 - compendium of bibliographic data bases for (table), 121-126
 - consensus development, 64, 100, 144-145
 - cost-benefit analysis in, 11, 39
 - cost-effectiveness analysis in, 11, 14, 39, 40, 41, 46, 60-62, 67
 - critique of current system for, 91-102
 - data sources for, 24-27
 - dissemination of information on, 101-102
 - of economic effects, 24
 - encouragement of private sector leadership in, 108
 - experimental studies in, 34-35
 - group decision methods in, 62-66, 93
 - of health effects, 23, 33-39
 - identification of medical technologies needing, 94-97
 - information for, 23-30
 - interpretation of studies, 128-137
 - integrated system of, 105
 - literature review in, 57-58
 - methodological considerations in, 127-149
 - objective of, 91
 - of performance standards, 23-24
 - Process phases, 94-102
 - proposed organization for, 106-107
 - relationship to innovation, 146-149
 - of social effects, 24
 - social values in, 45-53
 - statistical data sources for (table), 113-121
 - synthesis activities in, 57-60, 100-101, 137-146
 - testing phase, 98-100
 - uncontrolled study designs in, 136-137
 - validity of research, 128-129
- Bibliographic Retrieval Service, 28
- BIOSIS, 28
- Blue Cross/Blue Shield, 7, 26, 81, 92
 - Medical Necessity Project, 78, 98
- Blue Cross of Massachusetts, 78
- Blue Shield of California, 78, 82
 - Ambulatory Surgery Project, 78
 - Medical Policy Committee, 78
- Brook, Robert, 192
- Bunker, John, 192
- caesarian delivery, 52, 129
- California Podiatry Association, 78
- cancer
 - chemotherapy, 75
 - endometrial, 38
 - Halsted radical surgery, 129
 - screening, 75
- case-control study, 37-38
- case studies, 10-11, 128
- Centers for Disease Control (CDC), 13, 51, 85
- Central Intelligence Agency (CIA), 13, 51
- chemotherapy, 37, 75
- clearinghouses, 29-30
- Cleveland Clinic, 77
- clinical trials, 131-137
 - cohort design in, 35-36, 132
 - historical controls, 134-135
 - matching in, 132-133
 - retrospective case-control studies, 133-134
 - time-series design, 135-136
- cobalt therapy, 83
- Commission on Professional and Hospital Activities (CPHA), 26-27
- Community Services Administration, 29
- computed tomography (see CT scanning)
- Congress
 - acts of (see legislation)
 - House Committee on Energy and Commerce, 193
 - options for (see Policy options), 18
 - Senate Committee on Labor and Human Resources, 193
- consensus development, 63
- construct validity, 129, 139
- coronary artery bypass graft surgery, 52, 129, 131
- coronary care units (CCUs), 37
- Coronary Drug Project, 130
- cost-effectiveness analysis (CEA), 61
- costs vs. prices, 40-41
- CT scanning, 40, 46, 78, 84
- data bases, 25, 78
 - Basic Vital Statistics, 113
 - Bioethicsline (table), 121
 - BIOSIS Previews (table), 121
 - Blue Cross/Blue Shield Systems (table), 117
 - Boston Collaborative Drug Surveillance Program (table), 119
 - Boston University Medical Center Drug Epidemiology Unit (table), 119
 - Bureau of Labor Statistics Annual Occupational Injuries and Illness Survey (table), 117
 - Cambridge Scientific Abstracts (table), 122, 125
 - CANCERLIT (table), 121
 - CANCERPROJ (table), 121
 - Centers for Disease Control Birth Defects Monitoring System (table), 114
 - Centers for Disease Control Hepatic Angiosarcoma Surveillance Finding Effort (table), 114
 - Centers for Disease Control National Disease Surveillance Program (table), 113
 - Centers for Disease Control Smoke, Nuclear Test Cohort Study (table), 114
 - Chemical Abstracts Service (table), 121
 - Child Abuse and Neglect (table), 122
 - CLINPROT (table), 122
 - compendium of bibliographic (table), 121-126

- Comprehensive Dissertation Index (table), 122
 Conference Papers Index (table), 122
 Department of Commerce Census of the Population (table), 117
 Department of Defense Civilian Health and Medical Program of the Uniformed Services (table), 117
 Department of Defense TRI-Service Medical Information Systems (table), 117
 DES Vaginal Cancer Registry (table), 118
 DRUGINFO and Alcohol Use/Abuse (table), 122
 Duke University Cardiovascular Data Bank (table), 118
 Dunedin Program (table), 119
 ENVIRONLINE (table), 122
 EPILEPSYLINE (table), 122
 Excerpta Medica EMBASE (table), 122
 Foods ADLIBRA (table), 122
 Food and Drug Administration Adverse Drug Reaction Spontaneous Recording System (table), 114
 Food and Drug Administration Boston Collaborative Drug Surveillance Program (table), 119
 Food and Drug Administration for Implanted Cardiac Pacemakers (table), 115
 Food and Drug Administration Medically Oriented Data System (table), 115
 Food and Drug Administration Nationwide Evaluation of X-Ray Trends (table), 115
 Food and Drug Administration National Registry for Drug-Induced Ocular Side Effects (table), 115
 Food and Drug Administration Poisoning Control Case Registry (table), 114
 Food and Drug Administration Registry of Adverse Reactions to Contrast Media (table), 115
 Food and Drug Administration Registry of Dermatological Reactions to Drugs (table), 114
 Food and Drug Administration Registry of Tissue Reactions to Drugs (table), 114
 Health Index Info (table), 122
 Health Planning & Admin, 28, 29
 Health Planning and Administration data base (table), 122
 HISTLINE (table), 122
 Hospital Discharge Data Systems (table), 118
 International Pharmaceutical Abstracts (table), 122
 IRL Life Sciences Collection (table), 122
 Johns Hopkins University POPLINE (table), 122
 Kaiser-Permanente Health Services Research Center (Oregon Region) System (table), 120
 Laboratory Animal Data Bank (table), 122
 Manitoba Health Services Commission Databank (table), 120
 Massachusetts General Hospital Computer-Stored Ambulatory Record System (table), 118
 Massachusetts General Hospital Intensive Care Databank (table), 119
 Medicare Claims File (table), 116
 Medicaid Management Information System (table), 116
 MEDLINE (table), 122
 MEDOC (table), 122
 National Academy of Dermatology Registry of Dermatological Reactions to Drugs (table), 114
 National Cancer Institute Surveillance, Epidemiology, and End Results Program (table), 115
 National Clearinghouse for Mental Health Information (table), 122
 National Health Interview Survey (table), 113
 National Health and Nutrition Examination Survey (table), 113
 National Hospital Discharge Survey (table), 113
 NCHS Basic Vital Statistics (table), 113
 NCHSR Computer-Stored Ambulatory Record System (table), 118
 NCHSR/Duke University Cardiovascular Data Bank (table), 118
 NCHS National Ambulatory Medical Care Survey (table), 113
 NCHS National Death Index (table), 113
 NCHS National Fetal Mortality Survey (table), 113
 NCHS National Health Interview Survey (table), 113
 NCHS National Health and Nutrition Examination Survey (table), 113
 NCHS National Hospital Discharge Survey (table), 113
 NCHS National Natality Index (table), 113
 NCHSR Problem Oriented Medical Information Systems (table), 118
 New York Hospital databank on patients in coma for causes other than head injury (table), 118
 NHLBI Coronary Artery Surgical Study (table), 116
 NHLBI Framingham Heart Study (table), 115
 NHLBI Hypertension Detection Second Followup Program (table), 115
 NHLBI Multirisk Factor Intervention Trial (table), 115
 NHLBI Percutaneous Transluminal Coronary Angioplasty Registry (table), 116
 NIAAA Alcoholism Program Monitoring System (table), 114
 NIAMDD National Diabetes Data Group (table), 116
 NIDA Client Oriented Data Acquisition Process (table), 114
 NIDA Drug Abuse Warning Network (table), 114
 NIDA National Drug Abuse Treatment Utilization Survey (table), 114
 NIOSH Registry of Toxic Effects of Chemical Substances (table), 125
 Olmstead County, Minnesota System (table), 119
 Pediatric Drug Surveillance Program (table), 119
 Pittsburgh Diabetes Registry (table), 118
 PRE-MED (table), 125
 PSRO Hospital Discharge Data Set (table), 116
 Rhode Island Diabetes Registry (table), 118
 Rhode Island Health Services Research, Inc. SEARCH (table), 119
 RINGDOC (table), 125
 Science Citation Index SCISEARCH (table), 125
 Seattle Group Health Cooperative System (table), 119
 Seattle Heart Watch (table), 120
 SERLINE (table), 125
 SOCIAL SCISEARCH data base (table), 125
 SSI Annual Disability Determination/Social Security Income Extract (table), 117

- SSI Continuous Disability History Survey (table), 117
 SSIE (table), 126
 SSI Leed File (table), 117
 statistical (table), 113-120
 Toxicology Data Bank (table), 126
 TOXLINE (table), 126
 University of North Carolina Population Bibliography (table), 124
 University of Vermont Problem Oriented Medical Information Systems (table), 118
 Utah Genealogical Data Base (table), 116
 VETDOC (table), 126
 Veterans Administration Compensation and Pension System (table), 117
 Veterans Administration Patient Treatment File (table), 117
 decisionmaking, 66-67
 Delphi technique, 15, 65, 66, 93, 145-146
 features of, 62
 Department of Agriculture, 29
 Department of Commerce, 29, 30
 Department of Defense (DOD), 13, 30, 51, 105
 Department of Education, 29
 Department of Energy (DOE), 29, 30
 Department of Health, Education, and Welfare (see Department of Health and Human Services)
 Department of Health and Human Services (DHHS), 9, 16, 18, 25, 29, 80, 85, 96, 108, 109
 Ethics Advisory Board, 13, 50, 51
 Technology Coordinating Committee, 9, 84, 107
 Department of Housing and Urban Development, 29
 Department of Justice, 29
 Department of Labor, 29
 Department of Transportation (DOT), 29
 DHEW (see Department of Health and Human Services)
 DHHS (see Department of Health and Human Services)
 DIALOG Information Service, Inc., 28
 discounting, 41
 DOE (see Department of Energy)
 DOT (see Department of Transportation)
 drugs, 9, 71-72
 advertising of, 86
 adverse reactions to, 98
 Federal regulation of, 78-79
 investigational new (IND), 79
 new drug application (NDA), 9, 12, 79
 Phase I studies of, 79
 Phase II studies of, 79
 Phase III studies of, 79
 surveillance of, 36, 97-98
 Duke University, 25
 electroencephalograph, **83**
 Emergency Care Research Institute (ECRI), 78
 endoscopy, 82
 end-stage renal disease (ESRD), 48
 End-Stage Renal Disease Program, 48
 ESRD (see end-stage renal disease)
 estrogen, 38
 Excerpta Medica, **28**
 external validity, 129, 139
 FDA (see Food and Drug Administration)
 fetal monitoring, 57, 129
 Food and Drug Administration (FDA), 3, 7, 8, 9, 17, 72, 74, 78, 79, 80, 85, 87, 88, 92, 94, 95, 96, 105, 127
 regulation of drugs and devices by, 77, 99
 reporting system for adverse drug reactions, 98
 role in medical technology assessment, 12-13
 surveillance of drugs, **97-98, 98**
 Fowles, Jinnet, 192
 gastric freezing, 4, 130, 167
 glossary, 198-202
 group decision methods, **93, 144-146**
 advantages and disadvantages of, 65-66
 Hartford Foundation, **78**
 HCFA (see Health Care Financing Administration)
 Health Care Financing Administration (HCFA), 7, 9, 17, 18, 25, 48, 52, 74, 75, 84, 87, 88, 92, 94, 95, 96, 97, 98, 99, 100, 101, 105, 106, 109
 Health Standards and Quality Bureau, 77
 Office of Coverage Policy, 77
 Office of Research and Demonstrations, 13, 76, 77, 95
 proposal to allow reimbursement for experimental technologies, 107-108
 research programs of, 76-77
 role in medical technology assessment, **9**
 health maintenance organizations (HMOs), 80
 Health Resources Administration (HRA)
 Bureau of Health Planning, 29, 30
 hemodialysis and kidney transplant surgery
 case study of, 175-184
 informed consent, 49
 innovation
 case studies of medical, 167-184
 characteristics of successful, 151-152
 definitions of, 150
 process for drugs and devices, 152-155
 process for medical and surgical procedures, 155-157
 public accountability in, 157-165
 research on, 150-151
 Institute for Health Care Evaluation, 19
 model of, 185-191
 proposal for, 107
 insurance claims records, 25
 internal validity, 138-139
 Johns Hopkins Hospital, 78
 W. K. Kellogg Foundation, 26
 legislation
 Alcohol Abuse and Alcoholism Act, 80
 Community Mental Health Centers Act, 80

- creation of the National Center for Health Care Technology (NCHCT), 106
- Food, Drug, and Cosmetic Act, 79, 93
- Freedom of Information Act, 51
- Medical Device Amendments (to Food, Drug, and Cosmetic Act), 9, 79, 127
- National Health Planning and Resources Development Act, 13, 80
- Public Health Services Act, 80
- Social Security Act, 6, 80, 81
- State certificate-of-need laws, 80
- Library of Congress
- National Referral Center, 29
- Lohr, Kathleen, 192
- macroallocation, 49
- mammary artery ligation, 130
- Manitoba Health Services Commission, 36
- maternal serum alpha-fetoprotein (MSAFP), 48, 96
- case study of, 174-175
- Mayo Clinic, 37, 77
- Medicaid, 26, 48, 76, 80, 81, 83, 98-
- medical devices, 72
- Federal regulation of, 79-80
- Medical Literature Analysis and Retrieval System (see MEDLARS)
- medical technologies
- assessment strategies for, 3-4, 6, 92-93
- capital investment in, 161
- conceptual framework for assessing, 7
- cost-effectiveness of, 52
- definition of, 3
- development, diffusion, and use of, 71-88
- economic effects of, 11-12, 14-15, 52
- effectiveness of, 52
- efficacy of, 33
- ethical issues in, 48-49, 52
- Federal role in assessing, 4, 6
- health effects of, 10-11, 14-15, 33-39
- health professionals and, 5
- identification of assessment needs, 8-10, 16-17
- industry, 5-6, 99
- information dissemination on, 15-16, 17-18, 84-85, 85-86
- innovation process for, 71-74, 150-166
- legal implications of, 52
- marginal valuation of, 39-40
- market for, 6
- medical devices, 72, 159-160
- medical and surgical procedures, 73, 99, 160-161
- opportunity cost of, 39
- pharmaceutical industry, 71-72
- public concern over, 4-5
- regulation of, 86-87, 158-161
- reimbursement policy effects on, 81-84, 161-165
- research findings on, 14
- safety of, 33, 52
- social effects of, 12, 14-15, 47-50, 52
- testing of, 10-13, 17
- value premises of assessment of, 45-47
- Medicare, 4, 6, 7, 26, 52, 75, 76, 80, 81, 83
- MEDLARS, 18, 28, 29
- MEDLINE, 28
- subject coverage of, 101
- menisectomy, 82
- meta-analysis, 58-59, 128, 142-143
- methotrexate, 37
- MSAFP (see maternal serum alpha-fetoprotein)
- multiple sclerosis, 78
- Multiple Sclerosis Foundation, 78
- National Academy of Sciences (NAS)
- Institute of Medicine, 106
- National Cancer Institute (NCI), 30
- Surveillance, Epidemiology, and End Results (SEER) program, 26
- National Center for Health Care Technology (NCHCT), 9, 13, 17, 18, 50, 52, 63, 75, 77, 84, 85, 87, 94, 95, 96, 98, 108, 110, 127
- Clinical Data Acquisition Plan, 99
- health care research programs of, 76
- proposal to refund, 107
- role in medical technology assessment, 9, 13
- National Center for Health Services Research (NCHSR), 9, 17, 18, 25, 75, 84, 95, 97, 99-100, 105, 109
- health services research programs of, 75-76
- User Liaison Program, 15, 84
- National Center for Health Statistics (NCHS), 24-25, 27
- National Commission, 13, 50-51
- National Health Planning Information Center, 29
- National Heart and Lung Institute (see National Heart, Lung, and Blood Institute)
- National Heart, Lung, and Blood Institute, 26, 49
- National Institutes of Health (NIH), 9, 17, 18, 25, 28, 51, 57, 63, 65, 66, 74, 77, 88, 92, 95, 96, 97, 99, 101, 105, 109
- basic research funding by, 74-75
- clinical trials supported by (table), 75
- consensus development in, 144-145
- consensus development meetings of (table), 64
- Office for Medical Applications of Research (OMAR), 16, 63, 85, 94, 98, 100, 109
- role in medical technology assessment, 9, 13
- National Library of Medicine (NLM), 15, 16, 28, 29, 30, 65, 109
- data bases of, 18, 28, 101, 102
- expansion of data base to include more Governmental research reports, 110
- Hepatitis Knowledge Base, 63-64, 100-101, 102
- Lister Hill National Center for Biomedical Communications, 63
- National Science Foundation (NSF), 13, 29, 51
- National Technical Information Service (NTIS), 16, 28, 30, 102
- data base of (table), 122
- NCHSR (see National Center for Health Services Research)
- NIH (see National Institutes of Health)
- NLM (see National Library of Medicine)
- nominal group technique, 62-63

- non-randomized clinical trials, 127
- NSF (see National Science Foundation)
- NTIS (see National Technical Information Service)
- observational studies, 35-38
- Office of Science and Technology (see White House Office of Science and Technology)
- Office of Technology Assessment (OTA), 3, 14, 16, 19, 24, 25, 30, 33, 39, 46, 47, 57, 60, 61, 67, 94, 109, 129
 - acknowledgments to contributors to this report, 195-197
 - conclusions on adequacy of testing for safety and efficacy, 100
 - conclusions on communication of information on medical technologies, 102
 - conclusions on identification of medical technologies, 96, 97, 98
 - conclusions on synthesis phase of assessment, 101
 - functions of, 50
 - health-related reports of, 13
 - methods used in this study, 192-194
 - other volumes produced by this study, **193-194**
- OMAR (see under National Institutes of Health)
- osteosarcoma, 37
- OTA (see Office of Technology Assessment)
- overhead costs, 40
- Pap test program, 40
- peptic ulcer, 4
- percutaneous transluminal coronary angioplasty (PTCA), 26, 87
 - case study of, 168-174
- Peter Bent Brigham Hospital, 78
- phakoemulsification, 82
- Phase I studies, 12, 79
- Phase II studies, 12, 79
- Phase III studies, 12, 79
- plasmapheresis, 78
- policy options, 18, 105-110
 - for congressional oversight, 108-110
 - for coordination of technology assessment, 110
 - for dissemination activities, 109-110
 - for education of researchers, 108
 - for identifying medical technologies for assessment, 109
 - legislative, 106-109
 - organizational, 106-107
 - for private sector oversight, 108
 - for **research** funding, 107-108
 - for synthesizing research information and group decisionmaking activities, 109
 - for testing medical technologies, 109
- policy-related activities, 50-52, 74-86
- President's Commission, 13, 50-52
- prices vs. costs, 40-41
- Professional Standards Review Organizations (PSROs), 13, 80, 92, 95, 97, 98, 101, 105, 106, 109
- Project Share, 29-30
- prospective studies, 10
- PSROs (see Professional Standards Review Organizations)
- psychotherapy, 59, 73
- Public Health Service, 25, 77, 96, 107, 109
 - Health Services Research Coordinating Committee, 84
- radiology, 52, 83
- Rand Corporation, 62
- randomized clinical trials (RCT), 10, 11, 34-35, 39, 57, 74, 78, 91, 93, 105, 106, 109, 127, 128
 - attributes of, 130-131
 - basis for conducting, 149
- RCT (see randomized clinical trials)
- Reiss, John, 192
- research and development (R&D), 11, 15
 - costs of, **40**
 - in development, diffusion, and use of medical technologies, **74-78**
 - Federal activities in, 75-77
 - private sector activities in, **77-78**
 - protection of human subjects, 50-52
- research (see research and development)
- Royal Perth Hospital, 37
- schizophrenia
 - hemodialysis treatment of, 167-168
- SEER program (see under National Cancer Institute)
- Simpson's paradox, 58
- Southwestern Michigan Hospital Council, 27
- spina bifida, 48
- Stanford University, 25
- statistical conclusion validity, 34, 129, 139
- synovectomy, 82
- System Development Corp., 28
- third-party payers, 73, 81-84, 86-87
- tomography (see CT scanning)
- Toxicology Information Online (see TOXLINE)
- TOXLINE, 28
- Veterans Administration, 13, 51, 105, 130
- vital statistics, 25
- voting method, 58, 141
- Wennberg, John, 192
- White House Office of Science and Technology, 13, 51
- Williamson, John, 192
- Winkler, John, 192
- Woolf, Patricia, 192
- Wortman, Paul, 192