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Health Care Technology Assessment in VA

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MDRC
MANAGEMENT DECISION
AND RESEARCH CENTER

VA HSR&D
Health Services Research & Development Service

Health Care Technology Assessment in VA

Primer

VA's Health Services Research and Development Service provides exper-
tise in health services research, a field that examines the effects of organi-
zation, financing and management on a wide range of problems in health
care delivery — quality of care, access, cost and patient outcomes. Its pro-
grams span the continuum of health care research and delivery, from basic
research to the dissemination of research results, and ultimately to the
application of these findings to clinical, managerial and policy decisions.

Health Care Technology Assessment in VA

Clifford Goodman, Ph.D.
Gordon Snider, M.D.
Karen Flynn, D.D.S.

The primer describes the role of technology assessment as a management tool in health care delivery, regulation and payment, and provides a basic framework for understanding technology assessment programs.

Purpose of Primer Series: to help policy makers, managers, clinicians and health services researchers work together to improve the quality and cost-effectiveness of health care for veterans. The primer series is part of a larger set of dissemination initiatives developed by the Department of Veterans Affairs' Management Decision and Research Center in collaboration with the Association for Health Services Research.

Purpose of Health Care Technology Assessment in VA: to introduce the purposes, scope and general approach of technology assessment in health care. The primer describes the role of technology assessment as a management tool in health care delivery, regulation and payment, and provides a basic framework for understanding technology assessment programs. The primer is intended to strengthen the roles of health care decision makers in technology assessment and to help them become more informed users of technology assessments. Rather than an exhaustive text or a how-to manual, this is a general guide to the field. A list of more in-depth reference material is provided in the bibliography.

Suggested Audience: health care professionals involved in technology-related decision-making at the local and national levels. This includes network and hospital managers involved in administration, clinical care, financial and strategic planning, and technology procurement. Other users include health care information specialists, educators and students.

Suggested Uses: n guide for developing assessment requests or evaluating previous assessments, n resource for strategic planning, n technology assessment training programs in health care networks and hospitals, n orientation for members of technology assessment committees, and n curriculum for medical schools, schools of business administration and public health, continuing medical education courses, and other medical and health professional training programs.

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Contributors

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Preface

The Veterans Integrated Service Networks (VISNs) are responsible for achieving the greatest possible health care value with the resources that have been allocated. To fulfill this responsibility, VISN managers will need technology assessment information on an ongoing basis.

Health care cost and inequity of access to care have become dominant themes of public debate in the United States. There is widespread concern that we spend far more on health care than is justified by the overall benefit we achieve. While various approaches to controlling costs and increasing access have been attempted (including political processes, prepaid or capitated insurance coverage, limited access to specialists, practice guidelines, and diagnosis-related groups for hospital reimbursement), none of these approaches has been highly successful.

Health care technology has a paradoxical role in our culture and health care system. It is frequently cited as a significant contributor to unacceptable increases in health care costs. On the other hand, technological innovation is seen as a strength of the United States' health care system and its research and development infrastructure. Both health care providers and consumers tend to want access to any technology that may prove beneficial.

Clinicians, patients and insurers have different motives and expectations regarding whether to adopt and pay for new technologies. Ideally, these decisions should be knowledge-based. However, in the age of information overload even the most informed clinician can find it virtually impossible to keep abreast of all the research results that are relevant to his or her practice. Patients and policy makers may have difficulty interpreting research results. Clinicians, patients and policy makers must deal with the dilemma when multiple studies of the same technology have conflicting results, making the information from these studies difficult to synthesize and interpret.

The Department of Veterans Affairs (VA) is committed to maintaining access to appropriately-used health care technologies and to improving quality of care and outcomes for the veterans it serves. VA actively supports technology assessment processes and the use of technology assessment information to make evidence-based decisions. The Veterans Integrated Service Networks (VISNs) are responsible for achieving the greatest possible health care value with the resources that have been allocated. To fulfill this responsibility, VISN managers will need technology assessment information on an ongoing basis.

Health Care Technology Assessment in VA offers an overview of the processes and uses of health care technology assessment. Readers will find the primer a useful entry point to wider reading and thinking about incorporating evidence into health care delivery decisions. VA decision makers should employ this approach, whenever feasible, in developing assessment requests, evaluating previous assessments and incorporating technology assessment information into the management of health care systems.

Thomas L. Garthwaite, M.D.
Deputy Under Secretary for Health
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Introduction

The Department of Veterans Affairs (VA) cannot stand apart from critical self-examination and, indeed, the Secretary, Under Secretary, Directors of Veterans Integrated Service Networks and hospital managers — are examining all aspects of health care delivery with a sense of urgency. As part of this examination and evaluation process, the Health Services Research and Development Service, through the Management Decision and Research Center (MDRC), is actively engaged in technology assessment and in information dissemination. This primer is part of MDRC's contribution to a broader effort throughout VA to understand how to use technology assessment results for better resource management.

This primer's comprehensive definitions of health care technology and health care technology assessment may prompt questions of how technology assessment is different from other kinds of research. Health care technology assessment is an emerging interdisciplinary field that draws on many other types of inquiry in health care. Rather than attempting to define precisely technology assessment as a single kind of research, it may be more productive to look at it as a process involving several types of actions. These include identifying technologies needing assessment, collecting and analyzing data about technologies, synthesizing existing information and the results of data collection and disseminating findings and recommendations.

Technology assessment may also be seen as an analytic framework that encourages critical thinking about everything we do in health care, constantly reinforcing the need to base decisions and actions on evidence to the greatest extent possible. The reader is encouraged to look at technology assessment information as an everyday tool to support evidence-based health care decision-making.

The primer provides a description of the process of technology assessment. Three appendices offer practical suggestions on where to go for more information on technology assessment.

I commend the authors for producing this primer and hope that network and hospital administrators, physicians, house staff, nurses and many others — inside and outside VA — find it valuable.

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What is health care technology?

Health care technology is the practical application of knowledge to the prevention, diagnosis and treatment of disease.

Health care technology is the practical application of knowledge to the prevention, diagnosis and treatment of disease. Although many health care providers have classified only equipment, devices and other hardware as technology, the discipline of health care technology assessment has embraced a broader definition that also encompasses drugs, clinical procedures and managerial systems. The broad definition recognizes the multiple and complex interactions between health care technologies and the wide range of human activities and social organizations that adopt and incorporate technologies.

Health care technologies can be grouped into the following broad categories:

n **Devices, equipment and supplies.** Examples include cardiac pacemakers, computed tomography (CT) and positron emission tomography (PET) scanners, surgical gloves, diagnostic test kits.

n **Drugs**. Examples include aspirin, beta-blockers, penicillin, vaccines, blood products, colony stimulating factors, monoclonal antibodies.

n **Medical and surgical procedures.** Examples include psychotherapy, coronary angiography, gall bladder removal.

n **Systems of care.** Examples include special care units (e.g. coronary care, medical, surgical and neurological intensive care), rehabilitation programs, screening programs.

n **Support systems.** Examples include paper and electronic patient record systems, telemedicine systems, blood banks, clinical laboratories.

n **Organizational and managerial systems.** Examples include prospective payment using diagnosis-related groups, alternative health care delivery configurations such as vertically integrated health care systems and clinical pathways.

What is health care technology assessment?

Health care technology assessment (HCTA) is the systematic evaluation of the properties and effects of health care technology.

Health care technology assessment (HCTA) is the systematic evaluation of the properties and effects of health care technology. It may involve the investigation of one or more of the following attributes of technologies:

n **Performance characteristics.** Performance characteristics include sensitivity and specificity of diagnostic tests, and conformity with specifications for design, manufacturing, reliability, ease of use and maintenance.

n **Clinical safety.** Safety is a judgment of the acceptability of risk (a measure of the chances of an adverse health outcome and its severity) associated with using a technology in a particular situation.

n **Efficacy.** Efficacy refers to the benefit of using a technology to address a particular problem under ideal conditions (e.g., within the protocol of a carefully managed randomized controlled trial, involving patients meeting narrowly defined criteria, or conducted at a "center of excellence").

n **Effectiveness.** Effectiveness refers to the benefit of using a technology for a particular problem under general or routine conditions (e.g., by a physician in a community hospital treating a variety of patient types).

n **Economic impacts.** Health care technologies can have a wide range of microeconomic and macroeconomic impacts. Microeconomic concerns may include costs, charges or payment levels associated with individual technologies. Cost effectiveness, cost utility and cost benefit analyses compare resource requirements and benefits of technologies for particular applications. Macroeconomic impacts of health care technologies include the impact of new technologies on national health care costs, the effect of technologies on resource allocation among different health programs or among health and non-health sectors, and the effects of new technologies on outpatient versus inpatient care. Other macroeconomic issues that pertain to health care technologies include the effects of regulatory policies, health care reforms and new policies on technological innovation, technological competitiveness, technology transfer and employment.

n **Social, legal, ethical and political impacts.** Many technologies raise social, legal, ethical and political concerns. For example, genetic testing, fertility treatments, organ transplants and life-support systems for the critically ill challenge legal standards and societal norms. Ethical questions continue to prompt improvements in informed consent procedures for patients involved in clinical trials. Allocating scarce resources to technologies that may be expensive, inequitably used or non-curative raises broad social concerns.

Other key concepts in health care technology assessment:

n **Appropriate and medically necessary.** The terms "appropriate" and "medically necessary" often are used to encompass one or more of the attributes discussed above for particular circumstances to which a technology is applied. For example, the appropriateness of a diagnostic test may depend on its safety, effectiveness and cost for a given set of patient indications, clinical settings, resource constraints or availability of other technological options.

n **Evidence-based medicine.** In the U.S. and elsewhere, technology assessment organizations consider most or all of the attributes listed above by synthesizing the available research findings (the "evidence") and other relevant information into technology assessment reports. Increasingly, this involves grading and weighing the available evidence according to its underlying methodological rigor. Evidence-based medicine refers to the practice of medicine that is guided by or based on scientific fact. HCTA is a process in which available evidence is used to formulate findings for guiding technology-related decisions, some of which are for clinical/medical purposes. The terms – evidence-based medicine and HCTA – are related, but not synonymous.

n **Systematic review and meta-analysis.** "Systematic review" and "meta-analysis" are methods used in the synthesis component of technology assessment. Systematic reviews are the result of using scientific methods for identifying, assembling and synthesizing the medical literature. When systematic reviews apply statistical methods for combining the findings of multiple research studies, they are called meta-analyses. (See page 10.)

What is the purpose of health care technology assessment and why is it important?

The purpose of HCTA is to assist health care policy makers, managers and clinicians at local, network and national levels in making informed decisions.

Health care technology assessment information may be particularly useful in supporting decisions when: n a technology has high unit or aggregate cost; n explicit trade-off decisions must be made in allocating resources among technologies; n a technology is highly complex, precedent-setting or involves significant uncertainty; n a proposed provision of a treatment, diagnostic test or medical equipment is innovative or controversial; or n an established technology is associated with significant variations in utilization or outcomes.

An assessment is usually carried out to meet a clearly defined policy, managerial or clinical goal as illustrated below:

n An organization responsible for financing or providing health care (e.g., VA) might request an assessment of the relative merits of medical versus surgical treatment of a particular disease.

n A network director might request an assessment of two leading inter-hospital medical information systems to help decide which would be most appropriate to purchase.

n A VA hospital director who approves patient referrals to other facilities might request a number of assessments to determine what therapies are appropriate for patients with specific medical profiles. The assessment information may also help the director decide whether to acquire a certain technology for the hospital, rather than referring patients to other treatment centers.

n A hospital pharmacy and therapeutics committee might request an assessment of two different drug formulations and dosage schedules (e.g., a less expensive several-times daily formulation versus a much more expensive twice-daily formulation) to inform the development of its hospital guidelines.

n A primary care physician might request an assessment of a test (e.g., spirometry–measurement of lung function) to determine whether the test should be introduced into routine ambulatory care practice.

n An HMO might request an assessment of simultaneous pancreas and kidney transplantation to support the design and interpretation of covered benefits, case management and contracting arrangements with "centers of excellence."

Health care decision makers have a responsibility to ensure the availability of the most effective technologies. They are also responsible for limiting the inappropriate use of technologies, especially in an era of increasingly limited resources.

> **An assessment is usually carried out to meet a clearly defined policy, managerial or clinical goal.**

When are health care technology assessments requested?

Assessments can be requested and conducted at any stage in a technology's life cycle (i.e., stage of development and diffusion). Stages include:

n **conceptual:** in the earliest stages of development;

n **experimental or investigational:** undergoing initial testing and evaluation;

n **pre-established:** adoption of an innovation by certain individuals and institutions;

n **established:** considered to be a standard approach and diffused into general use; and

n **outmoded:** superseded by another technology or demonstrated to be ineffective or harmful.

These stages often are not clearly delineated, and technologies do not necessarily mature through them in a linear fashion. A technology may be established for certain applications and may be investigational for others. A technology once considered obsolete may return to established use for a better defined or entirely different purpose. Technologies often undergo multiple incremental innovations after their acceptance into practice.

Since technology is constantly evolving, HCTA must be viewed as an iterative process. It may be necessary to revisit a technology when competing technologies are developed, the technology itself evolves or new information is introduced. Reassessment may require additional data collection and ongoing assessments may be enhanced with techniques that aggregate results of research.

> **Assessments can be requested and conducted at any stage in a technology's life cycle.**

What role do other organizations play in technology assessment?

A number of organizations in the public and private sectors use HCTA to inform decision-making.

Public sector

n The Food and Drug Administration (FDA) — concerned primarily with safety and efficacy — makes decisions about whether or not to permit the commercial use of drugs, devices and certain other technologies.

n The Department of Veterans Affairs — one of the few federal agencies actively engaged in the delivery of health care — develops disease management programs and makes technology acquisition and management decisions. It also supports a technology assessment program to coordinate assessment activities, conduct selected assessments, and supply senior managers with technology assessment information.

n The Center for Health Care Technology within the Agency for Health Care Policy and Research (AHCPR) supplies the Health Care Financing Administration (HCFA) with information that is used to develop Medicare coverage and reimbursement policies.

n   The National Institutes of Health (NIH) conduct consensus development conferences to define the optimal use of technologies indicated by currently available data.

n   The U.S. Preventive Services Task Force in the Department of Health and Human Services develops preventive services recommendations based explicitly on evidence-based approaches.

n   AHCPR supports the development of patient outcomes research teams (PORTs) and clinical practice guidelines, both of which involve technology assessment.

Private sector

n   Private payers (such as Blue Cross and Blue Shield plans, HMOs, and commercial insurers) support technology assessment programs that use consensus methodologies to support coverage decisions.

n   The University HealthSystem Consortium reviews specific technologies and coordinates small primary data collection studies among its member institutions to support purchasing decisions, guide clinical protocols and select drugs for formularies.

n   A number of private organizations (such as ECRI) offer technology assessment services (e.g., to assist hospitals, payers and others in decision-making).

n   Hospital biomedical engineering departments and pharmacy and therapeutics committees use technology assessment for technology acquisition, management and related activities.

Appendix III lists contact information for many of these organizations.

What is the role of ethics in technology assessment?

Conducting a technology assessment requires careful attention to ethical questions.

The discipline of medical ethics has developed in response to the effects of technology on human interactions and the human condition. Since technology assessment is used to make judgments about what ought to be done with health care technologies, there is significant overlap between it and medical ethics. Conducting a technology assessment requires careful attention to ethical questions, such as:

n   Should all assessments be driven by cost concerns?

n   Are the individuals involved in the selection of topics, the conduct of the assessment, and the use of its results free of conflicts of interest?

n   Are judgments of value implicit in the statement of the assessment problem or the choice of methodology?

n   Are informed consent, patient confidentiality and related means for protecting patient welfare in clinical investigations properly implemented?

n   Do assessments provide means (e.g., in data collection, synthesis and reporting) to determine how technologies challenge prevailing legal standards and societal norms?

n   Are the assessment's recommendations ethically justified?

How is technology assessment conducted?

The ten steps listed below provide a basic framework for conducting a technology assessment. This framework also may be used to guide the development of an assessment request or the evaluation of an assessment. Not all assessments involve each of these steps or conduct them in the same sequence.

Two case examples — one based on VA experience and another from a private sector HMO — illustrate some of the ten steps. In the VA example, the assessment was performed by a VA physician with technical assistance from a VA technology assessment program. In the private sector example, the assessment was performed by an HMO with assistance from a private sector technology assessment consultant, using evidence from the literature and the HMO's internal data sources.

TEN STEPS OF HEALTH CARE TECHNOLOGY ASSESSMENT

1. Identify and rank assessment topics

2. Specify assessment problem

3. Determine locus of assessment

4. Retrieve available evidence

5. Collect primary data (as appropriate)

6. Interpret evidence

7. Synthesize and consolidate evidence

8. Formulate findings and recommendations

9. Disseminate findings and recommendations

10. Monitor impact of assessment reports

Step 1. Identify and rank assessment topics

Processes for soliciting candidate assessment topics and ranking assessment priorities range from being informal to highly formal.

Identifying potential topics. To a large extent, assessment topics are determined, or at least bounded, by the mission or purpose of an organization. For instance, VA's mission includes providing the highest quality health care to eligible veterans. VA policy makers are particularly interested in technologies that address the health care needs of the veteran population.

Ranking topics. Some assessment programs have explicit procedures for setting priorities. Others set priorities in ad hoc or informal ways. Given limited resources for assessment and increased accountability of assessment programs to their respective stakeholders, it is important for assessment programs to clearly articulate how assessment topics are ranked and selected.

The following are examples of criteria — listed in no particular order — that might be used to set assessment priorities:

n high burden of morbidity or mortality;

n large number of patients affected;

n high unit or aggregate cost of a technology or health problem;

n substantial variations in practice;

n high potential to improve health outcomes or reduce health risks;

n availability of sufficient research findings to perform the assessment;

n scientific, professional or public controversy;

n need to make regulatory decision;

n need to make payment decision;

n available findings not widely disseminated or used by practitioners.

Step 2. Specify assessment problem

One of the most important aspects of an assessment is to specify clearly the question(s) to be addressed; this will affect all subsequent aspects of the assessment. Assessment problem statements should recognize the relation of the new technology to existing technology. For example, although a new diagnostic technology may yield superior information it may not affect treatment or improve health outcomes. The team charged with conducting the assessment should have an explicit understanding of the purpose of the assessment and the intended users of the assessment.

The following two examples illustrate the importance of how assessment problems are constructed; the first is flawed, the second is workable.

n **Should our medical center set up a referral mechanism so that patients have access to positron emission tomography (PET) imaging?** The question as stated does not specify the types of patients for whom the technology would be used, the alternatives to the technology, or the kinds of information that the policy maker would find useful. It would be difficult to design and implement an assessment to answer this question.

n **When patients are being diagnosed and staged for cancer, does PET imaging provide superior diagnostic information over more readily available diagnostic technologies such as CT, MRI or SPECT?** This clear and precise assessment question could be productively addressed.

The intended users or target audiences of the assessment report should affect its content, presentation and dissemination strategy. Health care professionals, patients, politicians, researchers, hospital managers, company executives and others have different interests and levels of expertise. Needs regarding the scientific or technical level of reports, the presentation of evidence and findings, and the format (e.g., length and appearance) of reports vary by target audience.

Step 3. Determine locus of assessment

The nature of an assessment problem will affect the determination of the most appropriate organization or group to conduct the assessment.

A comprehensive assessment addressing multiple attributes of a technology can be very resource-intensive. It can require considerable training and experience in the methods of evidence-based medicine. Hospitals, smaller insurers and HMOs often obtain technology assessment reports from organizations that specialize in technology assessment. Larger insurers, HMOs, or health care systems may have internal programs for technology assessment. Such programs usually dedicate a core staff to information retrieval and synthesis, supplemented by clinical and methodologic expertise as needed. In some cases, a health care organization may decide to commission one component of an assessment, such as a systematic review, and perform the other steps in-house.

Factors that influence a HCTA "make or buy" decision include:

n Is an existing assessment available? If an existing assessment is available, does it address the specific issues of concern to the organization? How recently was it conducted? Is the methodology used sufficiently credible?

n If an existing assessment needs to be updated or is not available, do people in the organization have the time and expertise to perform the required data collection and analyses? If a synthesis of existing information is needed, does the organization have database searching capabilities, staff to retrieve full text articles, and staff trained in the conduct of systematic reviews? If new data are needed, does the organization have the requisite resources and expertise?

n What methodology will be used? If a consensus of clinical experts is the preferred methodology, does that consensus need to incorporate and reflect the opinions of the organization's own clinicians? Will local clinicians accept the results and report recommendations if they do not participate in the assessment?

Step 4. Retrieve available evidence

One of the great challenges in HCTA is to assemble all of the evidence relevant to a particular technology before conducting a qualitative or quantitative synthesis. Although some sources are devoted exclusively to health care topics, others cover the sciences more broadly. Multiple sources should be searched to increase the likelihood of retrieving all relevant reports. Useful sources for relevant evidence include:

n computer databases of published literature;

n computer databases of clinical and administrative data;

n printed indexes and directories;

n government reports and monographs;

n reference lists in available studies, reviews and meta-analyses;

n special inventories of reports;

n health newsletters and newspapers;

n company reports; and

n colleagues and other investigators.

One of the great challenges in HCTA is to assemble all of the evidence relevant to a particular technology before conducting a qualitative or quantitative synthesis.

Information specialists at health science libraries can be extremely valuable in assisting with these literature searches. Increasingly, most of the sources are accessible via the Internet. Further information on specific technology assessment information resources is provided in Appendix II.

Step 5. Collect primary data

Compiling evidence for an assessment may entail collecting new primary data after determining that existing evidence will not adequately address the assessment question(s).

Methods for generating new data on the effects of health care technology include:

- large randomized controlled trial (RCT);
- small RCT;
- nonrandomized trial with contemporaneous controls;
- nonrandomized trial with historical controls;
- cohort study;
- case-control study;
- cross-sectional study;
- surveillance (e.g., using databases, registers, or surveys);
- series of consecutive cases; and
- single case report.

These methods are listed in rough order of most to least scientifically rigorous for internal validity, (i.e., for accurately representing the causal relationship between an intervention and an outcome). There are other variations of these methodologic designs and some investigators use different terminology for certain methods. The demand for studies of higher methodological rigor (e.g., RCTs) is increasing among health care technology regulators, payers, providers and other decision makers.

Step 6. Interpret evidence

Evidence interpretation involves classifying the studies, grading the evidence and determining which studies will be included in the synthesis. Assessors should use a systematic approach to critically appraise the quality of the available studies. Interpreting evidence requires knowledge of investigative methods and statistics.

Step 7. Synthesize and consolidate evidence

For many topics in technology assessment, a definitive study that indicates one technology is better than another does not exist. Even where definitive studies do exist, findings from a number of studies often must be combined, synthesized or considered in broader social and economic contexts in order to respond to the particular assessment questions.

Methods used to combine or synthesize findings from different studies include:

- **Non-quantitative literature reviews.** Non-quantitative literature reviews are summaries of existing literature made by one or more authors who select and weigh findings available from the literature. The procedures used to select studies and cognitively weigh them can be quite subjective and poorly documented. Given increased attention to the relative methodological rigor of available

evidence and improvements in quantitative approaches, non-quantitative literature reviews are regarded less often as standard approaches for consolidating evidence.

n **Meta-analysis.** Meta-analysis refers to a group of statistical techniques for combining results of multiple studies to obtain a quantitative estimate of the overall effect of a particular technology on a defined outcome. Meta-analysis may produce a stronger conclusion than would be yielded by any single study. Meta-analysis typically is used for topics that have no definitive studies or topics for which studies disagree. The appropriate application of meta-analytic technologies can be controversial. Although the statistical techniques for combining RCTs have been well defined, such techniques may not account for certain methodological biases when used with the weaker study designs. In all cases, careful attention to the rationale and techniques for pooling study results is essential.

n **Decision analysis.** Decision analysis identifies alternative choices and their associated potential outcomes in a series of sequenced decisions. Decision models often are shown in the form of decision trees with decision points, branching steps, outcomes and values associated with those outcomes. Decision models can be used to:

n predict the distribution of outcomes for patient populations and associated costs of care;

n help develop clinical practice guidelines for specific health problems; and

n predict the likelihood of outcomes of alternative clinical strategies.

n **Group judgment or consensus development.** Group judgement or consensus development has multiple forms and purposes (e.g., to make regulatory, payment and technology acquisition decisions; to formulate practice guidelines; and to define the state-of-the-art of practice). Consensus development refers to discrete group judgment processes that contribute to an assessment, or it can refer to particular consensus-development programs, such as that of the National Institutes of Health (NIH). Ranging from very informal to more structured processes, consensus development is more or less subject to the biases that may arise in group interaction. Consensus processes do not necessarily involve systematic retrieval or critical analysis of the available evidence. However, virtually all HCTA efforts involve group judgment at some juncture, particularly in formulating findings and recommendations.

Step 8. Formulate findings and recommendations

Although the terms "findings" and "recommendations" are sometimes used interchangeably, they have different meanings. Findings are the results or conclusions of an assessment; recommendations are the suggestions, advice, or counsel that follow from the findings. Recommendations can be made in various forms, such as options, practice guidelines or directives.

Assessments should link explicitly the quality of the available evidence to the strength of their findings and recommendations. Doing so facilitates an understanding of the rationale behind the assessment findings and recommendations. It also provides a more substantive basis on which to challenge the assessment as appropriate. Further, it helps assessment programs and decision makers determine if a reassessment is needed as relevant new evidence becomes available.

Recommendations can be made in various forms, such as options, practice guidelines or directives.

Step 9. Disseminate the findings and recommendations

Dissemination strategies depend upon the mission or purpose of the organization sponsoring the assessment. Dissemination should be planned at the outset of an assessment along with other assessment activities and should include a clear description of the target audience as well as appropriate mechanisms to reach them. The costs, time and other resources needed for dissemination should be budgeted accordingly. Dissemination plans do not have to be rigid. The nature of the findings and recommendations themselves may alter the choice of target groups and the types of messages to be delivered. Dissemination should be designed to influence the behavior of relevant decision makers.

Step 10. Monitor impact of assessment reports

The impact of HCTAs, from RCT reports to expert consensus statements, are variable and inconsistently evaluated. Plans for monitoring the impact of an assessment report should be considered in the assessment design.

Some HCTA reports are translated directly into policies with clear and quantifiable impacts, while the findings of some definitive RCTs and authoritative, well-documented assessment reports go unheeded and are not readily adopted into general practice.

As is the case for the technologies that are the subjects of HCTA, disseminated HCTA findings and recommendations can have intended and unintended outcomes. Some of the effects of a HCTA report include:

- acquisition or adoption of a new technology;
- reduction or discontinuation in the use of a technology;
- change in clinician behavior;
- change in patient behavior;
- change in the use rate of a technology;
- change in the organization or delivery of care;
- reallocation of national or regional health care resources;
- change in regulatory policy;
- modification of marketing plan for a technology; and
- change in third-party payment policy.

Two case examples

Two case examples illustrate practical applications of technology assessment. As stated earlier, not all assessments involve the sequence of ten steps outlined in this primer. Each example demonstrates some of the ten steps; the reader is reminded that technology assessment in an iterative process.

In the first case, a VA pulmonologist undertook an assessment of lung volume reduction surgery for emphysema to assist in promoting responsible, evidence-based practice and to enhance quality of care for VA patients. The assessment consisted of a systematic review of the literature, which ultimately resulted in a proposal to a national professional organization to sponsor new data collection efforts.

In the second case, a large HMO used existing assessment information to project utilization and outcomes associated with treatment

for high cholesterol for its enrolled population. It then conducted its own evidence-based synthesis of the literature to modify the treatment recommendations to achieve better outcomes at a lower cost.

Case example:
Technology Assessment of Reduction Pneumoplasty Surgery for Emphysema

Topic identification
A VA Medical Service Chief (a pulmonologist) had been watching the development of a new surgical procedure, reduction pneumoplasty for emphysema, since the first reports were presented at a national meeting in April, 1994. Patients with end-stage chronic obstructive pulmonary disease (COPD), most of whom have emphysema, make up a large share of the practice of pulmonologists. Previously, the only other procedure known to increase lung function in emphysema was lung transplantation. The physician was concerned that the new procedure would diffuse rapidly (including within VA) prior to adequate evaluation of its long term outcomes, institutional support, rehabilitation requirements and optimal patient selection criteria.

Assessment problem(s) and locus of assessment
The physician wanted to conduct a systematic review that would then be used to help set a national technology assessment agenda (through a national professional organization) for the procedure. He wanted to explore the potential usefulness of a multi-center registry. The physician requested assistance from VA's Management Decision and Research Center Technology Assessment Program.

Available evidence
VA's Technology Assessment Program provided the physician:

◻ readings in technology assessment specific to the identified assessment problem, including materials on assessing surgical procedures, critical evaluation of the literature, construction of evidence tables, and the use of registries in technology assessment;

◻ names of contacts at existing registries who could offer advice on the practical aspects of setting up a large-scale, multi-center registry;

◻ assistance in searching databases and generating selection criteria for published articles to be included in the review; and

◻ editorial advice on writing a technology assessment report for submission to a professional journal.

Interpretation, synthesis and consolidation of evidence
The physician produced an evidence-based report summarizing relevant studies.

◻ A surgical team, based at a large lung transplant center, had published its results for the open-chest version of the procedure in a relatively small series of patients (in two peer-reviewed journal articles and four abstracts); there was no early or late mortality in these patients, and there were significant improvements in lung function and quality of life.

◻ A second team using the open-chest procedure had presented its results in one abstract, reporting no mortality and significant lung function improvement in a very small series of patients.

◻ Several surgical teams had published results with a related procedure (thorascopic laser ablation of pulmonary bullae and diffuse emphysema) in a small series of patients; while modest improvement

The physician was concerned that the new procedure would diffuse rapidly (including within VA) in the absence of adequate evaluation of its long term outcomes.

in lung function was reported, the post-operative death rates were as high as 21 percent.

The assessment concluded that short term outcomes of the open-chest procedure in highly selected patients at a treatment center with lung transplantation support and expertise were encouraging. However, no data documenting the procedure's outcomes in other settings were available. In addition, technical details of the procedure and its long term survival and functional benefits remained to be defined, as did the results of the thorascopic laser procedure.

Findings and recommendations
There was sufficient improvement in many patients that a randomized clinical trial — for which some patients would receive the treatment and others would not — raised ethical considerations. A multi-center registry, for which specifics were defined, was proposed. The registry raised no ethical issues, would permit rapid, prospective data collection and evidence-based assessment of many questions. However, because of limited control of bias, a registry would have much less power than a randomized clinical trial.

Epilogue: Some months later, in the course of a feasibility study for a clinical trial of reduction pneumoplasty, a planning meeting was convened with a biostatistician, clinical trial specialists, epidemiologists, thoracic surgeons and pulmonologists. At that meeting, a design for a randomized clinical trial which resolved ethical concerns was developed.

Dissemination
The assessment findings and registry proposal were presented at national meetings and in the peer-reviewed literature. VA's Technology Assessment Program distributed a summary of the assessment to VA network and Medical Center Directors, alerting them to the need for additional information before making the procedure widely available.

For a citation of this case study, refer to Snider (1996) in Appendix I.

Case example:
Technology Assessment of Treatment for High Cholesterol Levels

Topic identification
In pursuit of its mission to maximize the health of the population it serves — subject to resource limitations— a large HMO was preparing to implement high blood cholesterol treatment recommendations issued by the Second Adult Treatment Panel of the National Cholesterol Education Program (NCEP II, 1993).

Assessment problem
The NCEP II treatment guidelines used a simplified risk-assessment protocol. The panel had hoped this simplicity would increase the probability of adoption of their recommendations. The HMO hypothesized that some efficiency may have been sacrificed to achieve NCEP II's simplicity and set out to determine the utility of a more efficient strategy that would categorize patients by relevant risk categories when determining who should get the treatment.

Locus of the assessment
The HMO hired a technology assessment consultant to work with its staff.

> **The HMO. . . set out to determine the utility of a more efficient strategy that would categorize patients by risk when determining who should get the treatment.**

Available evidence and primary data collection
Expected outcomes were assessed for the HMO's population under three scenarios: current practice (status quo); NCEP II recommendations; and the HMO's more risk-sensitive treatment protocol.

The assessment team used the best available evidence from the literature on the epidemiology of different risk factors and the effectiveness of drug treatment. The HMO's information system supplied data on population characteristics and the costs of treatment, which were then used to model the impact of the three alternative protocols.

Synthesis of evidence and findings
n If the HMO were to maintain current practice, it could expect to see 40,600 sudden deaths or myocardial infarctions (MIs) in its enrolled population during the next five years, generating treatment costs of $887 million.

n If the HMO were to adopt the NCEP II treatment recommendations, 35,800 sudden deaths and MIs would be expected (i.e., 4,800 less than with current practice) during the five year period, generating treatment costs of $933 million (i.e., $46 million more than current practice).

n If the HMO were to use the more risk-sensitive protocol, a larger number of sudden deaths and MIs could be prevented. It could accomplish this by treating less than half the number of people who would have been treated under NCEP II recommendations. The HMO could expect 35,500 sudden deaths and MIs (i.e., 5,100 less than current practices and 300 less than NCEP II's protocol) during the five-year period. Treatment costs would be significantly lower with the HMO's risk sensitive protocol ($74 million for cholesterol-lowering drugs plus $775 million for CHD treatment for a total of $850 million); The HMO's protocol would result in savings of $37 million over five years compared to current practice, and savings of $9 million over the NCEP II recommendations.

Recommendations
The assessment team recommended implementation of the more risk-sensitive treatment protocols.

For a citation of this case study, refer to Eddy (1994) in Appendix I.

Concluding remarks

. . . technology assess-ment informs decisions by providing a systematic, thorough evaluation of available information. . .

The primer introduces fundamental concepts of the dynamic field of health care technology assessment. Health care technology assessment methods are evolving and applications for assessment results are increasingly diverse. Broader participation of people from a variety of disciplines and roles in health care is enriching the field. Heightened demand for technology assessment arising from private and public organizations' quest for value in health care, including VA, is pushing the field to evolve keener processes and assessment reports tailored for particular user groups.

Rather than make decisions for policy makers, network and hospital managers or clinicians, technology assessment informs decisions by providing a systematic, thorough evaluation of available information — as permitted by available resources.

Appendix I: Bibliography

For more in-depth information about technology assessment and its role in health care delivery, the following publications may be helpful:

n Banta, H.D., and Luce, B.R. Health Care Technology and its Assessment: An International Perspective. New York: Oxford University Press, 1993.

n Department of Veterans Affairs, Health Services Research and Development Service (in conjunction with Association for Health Services Research). "Technology Assessment and the Cochrane Collaboration," Forum 1996; (suppl): 1-8, February.

n Eddy, D.M. A Manual for Assessing Health Practices and Designing Practice Policies: The Explicit Approach. Philadelphia: American College of Physicians, 1992.

n Eddy, D.M. "Rationing Resources While Improving Quality: How to Get More for Less." Journal of the American Medical Association, 1994; 272 (10):817-24.

n American College of Physicians and British Medical Journal. Evidence-Based Medicine, 1995 1(1) (new medical journal).

n Eysenck, H.J. "Meta-analysis and Its Problems." British Medical Journal, 1994; 309 (6957): 789-92.

n Frazier, H.S. and Mosteller, F., eds. Medicine Worth Paying For: Assessing Medical Innovations. Cambridge: Harvard University Press, 1995.

n Guyatt, G.H., Sackett, D.L., and Cook, D.J. "Users' Guides to the Medical Literature. II. How to Use an Article about Therapy or Prevention." Journal of the American Medical Association, 1993; 270 (21):2598-601.

n Heitman, E., and Sulmasy, D. "Ethical Considerations in Technology Assessment," (paper written for Department of Veterans Affairs, Health Services Research and Development Service, and Association for Health Services Research), 1995, unpublished.

n Hasselblad, V., and McCrory, D.C. "Meta-analytic Tools for Medical Decision Making: A Practical Guide." Medical Decision Making, 1995;15 (1):181-96.

n Institute of Medicine. Assessing Medical Technologies. Washington, DC: National Academy Press, 1985.

n Laird, N.M., and Mosteller, F. "Some Statistical Methods for Combining Experimental Results." International Journal of Technology Assessment in Health Care, 1990; 6 (1):5-30.

n Snider, G.L. "Health Care Technology Assessment of Surgical Procedures: The Case of Reduction Pneumoplasty for Emphysema." American Journal of Respiratory and Critical Care Medicine, 1996; 153 (4 Part 1):1208-13.

n Tunis, S.R. and Gelband, H. "Health Care Technology in the United States." Health Policy, 1994; 30 (1-3):335-96.

n U.S. Congress, Office of Technology Assessment. Identifying Health Technologies That Work: Searching for Evidence. OTA-H-608. Washington, DC: U.S. Government Printing Office, 1994.

Appendix II: Computer databases: sources of information for health care technology assessment

There are hundreds of publicly available computer databases in health care and biomedicine of various types. Bibliographic databases have indexed citations for journal articles and other publications. Factual databases provide information in the form of guidelines for diagnosis and treatment, patient indications and contraindications, and other authoritative information. Referral databases provide information about organizations, services and other information sources.

Examples of large bibliographic databases covering biomedicine are MEDLINE, which is one of more than 40 MEDLARS (Medical Literature and Retrieval System) databases provided by the National Library of Medicine (NLM), and EMBASE (Excerpta Medica) produced by Elsevier. In addition, there are many specialized databases in such areas as AIDS, bioethics, cancer treatment, and pharmaceutical research and development. Many databases are available from vendors that repackage or reformat existing databases.

Two new NLM databases of particular relevance to HCTA are HealthSTAR and HSTAT. HealthSTAR is a bibliographic database for health services research, technology assessment, planning and administration; it includes citations to journal articles, technical and government reports, books and book chapters, meeting abstracts and newspaper articles. HSTAT (Health Services/Technology Assessment Text) includes the full text of practice guidelines, consensus development reports and certain other HCTA reports sponsored by U.S. government agencies.

Examples of clinical trial registries in particular clinical areas are the AIDSTRIALS database and the PDQ database on cancer treatment, both of which are available on MEDLARS. NIH and the Department of Veterans Affairs maintain cross-topic registries of controlled clinical trials sponsored by those respective agencies. The Cochrane Collaboration is an international organization that prepares, maintains and disseminates a database of systematic reviews of RCTs of treatments in more than 20 clinical areas.

See chart on the next page for more extensive listing of information sources.

NLM DATABASES

AIDSDRUGS: descriptions of substances used in AIDS-related trials

AIDSLINE: references to recent AIDS literature

AIDSTRIALS: description of AIDS-related clinical trials

BIOETHICS: references to bioethics literature

CANCERLIT: references to journal literature in cancer

CATLINE: references to books, monographs

DIRLINE: directory of organizations

HSRProj: ongoing health services research projects

HealthSTAR: references to health services research, technology assessment, and planning and administration literature

HSTAT: full text of AHCPR clinical practice guidelines and technology assessment reports, NIH consensus development conference and technology assessment reports, U.S. Preventive Services Task Force Guide to Clinical and Preventive Services, and other federally sponsored guidelines

MEDLINE: references to biomedical journals

PDQ: descriptions of cancer treatment, supportive care, screening, prevention, clinical trials

OTHER DATABASES

EMBASE: references to biomedical journals

SCISEARCH: references to scientific journals

Current Contents: tables of contents of scientific journals

CDC WONDER: data sets and full text of public health reports

*HealthSTAR was formed by the 1996 merger of the Health and HSTAR databases

Appendix III: Contacts for more information

For more information about technology assessment services and resources, the following contacts inside and outside VA may be helpful:

Contacts within VA

n Biomedical engineering departments in VA Medical Centers can provide information on vendors, costs, maintenance requirements and technical specifications for equipment.   VA Headquarters also provides biomedical engineering support for technology assessment and equipment acquisition activities.

Contact: Steven Wexler, M.S., Chief, Biomedical Engineering (138-C2), Veterans Health Administration,
810 Vermont Avenue, N.W., Washington, DC 20420.
Commercial phone: (202) 273-5881
E-mail: wexler@101cmoob.med.dvacm.gov

n Pharmacy and therapeutics committees at VA Medical Centers evaluate drugs for inclusion in formularies. VA Headquarters Clinical Pharmacy is one of VA's contacts (along with the MDRC Technology Assessment Program, below) for the University HealthSystem Consortium Technology Assessment and Drug Monograph Programs.

Contact: Andy Muniz, M.S., Chief of Field Operations, Pharmacy Service (111-H),
Veterans Health Administration, 810 Vermont Avenue, N.W., Washington, DC 20420.
Commercial phone: (202) 565-5302
E-mail: muniz.andrew@forum.va.gov

n VA's Technology Assessment Program in the Management Decision and Research Center, supplies technology assessment information (updated existing assessments from other national and international technology assessment agencies, systematic reviews on request to Network directors, support for Medical Center and Network assessment activities, and contacts with other VA technology assessment offices), and conducts major assessments for the VA system (e.g. effectiveness of positron emission tomography as a diagnostic procedure). The Program supports and works closely with the San Antonio VAMC Cochrane Center (see below).

Contact: Karen Flynn, D.D.S., Program Manager, VA Medical Center (152-M),
150 South Huntington Avenue, Boston, MA 02130.
Commercial phone: (617) 278-4469
E-mail: flynn.karen@forum.va.gov

n The San Antonio VAMC Cochrane Center, a component of the international Cochrane Collaboration, supports the Collaborative Review Groups that produce Cochrane systematic reviews and trains interested VA investigators in the Collaboration methods. The Center maintains databases of existing reviews, review groups and of randomized clinical trials in some specified areas.

Contact: Gilbert Ramirez, Ph.D., Co-Director, San Antonio Cochrane Center (11C6),
Audie L. Murphy Memorial Veterans Hospital,
7400 Merton Minter Boulevard, San Antonio, TX 78284.
Commercial phone: (210) 617-5190.
E-mail: gramirez@merece.uthscsa.edu

n The Hybrid Open Systems Technologies (HOST) program evaluates commercial information on technologies and software for integration with the Decentralized Hospital Computer Program.

Contact: Kathleen Meyers, VA HOST Program Office Coordinator (192-8),
VA Medical Center, Martinsburg, WV 25401.
Commercial phone: (304) 264-4485.
E-mail: meyers.kathleen@forum.va.gov

n The National Center for Cost Containment (NCCC) generates models for efficient resource allocation for use by decision makers throughout VA. NCCC focuses on comparative data analyses (e.g. erythropoietin utilization and costs at a number of VA dialysis sites), protocols and guidelines (e.g. Home Oxygen Program Guidance), and an information clearinghouse for policies, practices, and methods (National Laboratory Resource Guide).

Contact: Christian L. Houterman, M.S., M.B.A., Technology Assessment Coordinator,
National Center for Cost Containment, Veterans Health Administration,
5000 West National Avenue, Milwaukee, WI 53295.
Commercial phone: (414) 384-2000, extension 2356
E-mail: houterman.christian@forum.va.gov

Contacts outside VA

n A wide range of existing technology assessments from national and international agencies are available in the public domain. These include assessments from: AHCPR/Center for Health Care Technology; National Institutes of Health/Office of Medical Applications of Research (consensus development conferences); U.S. Preventive Services Task Force; American College of Physicians; American Medical Association's DATTA program; and agencies in Canada, United Kingdom, France, Spain, Sweden, Australia, and Netherlands.

VA's Management Decision and Research Center (MDRC) Technology Assessment Program maintains a library of these assessments for use by VA decision makers.

Contact: Karen Flynn, D.D.S., Program Manager, VA Medical Center (152-M),
150 South Huntington Avenue, Boston, MA 02130.
Commercial phone: (617) 278-4469
E-mail: flynn.karen@forum.va.gov

A number of private sector and nonprofit agencies make technology assessment reports and services available for purchase:

n The Blue Cross and Blue Shield Association's Technology Evaluation Center (TEC) evaluates technologies to determine their eligibility for coverage by BC and BS plans. TEC reports are published in cooperation with Kaiser Foundation Health Plan and Southern California Permanente Medical Group, and are available for purchase.

Contact: Ellen Pearson, TEC Marketing Director, Blue Cross and Blue Shield Association,
676 North St. Clair Street, Chicago, IL 60611.
Phone: (512) 440-6080

n ECRI is a nonprofit health services research agency and a Collaborating Center of the World Health Organization that operates a technology assessment service and maintains a technology assessment bibliographic database. A variety of health care organizations commission its evidence-based technology assessment reports.

Contact: ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462.
Phone: (610) 825-6000

n Hayes Incorporated provides several kinds of technology assessment information to subscribers. These include: the results of literature database searches, information on the regulatory status of technologies and qualitative syntheses of existing information.

Contact: Pat Dehan Williamson, Account Executive, Hayes Incorporated,
P.O. Box 190, Worcester, PA 19490.
Phone: (215) 584-8354

Reader comments

MDRC, AHSR and the authors are interested in your comments on Health Care Technology Assessment in VA, the primer series in general and any suggestions for future primer topics. Please copy and complete the form below and mail or fax to:

Management Decision and Research Center (152-M)
VA Medical Center
150 So. Huntington Avenue
Boston, MA 02130

Fax (617) 278-4438

Name:_____

Title:_____

Address:_____

_____

_____

_____

Telephone:_____Fax: _____

Comments:_____

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