

EMS Technology Assessment Template



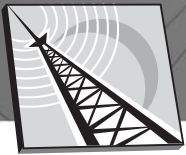


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INTRODUCTION

New medical devices and information technologies are being proposed and marketed to Emergency Medical Services (EMS) on an ongoing basis. EMS agencies, systems, and EMS medical directors are regularly faced with the responsibility of determining which new technologies should be adopted for patient care. In addition, they are also faced with having access to new types of information about emergencies, which are available from third parties, and could be provided to various components of the emergency response chain (e.g., 9-1-1, EMS, hospitals). Decisions about the value of these offerings are often made in a relative vacuum without objective data to determine the value of the new technology.

Although the Food and Drug Administration (FDA) approval of new devices is required before introduction, the FDA allows approval of devices that are “substantially equivalent” to previously approved devices based on the FDA 510(k) process.¹ A medical device approved based on the 510(k) process is not required to have demonstrated efficacy or proof of superiority over previously existing products. The FDA also does not address the important issues of interoperability and open architecture as they apply to the EMS environment.

Technology assessment can be a very complicated process. The “gold standard” for clinical research evaluation of new therapies is traditionally the randomized controlled trial (RCT). The RCT is generally costly and difficult to produce. It is not feasible to expect RCT levels of evidence for each incremental change or improvement of a patient care device.

In addition to the RCT, there may be other types of evaluation that could provide sufficient evidence for the EMS technology and information consumer to make an informed decision in making investments in new technology. Even when data is available, it often relates to only a surrogate intermediate outcome measure rather than the end-patient outcome. Although not ideal, evaluation using an intermediate measure is a far simpler and less expensive undertaking than true RCT outcomes research. The advent of an emergency medical response

record, an electronically tallied set of events that could be tracked seamlessly through the various components of the health care system from initiation of care to patient outcome, would help to facilitate quality, low-cost EMS research.

Consumers of EMS technology would benefit from a guide designed to assist in the evaluation of new technology. This guide would help the consumer to ask informed questions when considering new technologies. Device manufacturers could also make use of a guide which describes the types of evidence to be developed to demonstrate the benefit of the device being marketed to EMS. Information technology vendors could use a guide that helps explain the needs and requirements of EMS technology consumers.

NHTSA and the National Association of EMS Physicians (NAEMSP) have jointly established the Technology and EMS Project’s Technical Consultation Committee (TCC). This group, comprised of experienced EMS personnel, administrators and medical directors as well as industry representatives, developed the EMS Technology Assessment Template contained in this document. It can be used by EMS technology developers, manufacturers, and consumers in the evaluation of new technology. The template may also help guide manufacturers and EMS technology consumers when considering the development of trials to evaluate the performance of new technology.

This technology assessment template is designed to evaluate information technology and EMS devices that provide data about patients, evaluation-oriented clinical patient information, or decision support tools. The template may also be used by consumers to determine assessment criteria for other types of EMS equipment and treatments.

This technology assessment template consists of two major sections followed by a scoring worksheet. Section A is a descriptive section and presents information about the technology that may not have peer-reviewed

1. Food and Drug Administration, Department of Health and Human Services. 510 (k) process. <http://www.fda.gov/cdrh/510khome.html>.

literature support. The information presented in this section may be theoretical, presumptive, or in many cases, an educated guess.

Section B asks for the objective literature and evidentiary evaluation of the technology, and describes levels and potential types of evaluation to be performed. Most technologies will have a very limited number of objective evaluations reported.

Section C is for use by the TCC, medical director, or EMS system to summarize and score the information provided through the use of the template. It starts with a summary of Section A. This is followed by a weighting of the four major components of the evaluation. Those doing the assessment will need to make a subjective judgment as to the importance of each of the components of the evaluation, as each medical device or information technology being assessed or compared will impact an EMS system differently. The available supportive literature from Section B is then rated. The composite score is the product of the assigned weights and literature evaluation scores.

By calculating a composite score, the template can be used to make a recommendation about the utility of the medical device or information technology before it is deployed in EMS. This document offers a scoring method that can be used to rate a device or information technology that can augment other alternative methods chosen to rate the product being evaluated.

As a new tool, the EMS Technology Evaluation Template has limitations. Not all the items in Section A and B will be applicable to every device or information technology being evaluated. Many may not apply to any individual device or information technology. Conversely, the items in Section A and Section B may not include all the aspects of the device or information technology that should be evaluated. There may be additional items that could be useful.

The final section, a literature review, presents journal, book and Internet references used during the development of this template as well as examples of various other technology assessment tools. Comments, summaries, and excerpts of these resources are included.

This document is designed as a tool for EMS medical directors, administrators, and organizations whose job it is to make decisions about medical device and information technology adoption. The goal is for this tool to serve as a starting point in an evolution toward the use of evidence-based decisions in the deployment of new technologies in the prehospital arena.



SECTION A: Descriptive Section

This section describes components of the technology or information source being assessed. Some items ask for assumptions and descriptions that may or may not have literature support. The descriptive section may be used to discuss potential pros and cons of the technology being evaluated.

Criteria	Description
<p>1) Type/purpose of technology</p>	<p>Provide a description of the technology being assessed. Explain the basic concepts behind the technology and provide an overview of its purpose.</p>
<p>2) Origin of technology</p>	<p>Describe the origin of the technology. Is this technology new, a modification of an existing technology, or designed as a replacement for an existing technology? If it is an information technology, is it offering new information about a patient, or a new analysis of information from a patient? Does it require special tools to receive the information?</p>
<p>3) Utility – Clinical setting</p>	<p>Describe the clinical setting in which the technology is designed to be used. Is this technology designed to be used in all clinical settings or are there specific settings that might have greater potential benefit than others? Examples may include differences in population distribution such as urban, rural or frontier. Examples may also include provider level specific technologies. The technology may be applicable to all levels of provider or may be geared toward ALS, BLS, or air medical providers. Is there a specific niche in which the technology may provide benefit?</p>
<p>4) System issues</p>	<p>Provide a description of the system changes that will be required to take advantage of the technology. Discuss the impact of the technology on the following:</p> <ul style="list-style-type: none"> • Indications for use • Time required for use • Utility in a mobile environment (moving ambulance or air unit) • Effect on EMS time intervals (e.g., scene time, transport time) • Frequency of potential use • Personnel training level required (9-1-1, FR, BLS, ALS) • Training required, maintenance of skills, evaluation of competence

Criteria	Description
<p>4) System issues <i>(continued)</i></p>	<ul style="list-style-type: none"> • Infrastructure changes needed to use the technology • New institutional or communications changes necessary to use the technology • IT interfaces required to be developed • Ownership of the incident data; availability of it to researchers • Political or other potential obstacles to implementation • Applicability to special populations, i.e., pediatric, geriatric or bariatric populations • IT decision support tools required to maximize the value of this information in concert with other data
<p>5) Cost</p>	<p>Describe the direct and indirect costs associated with the deployment and uses of the technology. Discuss costs associated with required changes in the following areas:</p> <ul style="list-style-type: none"> • Infrastructure changes • Effect on costs of various emergency response participants and aggregate costs for the system • 9-1-1 • EMS system • Implementation • Training, initial and new personnel • Recurrent costs: <ul style="list-style-type: none"> • Training • Equipment • Replacement • Disposable components • Quality review • Emergency departments • Other emergency agencies • Private sector (e.g., insurance) • Reimbursement issues



SECTION A: Descriptive Section *(continued)*

Criteria	Description
<p>6) Potential benefit</p>	<p>Describe how this technology will provide benefit to the patient, EMS provider, or EMS system and other affected parties. Discuss the effect of the technology on the following:</p> <ul style="list-style-type: none"> • Death/Mortality • Disease/Injury/Morbidity • Discomfort • Disability • Dissatisfaction • EMS, 9-1-1, hospital and other response costs, i.e., system costs • Time to definitive treatment • Reduced infrastructure damage • Resource impacts • Focused resource utilization • Productivity impact • Medical cost reduction • Reduced liability for response entities
<p>7) Potential harm</p>	<p>Describe any potential harm to the patient, EMS provider or EMS system. Discuss the effect of the technology on the following:</p> <ul style="list-style-type: none"> • Death/Mortality • Disease/Injury/Morbidity • Complications of treatment <ul style="list-style-type: none"> • Discomfort • Disability • Dissatisfaction • Medical costs • Effect on EMS intervals • Effect on time to definitive treatment • Potential increased liability

Criteria	Description
<p>8) Interoperability</p>	<p>Describe the information output of the technology and how it integrates into the EMS system. Is the information format proprietary or can it be freely manipulated within the 9-1-1, hospital, and EMS systems? Discuss the following:</p> <ul style="list-style-type: none"> • Data format; compliance with national and international XML standards – e.g., NEMESIS • Interface between device and personnel • Interface between device and other devices, applications and systems not owned by the vendor; does it comply with open architecture? Is the vendor actively willing to interface with third-party systems? • Communications interoperability • Data messaging capability / interoperability • Rationale for the communications band used – i.e., cellular, VHF, UHF, internet. • Techniques to analyze and store the data • Techniques to use the data to improve the system • Does the system own the data? • For information, patient data, and reporting devices, does the client have the ability to modify fields as needed? • How customizable is the product: initially and ongoing?
<p>9) Vendor qualifications and additional product issues</p>	<ul style="list-style-type: none"> • Company or supplier qualifications • Projected product life span • Ease of product upgrade • Customizability: initially and ongoing (future modifications) • Support available and associated costs <ul style="list-style-type: none"> • Availability and size of technical support staff • Length of contracts available • Warranty • Availability of replacement parts or repair <ul style="list-style-type: none"> • On-site versus send in • Cost of ownership • Financial stability of the vendor • Summarize MAUDE¹ database reported issues

1. Food and Drug Administration, Department of Health and Human Services. MAUDE database. www.fda.gov/cdh/maude.



SECTION B: Technology Assessment – Evaluation of the Literature

Ideally, a technology has a scientific basis for evaluation. The studies and evaluations may address a number of different issues related to implementation and use of the technology. The level of the evidence for each item may vary significantly or may not have been evaluated. New sources of data are unlikely to have such an evaluation. Decision support tools should, however be grounded in analysis of a significant number of events.

The levels of evidence may be described in a number of different fashions. The 2005 American Heart Association (AHA) guidelines use the following descriptions for the levels of evidence used to support its guidelines:

AHA Guidelines: Levels of Evidence	
Evidence	Definition
Level 1	Randomized clinical trial or meta-analyses of multiple clinical trials with substantial treatment effects
Level 2	Randomized clinical trials with smaller or less significant treatment effects
Level 3	Prospective, controlled, nonrandomized cohort studies
Level 4	Historic, nonrandomized cohort or case-control studies
Level 5	Case series; patients compiled in serial fashion, control group lacking
Level 6	Animal studies or mechanical model studies
Level 7	Extrapolations from existing data collected for other purposes, theoretical analyses
Level 8	Rational conjecture (common sense); common practices accepted before evidence-based guidelines

For the technology being assessed, a thorough literature search and description of all of the pertinent studies, as well as classification of the studies based on the above levels of evidence should be provided.

Criteria	Description
1) Existing evaluations	Describe all existing studies and cite all literature directly or indirectly related to the technology and/or information being assessed.
2) Efficacy	<p>Describe the performance of the technology under ideal or study conditions. Provide any data related to the following:</p> <ul style="list-style-type: none"> • Sensitivity • Specificity • False positive/negative rates • Mechanical failure modes • Durability <p>If the measures above do not directly apply to the technology, provide any information available that might be used in assessing the technology, including:</p> <ul style="list-style-type: none"> • Success rate of intervention

Criteria	Description
<p>3) Effectiveness</p>	<p>Describe the performance of the technology and/or information under routine or real world conditions. Describe any patient outcome or other literature related to the wide spread use of the technology in and across EMS and emergency response systems. Describe any literature related to the following:</p> <ul style="list-style-type: none"> • Wide distribution potential benefit/harm • Wide distribution costs • Potential lives saved • Potential decreased morbidity • Functionality
<p>4) Economic impact</p>	<p>Describe any literature which discusses a cost/benefit analysis of the technology. Describe literature related to the following:</p> <ul style="list-style-type: none"> • Cost per potential benefit • Number needed to treat per unit of benefit • Number needed to treat per unit of harm <p>Describe any other information related to any of the following:</p> <ul style="list-style-type: none"> • Cost/benefit • Cost/effectiveness • Cost/utility
<p>5) Further evaluation recommended</p>	<p>Discuss any further studies that would assist in the evaluation of the technology. Discuss the following in relation to this item:</p> <ul style="list-style-type: none"> • Studies needed to evaluate technology • Cost of evaluation • Number of patient evaluations necessary to demonstrate efficacy (power evaluation) • Risk of evaluation • Ownership of the incident data • Availability of data to researchers



SECTION C: Evaluation Worksheet

The evaluation worksheet is designed to be used by groups, manufacturers, EMS agencies, systems, or EMS medical directors to tabulate a technology assessment. There are both subjective and objective components which contribute to the overall score and resultant recommendation. They are as follows:

1) Technology description

- a) Provide a general description of the technology based on Sections A.1. through A.3, included in table on page four.

- b) Describe necessary system changes and costs related to implementation of the technology based on Sections A.4. and A.5, included in tables on page five.

- c) Describe the proposed benefit and potential harm of the technology based on Sections A.6. and A.7, included in table on page six.

- d) Describe the data output from the device, if applicable. Describe factors that will affect the use of the data in and out of the local EMS system based on Section A.8, included in table on page seven.

2) Weight of components of the technology assessment

Each technology being evaluated may have different strengths/weaknesses and different levels of supporting evidence. Based on the descriptive summary in Section B found on pages eight and nine, a subjective determination will need to be made as to the relative value of the following items:

Item	Weight
1) Existing evaluations	
2) Efficacy	
3) Effectiveness	
4) Economic impact	

Assign a relative value on a 1–10 scale with 1 being essential, 10 being meaningless.

3) Evaluation of the technology

Evaluate the weight of evidence for each of the components of the evaluation using the AHA scale of weight 1 – 8 (See table entitled, “Levels of Evidence” on page eight). Give a score to each of the following items:

Item	Weight
1) Existing evaluations	
2) Efficacy	
3) Effectiveness	
4) Economic impact	

4) Scoring the technology

Record the weight and evaluation for each component of the evaluation:

Evaluation item	Weight	X	Evaluation Score	=	Product
1) Existing evaluations		X		=	
2) Efficacy		X		=	
3) Effectiveness		X		=	
4) Economic impact		X		=	
Composite Score					



SECTION C: Evaluation Worksheet *(continued)*

4) Scoring the technology *(continued)*

Describe the need for further evaluations for this technology. This may come from Section B.5, found on page nine, or may be elucidated as part of the evaluation process.

5) Recommendation

Based on the Composite Score, make one of the following recommendations:

1) Recommend without reservation

The technology or information source is a valuable addition to EMS practice. It is safe. It has been shown to be effective in established EMS practice. There is a clear benefit of the technology that outweighs the cost to the system.

2) Recommend with recommendation for further evaluation

The technology or information source will probably be a valuable addition to EMS practice. It is safe. It appears to be efficacious; however, it needs further study to be shown effective in established EMS practice. There is a potential benefit of the technology that may outweigh the cost to the system.

3) Recommend in limited application

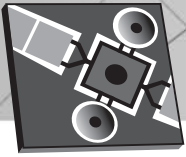
The technology or information source does not have sufficient evidence to recommend widespread implementation. The technology is safe. It appears to be efficacious in a specific setting. In this setting the potential benefit of the technology may outweigh the cost to the system.

4) Insufficient information to make a recommendation

There is not enough information available to make a specific recommendation. It appears safe. It does not have enough evaluation to determine it to be either efficacious or effective. There is not enough information to determine if there is a benefit that outweighs the cost.

5) Not recommended

The technology or information source has deficits that may include: lack of safety, not efficacious or effective, adverse cost/benefit ratio. It does not fit into EMS practice.



SECTION D: References With Comments

Journal Articles

1. **Physiologic monitoring systems.** *Health Devices*. Jan-Feb 1999;28(1-2):6-77.

This article describes a structured assessment of monitoring technology which is not directly applicable to the EMS Technology Assessment project. There is an interesting Health Devices Rating System:

Acceptable - Preferred. A product with this rating is considered outstanding and has few, if any, deficiencies and has significant advantages over the other evaluated units.

Acceptable. A product with this rating meets all major performance and safety criteria and has no serious shortcomings.

Conditionally Acceptable. A product with this rating can be used safely if the user takes corrective measures to overcome a basic performance or safety shortcoming. Corrective measures range from special training (e.g., to stress the importance of certain operating instructions) to ordering an upgrade or a modified unit. If the necessary changes are made, this product is rated Acceptable, and its ranking among other evaluated units will usually depend on additional factors. When the conditions are met, such a device may even be preferred over units rated Acceptable. When the conditions are not met, the product fails to meet significant and commonly accepted criteria for performance (e.g., in an accepted standard) or poses critical safety risks, and it is rated Unacceptable.

Acceptable - Not recommended. A product with this rating does what it is intended to do, but its performance may be significantly poorer, it may be more difficult to use or clean, or it may be less suitable for a specific application than an Acceptable product. If you own a unit that we rate Acceptable - Not Recommended, it is safe to use, and you do not have to withdraw it from service, however, we recommended against purchasing this product unless overriding considerations in your hospital or for your applications warrant it.

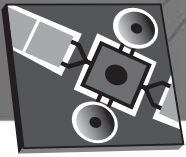
Conditionally Acceptable - Not Recommended. Even when the conditions for acceptability are met, a product with this rating is still rated Acceptable - Not Recommended. Also, such a unit may have conditions that are difficult to comply with - for example, the necessary corrective actions may be so cumbersome or time-consuming to perform that we do not believe that they justify the effort.

Unacceptable. A product with this rating fails to meet significant and commonly accepted criteria for performance (e.g., in an accepted standard) or poses critical safety risks. A hospital that does not own such a unit should not purchase it, barring compelling reasons. If your hospital has a unit that we have rated Unacceptable, review the risks of continuing to use it. Consider whether a modification of change in procedure is possible, and provide for a replacement in future budgets. If you decide to purchase or continue to use the product, carefully document the basis for your actions and the precautionary measures you undertake to minimize risks.

2. **Adang, E.M., Dirksen, C.D., Engel, G.L., & Baeten, C.G. Medical technology assessment: economic evaluation of new technologies.** *Br J Hosp Med*. Jun 7-20 1995;53(11):563-566.

Includes a discussion of:

- Cost-benefit
- Cost-effectiveness
- Cost-utility



SECTION D: References With Comments (*continued*)

3. **Ahrens, T. Impact of technology on costs and patient outcome. *Crit Care Nurs Clin North Am.* Mar 1998;10(1):117-125.**

Includes a template for evaluating the economic impact of a technology (p. 123)

Questions include:

- What will the technology do?
- What parameters will be reduced or eliminated by the technology?
- What clinical complications can be avoided by the technology?
- Educational costs associated with the technology
- Potential complications associated with using the technology
- Barriers to implementing technology
- Economic impact

4. **Brown, I.T., Smale, A., Verma, A., & Momandwall, S. Medical technology horizon scanning. *Australas Phys Eng Sci Med.* Sep 2005;28(3):200-203.**

Methodology table for searching the literature. Table on page 202.

5. **Clark, R.H. The safe introduction of new technologies into neonatal medicine. *Clin Perinatol.* Sep 1996;23(3):519-527.**

Template for technology introduction into neonatal medicine.

Steps to introduce a new tool:

- Literature review
- Determine if the new therapy will lead to an improvement in care
- Develop a team
- Define specific goals
 - Educational
 - Study versus no study
 - Approval given by human investigations committee
 - Approval given by the FDA
- Identify study managers and educators
- Consult the experts
- Test the therapy and measure outcomes

6. **Cutler, D.M., & McClellan, M. Is technological change in medicine worth it? *Health Aff (Millwood).* Sep-Oct 2001;20(5):11-29.**

Cost-benefit analysis methods presented and several case studies are discussed.

The Quality-adjusted life year (QALY) approach is discussed.

QALY is assumed to be worth \$100,000

7. **Davidoff, A.J., & Powe, N.R. The role of perspective in defining economic measures for the evaluation of medical technology. *Int J Technol Assess Health Care*. Winter 1996;12(1):9-21.**

A discussion of various perspectives for determining the cost associated with a new technology

The perspectives included:

- Provider
- Insurer
- Individual
- Society
- Taxpayer
- State or local government
- Employer

8. **Diamond, G.A., & Denton, T.A. Alternative perspectives on the biased foundations of medical technology assessment. *Ann Intern Med*. Mar 15 1993;118(6):455-464.**

Effective discussion of:

- Efficacy versus effectiveness
- Statistical significance versus clinical importance
- Objective versus Subjective outcomes

9. **Fleisher, L.A., Mantha, S., & Roizen, M.F. Medical technology assessment: an overview. *Anesth Analg*. Dec 1998;87(6):1271-1282.**

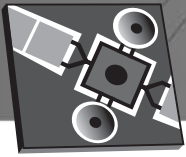
A good overview of Technology Assessment

Table on page 1275 presents examples of outcomes and measures of effectiveness:

- Mortality
- Morbidity
 - Major
 - Myocardial infarction
 - Pneumonia
 - Pulmonary Embolism
 - Minor
 - Nausea/Vomiting
 - Readmission
- Patient satisfaction
- Quality of life

10. **Ilsley, A.H., & Runciman, W.B. Assessment and evaluation of devices: an analysis of organisations providing information of comparative evaluation studies. *Anaesth Intensive Care*. Feb 1988;16(1):16-18.**

Discussion of organizations such as the Emergency Care Research Institute. One of the organization's publications, "Health Devices," is discussed. An example of a rating scale from Health Devices is listed in reference #1.



SECTION D: References With Comments (*continued*)

11. Jonsson, B. Economic evaluation of health care technologies. *Acta Endocrinol (Copenh)*. Jun 1993;128 Suppl 2:50-54.

Very good review paper that includes a section on the Characteristics of Economic Evaluation

- Types of economic valuation
- Cost-minimization analysis - identical outcome
 - Cost-of-illness study
- Cost-effectiveness analysis - one-dimensional physical outcome measure
 - Calculation on costs/Quality of Life-Year gain
- Cost-utility analysis - multidimensional outcome measure
- Cost-benefit analysis - monetary outcome measure
 - Willingness to pay - contingent valuation

12. Lang, A.C. Technology and health system reform. *Int Anesthesiol Clin*. Fall 1995;33(4):119-132.

Multidimensional discussion of technology assessment and system issues
Includes an introduction to cost-effectiveness, page 125.

What Is Cost-Effective?

There are three ways to meet the test of cost-effectiveness:

- Be at least as effective as another technology, but less costly.
- Be more immediately effective, cost more, but have significantly better outcomes.
- Be less costly and less effective, but patient outcomes do not justify alternative (more costly) technology.

The definitions usually applied to these tests include:

- Safety is the judgment of the acceptability of risk of using a technology in a specific situation.
- Clinical effectiveness refers to the medical technology used to improve patient's clinical status and use of the particular technology that demonstrates an advantage over alternative technologies.
- Outcomes combine effectiveness, safety and quality of life measures.
- Cost-effectiveness is outcomes versus costs, where cost is in monetary terms, and outcomes is quantitative terms.
- Diffusion research and development to general applications.

The article also presents the Blue Cross and Blue Shield Association medical technology coverage criteria (page 127):

- 1) The technology must have final approval from the appropriate governmental regulatory bodies.
- 2) The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- 3) The technology must improve the health outcome.
- 4) The technology must be as beneficial as any established alternatives.
- 5) The improvement must be attainable outside the investigational settings.
- 6) The technology must be cost-effective.

13. Mullahy, J. What you don't know can't hurt you? Statistical issues and standards for medical technology evaluation. *Med Care*. Dec 1996;34(12 Suppl):DS124-135.

Good article that discusses the statistical complications of performing good cost-effectiveness analysis. It discussed recent advances in statistical design. (From page DS124):

The various statistical aspects of cost-effectiveness analysis (CEA) are sufficiently complex that designing standards to govern all such statistical analyses is likely to be futile if the objective of such standard setting is ultimately to provide information that will improve the allocation of resources. There is sufficient uncertainty as to the first-order issues of which cost measures/ data to use, which outcomes are most relevant from the perspective of resource allocation, etc., that setting standards to govern the second-order issues of which statistical methodologies might best be employed to analyze such problems seems counterintuitive at this point in time.

Additionally from page DS125:

Any movement toward including in promulgated standards the statistical conduct of CEA studies should, if nothing else, recognize that main point in this discussion: good statistical CEA is an enormously complex undertaking.

It also outlines the steps involved in an applied statistical exercise:

- Specify the objectives of the analysis
- Specify the decision criterion
- Amass the data
- Statistical analysis, estimation and inference

14. Pearl, W.S. A hierarchical outcomes approach to test assessment. *Ann Emerg Med*. Jan 1999;33(1):77-84.

This article presents a template for the evaluation of diagnostic tests. This template has some direct applicability to the EMS Technology Assessment project. Some of the items are items which relate to our project.

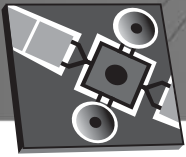
The endpoints for diagnostic test assessment include:

- Level 1. Technical efficacy
- Level 2. Diagnostic accuracy efficacy
- Level 3. Diagnostic thinking efficacy
- Level 4. Therapeutic efficacy
- Level 5. Patient outcome efficacy
- Level 6. Societal efficacy

15. Seifan, A., & Shemer. J. Economic evaluation of medical technologies. *Isr Med Assoc J*. Feb 2005;7(2):67-70.

Good article that includes a discussion of the popular methodologies for economic evaluations of medical technologies (EEMT). Includes a table on p. 69 that describes the following methodologies and provides an example of each:

- Cost-minimization
- Cost-benefit
- Cost-effectiveness
- Cost-utility



SECTION D: References With Comments *(continued)*

16. Shemer, J., Abadi-Korek, I., & Seifan, A. **Medical technology management: bridging the gap between theory and practice.** *Isr Med Assoc J.* Apr 2005;7(4):211-215.

Nice discussion about the limitations of an Electronic Equipment Maintenance Training System, its potential, and ethical issues.

17. **2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.** *Circulation.* 2005;112:IV-1-IV-2.

The introduction to the 2005 AHA guidelines describes the levels of evidence used by AHA to evaluate its recommendations for the various components evaluated.

Books

- 1) IOM (Institute of Medicine). *Assessing Medical Technologies.* Committee for Evaluating Medical Technologies in Clinical Use, Division of Health Sciences Policy, and Division of Health Promotion and Disease Prevention. 1985. Washington, D.C.: National Academy Press.

Comprehensive but older text on medical technology assessment, including techniques.

- 2) Annetine C. Gelijns and Holly V. Dawkins, editors. *Adopting New Medical Technology / Committee on Technological Innovation in Medicine, Medical innovations at the crossroads: v. 4 "Proceedings of the fourth workshop in the series "Examining coverage and adoption decisions about medical technologies," held in Washington, DC on September 18-19, 1992."* 1994. Institute of Medicine. Washington, D.C.: National Academy Press.

The book contains several examples of techniques of technology assessment, although no clear criteria are provided. Good discussions; may be helpful to some extent.

Internet References

- 1) Southern Nevada Health District, CCHD EMS99-42 revised 2/15/00, **Petition for Addition of New Drug/Equipment to the EMS Inventory.** http://www.cchd.org/ems/documents/ems_forms/ems99-42_000.pdf

EMS Document which provides one systems tool for evaluation of new drugs and technologies being considered for incorporation into their EMS system.

- 2) Hailey, D. **HTA Initiative #7, Local Health Technology Assessment: A Guide for Health Authorities,** Alberta Heritage Foundation for Medical Research, 2002, <http://www.ahfmr.ab.ca/download.php/bfcb64a010b6685dfd7d1c0b6c442719>.

Very nice Canadian guide to health technology assessment.

- 3) **A guide to the development, implementation development, implementation clinical practice guidelines**, <http://www7.health.gov.au/nhmrc/publications/files/cp30.pdf>, National Health and Medical Research Council, Australia, 1999
 Australian guide.

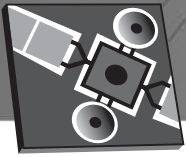
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Medical Services Advisory Committee: Guidelines for the assessment of diagnostic technologies, [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/C1F4569D79E542FACA257161001F1389/\\$File/guidelines2.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/C1F4569D79E542FACA257161001F1389/$File/guidelines2.pdf)
Medical Services Advisory Committee: Funding for new medical technologies and procedures: application and assessment guidelines, September 2005, [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/C1F4569D79E542FACA257161001F1389/\\$File/guidelines.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/C1F4569D79E542FACA257161001F1389/$File/guidelines.pdf)
 The principal role of the Medical Services Advisory Committee (MSAC) is to advise the Australian Minister for Health and Aging on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. This advice informs Australian Government decisions about public funding for new and in some cases existing medical procedures.

- 7) **Health Care Technology in the United States in U.S. Congress, Office of Technology Assessment, *Health Care Technology and Its Assessment in Eight Countries***, OTA-BP-H-140 Washington, DC: U.S. Government Printing Office, February 1995. <http://www.wws.princeton.edu/ota/disk1/1995/9562/9562.PDF>
 Pages 291 – 304 contain the history of technology assessment in the US; Pages 305 – 323 provide some case studies in technology assessment.

- 8) **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, September 1994. <http://www.wws.princeton.edu/ota/disk1/1994/9414/9414.PDF>
 Discussions of various techniques for technology assessment by Emergency Care Research Institute, an independent nonprofit health services research agency.

- 9) **Emergency Care Research Institute (ECRI), Health Technology Assessment Information Service**. <http://www.ecri.org/Products/Pages/HTAIS.aspx?sub=Evidence-Based%20Assessment>



SECTION D: References With Comments *(continued)*

- 10) AHRQ Technology Assessments, <http://www.ahrq.gov/clinic/techix.htm>, link to multiple technology assessments performed by AHRQ.

Good examples of technology assessments.

- 11) Health Technology Assessment database. <http://www.york.ac.uk/inst/crd/hfaq.htm>

Health Technology s a UK-based database of technology assessments that studies the medical, social, ethical and economic implications of development, diffusion, and the use of health technology and informs policy decisions. Its aim is to improve the quality and cost-effectiveness of healthcare.

- 12) Clinical Device Group, <http://www.clinicaldevice.com/Links.htm>

Links to world wide Technology Assessment sites.

- 13) Evidence-Based Medicine Toolkit, <http://www.med.ualberta.ca/ebm/biblio.htm>

Users' Guides to the Medical Literature, Prepared by the Evidence-Based Medicine Working Group and published in JAMA from 1993 – 1999.

- 14) How Can the Impacts of New Medical Technologies Be Assessed? In *Development of Medical Technology: Opportunities for Assessment*, Office of Technology Assessment, NTIS order #PBb-258117. Washington, DC: U.S. Government Printing Office, August 1976. <http://www.wws.princeton.edu/cgi-bin/byte-serv.prl/~ota/disk3/1976/7617/761706.PDF>

Chapter IV, p. 45 – 54; Old, but good discussion of medical technology assessment.



SECTION E: TCC Member Roster

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